NCT Number: NCT02026505
Study Title: Evaluation of Cardiotoxic Effects of Bortezomib
Study URL: https://beta.clinicaltrials.gov/study/NCT02026505
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to learn more about how a drug commonly used to treat multiple myeloma can affect the heart.

In this study, the investigators will learn whether a drug called how a drug (called bortezomib, or Velcade) receive for multiple myeloma affects the heart. Bortezomib is part of the standard treatment and its effects on multiple myeloma is not being studied here.

The investigators want to learn whether damage occurs to the heart after taking bortezomib for multiple myeloma, whether it is reversible, and we can predict damage to the heart before it occurs.
Study Results: NO
Conditions: Multiple Myeloma|Heart Failure, Systolic|Cardiotoxins
Interventions: DRUG: Bortezomib
Primary Outcome Measures: Global longitudinal strain by echocardiography, 6 months
Secondary Outcome Measures: Amount of late gadolinium enhancement by cardiac MRI, 6 months|High-sensitivity troponin T, 6 months|C-reactive protein, 6 months|Serum NT-proBNP, 6 months|Carboxyl-terminal telopeptide of collagen type I, 6 months|Amino-terminal peptide of procollagen type III, 6 months
Other Outcome Measures:
Sponsor: Oregon Health and Science University
Collaborators: Millennium: The Takeda Oncology Company
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 11
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IRB00010254
Start Date: 2014-03-01
Primary Completion Date: 2016-12-31
Completion Date: 2019-03-01
First Posted: 2014-01-03
Results First Posted:
Last Update Posted: 2019-03-13
Locations:
Study Documents:

NCT Number: NCT01790152
Study Title: Effects of Dexrazoxane Hydrochloride on Biomarkers Associated With Cardiomyopathy and Heart Failure After Cancer Treatment

Study URL: https://beta.clinicaltrials.gov/study/NCT01790152
Acronym:
Study Status: RECRUITING
Brief Summary: This clinical trial studies the effects of dexrazoxane hydrochloride on biomarkers associated with cardiomyopathy and heart failure after cancer treatment. Studying samples of blood in the laboratory from patients receiving dexrazoxane hydrochloride may help doctors learn more about the effects of dexrazoxane hydrochloride on cells. It may also help doctors understand how well patients respond to treatment.
Study Results: NO
Conditions: Hodgkin Lymphoma in Remission|Leukemia in Remission|Lymphoblastic Lymphoma|Osteosarcoma|Recurrent Leukemia|Recurrent Lymphoma|Recurrent Malignant Neoplasm
Interventions: OTHER: Assessment of Therapy Complications|OTHER: Laboratory Biomarker Analysis|OTHER: Quality-of-Life Assessment|OTHER: Questionnaire Administration
Primary Outcome Measures: Left ventricular function and measures of pathologic remodeling (i.e., thickness-to-dimension ratio) assessed using standard 2-dimensional, M-mode, and Doppler echocardiogram, Univariate tests will be used as well as examination of the entire cohort via multivariable regression adjusting for all a priori covariates of interest., Baseline|Differences in serum biomarkers (particularly cardiac troponins and natriuretic peptides), Univariate tests will be used as well as examination of the entire cohort via multivariable regression adjusting for all a priori covariates of interest., Baseline
Secondary Outcome Measures: Quality of life based on self-report instruments, An analytic Markov model will be created and used. Estimates and their 95% confidence will be included to explore the sensitivity of any quality-adjusted life years estimates., Baseline|Primary disease relapse, An analytic Markov model will be created and used., Baseline|Second cancer rates, An analytic Markov model will be created and used., Baseline|Longitudinal trajectory of 2-dimensional echocardiographic parameters, Will utilize generalized linear model-general estimation equation to model the trajectories of echocardiographic biomarker estimates (continuous outcomes) across time. Relevant model shapes will be evaluated, beginning with linear models, but also testing more flexible shapes (e.g., quadratic, cubic, or cubic spline functions with varying numbers of knots) to determine whether non-linear components are needed for fit. Will also examine interactions of dexrazoxane (DRZ) status with the selected functions of time to evaluate for differences in trajectories over time by DRZ status., From time of cancer treatment to subsequent follow-up
Other Outcome Measures:
Sponsor: Children's Oncology Group
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:

Enrollment: 420
Funder Type: NETWORK
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ALTE11C2|S0004187|ALTE11C2|COG-ALTE11C2|ALTE11C2|
R01CA211996|U10CA095861|UG1CA189955
Start Date: 2013-08-05
Primary Completion Date: 2022-12-31
Completion Date: 2023-12-31
First Posted: 2013-02-13
Results First Posted:
Last Update Posted: 2023-05-15
Locations: Children's Hospital of Alabama, Birmingham, Alabama, 35233, United States|Phoenix Childrens Hospital, Phoenix, Arizona, 85016, United States|Banner University Medical Center - Tucson, Tucson, Arizona, 85719, United States|Arkansas Children's Hospital, Little Rock, Arkansas, 72202-3591, United States|City of Hope Comprehensive Cancer Center, Duarte, California, 91010, United States|Valley Children's Hospital, Madera, California, 93636, United States|Kaiser Permanente-Oakland, Oakland, California, 94611, United States|Lucile Packard Children's Hospital Stanford University, Palo Alto, California, 94304, United States|Rady Children's Hospital - San Diego, San Diego, California, 92123, United States|Yale University, New Haven, Connecticut, 06520, United States|Golisano Children's Hospital of Southwest Florida, Fort Myers, Florida, 33908, United States| University of Florida Health Science Center - Gainesville, Gainesville, Florida, 32610, United States|Memorial Regional Hospital/ Joe DiMaggio Children's Hospital, Hollywood, Florida, 33021, United States|Nemours Children's Clinic-Jacksonville, Jacksonville, Florida, 32207, United States|Nemours Children's Hospital, Orlando, Florida, 32827, United States|Johns Hopkins All Children's Hospital, Saint Petersburg, Florida, 33701, United States|Saint Joseph's Hospital/ Children's Hospital-Tampa, Tampa, Florida, 33607, United States|Saint Mary's Hospital, West Palm Beach, Florida, 33407, United States| Children's Healthcare of Atlanta - Egleston, Atlanta, Georgia, 30322, United States|University of Hawaii Cancer Center, Honolulu, Hawaii, 96813, United States|Kapiolani Medical Center for Women and Children, Honolulu, Hawaii, 96826, United States|Lurie Children's Hospital-Chicago, Chicago, Illinois, 60611, United States|University of Illinois, Chicago, Illinois, 60612, United States|Advocate Children's Hospital-Oak Lawn, Oak Lawn, Illinois, 60453, United States|Saint Jude Midwest Affiliate, Peoria, Illinois, 61637, United States|Ochsner Medical Center Jefferson, New Orleans, Louisiana, 70121, United States|Maine Children's Cancer Program, Scarborough, Maine, 04074, United States|Sinai Hospital of Baltimore, Baltimore, Maryland, 21215, United States|Johns Hopkins University/Sidney Kimmel Cancer Center, Baltimore, Maryland, 21287, United States|Dana-Farber Cancer Institute, Boston, Massachusetts, 02215, United States|Wayne State University/Karmanos Cancer Institute, Detroit, Michigan, 48201, United States|Ascension Saint John Hospital, Detroit, Michigan, 48236, United

States|Hurley Medical Center, Flint, Michigan, 48503, United States| University of Mississippi Medical Center, Jackson, Mississippi, 39216, United States|Columbia Regional, Columbia, Missouri, 65201, United States|Washington University School of Medicine, Saint Louis, Missouri, 63110, United States|University Medical Center of Southern Nevada, Las Vegas, Nevada, 89102, United States|Sunrise Hospital and Medical Center, Las Vegas, Nevada, 89109, United States|Alliance for Childhood Diseases/Cure 4 the Kids Foundation, Las Vegas, Nevada, 89135, United States|Summerlin Hospital Medical Center, Las Vegas, Nevada, 89144, United States|Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire, 03756, United States|Hackensack University Medical Center, Hackensack, New Jersey, 07601, United States| University of New Mexico Cancer Center, Albuquerque, New Mexico, 87102, United States|Roswell Park Cancer Institute, Buffalo, New York, 14263, United States|The Steven and Alexandra Cohen Children's Medical Center of New York, New Hyde Park, New York, 11040, United States| University of Rochester, Rochester, New York, 14642, United States| Stony Brook University Medical Center, Stony Brook, New York, 11794, United States|State University of New York Upstate Medical University, Syracuse, New York, 13210, United States|Mission Hospital, Asheville, North Carolina, 28801, United States|Wake Forest University Health Sciences, Winston-Salem, North Carolina, 27157, United States| Children's Hospital Medical Center of Akron, Akron, Ohio, 44308, United States|Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, 45229, United States|University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, 73104, United States|Legacy Emanuel Children's Hospital, Portland, Oregon, 97227, United States| Oregon Health and Science University, Portland, Oregon, 97239, United States|Saint Christopher's Hospital for Children, Philadelphia, Pennsylvania, 19134, United States|Rhode Island Hospital, Providence, Rhode Island, 02903, United States|Medical University of South Carolina, Charleston, South Carolina, 29425, United States|BI-LO Charities Children's Cancer Center, Greenville, South Carolina, 29605, United States|Medical City Dallas Hospital, Dallas, Texas, 75230, United States|UT Southwestern/Simmons Cancer Center-Dallas, Dallas, Texas, 75390, United States|Cook Children's Medical Center, Fort Worth, Texas, 76104, United States|Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center, Houston, Texas, 77030, United States|University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78229, United States|University of Vermont and State Agricultural College, Burlington, Vermont, 05405, United States| Virginia Commonwealth University/Massey Cancer Center, Richmond, Virginia, 23298, United States|Seattle Children's Hospital, Seattle, Washington, 98105, United States|Providence Sacred Heart Medical Center and Children's Hospital, Spokane, Washington, 99204, United States|Children's Hospital of Wisconsin, Milwaukee, Wisconsin, 53226, United States|Princess Margaret Hospital for Children, Perth, Western Australia, 6008, Australia|Perth Children's Hospital, Perth, Western Australia, 6009, Australia|Alberta Children's Hospital, Calgary, Alberta, T3B 6A8, Canada|McMaster Children's Hospital at Hamilton

Health Sciences, Hamilton, Ontario, L8N 3Z5, Canada|Children's Hospital of Eastern Ontario, Ottawa, Ontario, K1H 8L1, Canada|Hospital for Sick Children, Toronto, Ontario, M5G 1X8, Canada|The Montreal Children's Hospital of the MUHC, Montreal, Quebec, H3H 1P3, Canada|Centre Hospitalier Universitaire Sainte-Justine, Montreal, Quebec, H3T 1C5, Canada|Centre Hospitalier Universitaire de Quebec, Quebec, G1V 4G2, Canada|San Jorge Children's Hospital, San Juan, 00912, Puerto Rico
Study Documents:

NCT Number: NCT00678405
Study Title: Trial of a Breathlessness Intervention Service for Intractable Breathlessness
Study URL: https://beta.clinicaltrials.gov/study/NCT00678405
Acronym:
Study Status: UNKNOWN
Brief Summary: The aim of this study is to evaluate the impact of a Breathlessness Intervention Service (BIS) on the quality of life of patients and families affected by intractable breathlessness. The questions to be addressed by this research are:

1. Is BIS more effective than standard care for patients with intractable breathlessness from advanced malignant or non-malignant disease?
2. Does it reduce patient and carer distress due to breathlessness, and increase patients' sense of mastery of the symptom?
3. What are the experiences and views of those who use BIS, their informal carers and the clinicians who refer to it?
4. Does BIS offer value for money for the NHS?
Study Results: NO
Conditions: Dyspnea
Interventions: BEHAVIORAL: Breathlessness Intervention Service|BEHAVIORAL: Best supportive care (Standard Care)
Primary Outcome Measures: Numerical rating Scale (NRS) for distress due to breathlessness, End of intervention (4 weeks after baseline for patients with a non-malignant diagnosis; 2 weeks after baseline for patients with malignant diagnoses)
Secondary Outcome Measures: Modified BORG, As for primary outcome measure|NRS Breathlessness at best/worst, as for primary outcome measure|Dyspnoea descriptors, as for primary outcome measure|CRQ, as for primary outcome measure|EQ-5D, as for primary outcome measure|HADS, as for primary outcome measure|CSRI, as for primary outcome measure|Charlson Co-morbidity score, as for primary outcome measure|Social Functioning, as for primary outcome measure|Karnofsky, as for primary outcome measure|Experience of breathlessness and expectations/views of BIS, as for primary outcome measure|Burden interview and caregiver Appr scale, as for primary outcome measure
Other Outcome Measures:
Sponsor: Cambridge University Hospitals NHS Foundation Trust
Collaborators: University of Cambridge|King's College London

Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: SINGLE (INVESTIGATOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: PB-PG-0107-11134|ISRCTN04119516
Start Date: 2008-08
Primary Completion Date: 2010-12
Completion Date: 2010-12
First Posted: 2008-05-15
Results First Posted:
Last Update Posted: 2010-06-25
Locations: Addenbrooke's Hospital, Cambridge, Cambridgeshire, CB2 0QQ, United Kingdom
Study Documents:

NCT Number: NCT03721952
Study Title: Facilitating Communication Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03721952
Acronym: FCS2
Study Status: RECRUITING
Brief Summary: This study is a randomized clinical trial of an intervention to improve outcomes for patients and their family by using ICU nurse facilitators to support, model, and teach communication strategies that enable patients and their families to secure care in line with patients' goals of care over an illness trajectory, beginning in the ICU and continuing to care in the community.
Study Results: NO
Conditions: Chronic Disease|Neoplasm Metastasis|Lung Neoplasm|Pulmonary Disease, Chronic Obstructive|Heart Failure, Congestive|Liver Cirrhosis|Kidney Failure, Chronic|Multiple Organ Failure|Health Care Quality, Access, and Evaluation|Intensive Care Units|Palliative Care, Health Services|Palliative Care, Patient Care|Lung Diseases|Cerebrovascular Disorders|Brain Injuries
Interventions: BEHAVIORAL: Facilitator-Based Intervention
Primary Outcome Measures: Hospital Anxiety and Depression Scale (HADS) - family, Family member symptoms of depression and anxiety assessed with the Hospital Anxiety and Depression Scale (HADS), which has become standard for ICU and post-ICU studies. The HADS is a reliable and valid 14-item, 2-domain (anxiety and depression) tool used to assess symptoms of psychological distress. Seven items evaluate anxiety and seven evaluate depression. Each item is scored on a 4-point scale (ranging from 0-3) with scores for each subscale (anxiety and depression) ranging from 0-21. HADS has been used in over 700 studies with evidence of reliability, validity and responsiveness among critically ill patients and their family., Change over time from

baseline through 6 months
Secondary Outcome Measures: Hospital Anxiety and Depression Scale (HADS) - patient, Patient symptoms of depression and anxiety assessed with the Hospital Anxiety and Depression Scale (HADS), which has become standard for ICU and post-ICU studies. The HADS is a reliable and valid 14-item, 2-domain (anxiety and depression) tool used to assess symptoms of psychological distress. Seven items evaluate anxiety and seven evaluate depression. Each item is scored on a 4-point scale (ranging from 0-3) with scores for each subscale (anxiety and depression) ranging from 0-21. HADS has been used in over 700 studies with evidence of reliability, validity and responsiveness among critically ill patients and their family., 1-, 3-, and 6-months after randomization|Goal-concordant care (SUPPORT items), Concordance between the care patients want and the care they are receiving will be measured with two questions from the SUPPORT study. The first defines patients' preferences: "If the patient had to make a choice at this time, would the patient prefer a course of treatment focused on extending life as much as possible, even if it means having more pain and discomfort, or would the patient want a plan of care focused on relieving pain and discomfort as much as possible, even if that means not living as long?" The second question assesses perceptions of current treatment using the same two options. The outcome is a dichotomous variable of whether the preference matches the report of care received. Although this creates a "false dichotomy" in that many patients want both, this "forced choice" helps identify patients' top priority. Based on prior studies, we expect only 50-60% of controls will report goal-concordant care., 1-, 3-, and 6-months after randomization|Impact of Event Scale-6 (IES-6) - patients and family, The Impact of Event Scale-6 (IES-6), derived from the IES-R, uses 6 self-report items to assess subjective distress caused by a traumatic event. Items are rated on a 5-point scale ranging from 0 ("not at all") to 4 ("extremely")., 1-, 3-, and 6-months after randomization|Perceived Competence Scale (PCS) - patients and family, The Perceived Competence Scale (PCS) is a short, 4-item questionnaire assessesing participants' feelings of competence. Items can be worded differently for different target behaviors. Validity was established in a study of medical students, and then in studies of diabetes self-management. Cronbach's alpha has consistently been above 0.80 in multiple studies. The scale has been used in several studies.The mean of 4 items is used as the scale score. The 4 items have also been used to form a latent variable, and assessed for change over time. Responses range from "Not at all true" (1) to "Very True" (7); higher score on the latent variable would indicate greater competence., 1-, 3-, and 6-months after randomization|Healthcare Costs and Utilization - patient, We will measure hospital readmission after initial hospital discharge through the electronic health record (EHR), institutional billing systems and, patient/family self-reports. All hospitals are in one system facilitating data collection. By using all three sources for data, we will capture hospitalizations regardless of healthcare system. Our primary focus will be readmission within 30 days as this

is a national standard, but we will also collect data from the EHR and from patient/family interviews to record all readmissions, emergency department visits, clinic visits, inpatient and outpatient palliative care consults, and home care over 6 months. All occasions of healthcare use will be confirmed through chart review and valued using the Medical Expenditure Panel Survey and the Healthcare Cost and Utilization project, with additional information from institutional financial systems, to capture costs of care rather than charges., 1-, 3-, and 6-months after randomization|Patient & Family Costs of Care, Patients and families will also be asked to provide estimates on the following direct costs: time costs (travel time, wait time, time with providers) and associated out-of-pocket expenses incurred. Indirect costs, such as informal care provided by family will be assessed, including time spent to provide support to patients in the home and to attend patient-related healthcare activities and their foregone opportunities. It will be valued primarily using the opportunity cost method, and also using the proxy-good method in sensitivity analyses., 1-, 3-, and 6-months after randomization|Comprehensive Score for Financial Toxicity (COST) - patients and family, Patient and family member assessment of perceived financial stress will be measured with the 11-item COST instrument which has demonstrated reliability and validity in measuring financial toxicity., 1-, 3-, and 6-months after randomization|QUAL-E, Measuring the quality of life of seriously ill patients. The QUAL-E is a validated instrument with \~25 items measuring of quality of life at the end of life with a four-domain structure: life completion, symptoms impact, relationship with health care provider, and preparation for end of life., 1-, 3-, and 6-months after randomization|QUAL-E (Fam), Measure of family experience of patients with serious illness. The QUAL-E (Fam) is a validated \~17-item companion instrument to the patient QUAL-E measure of quality of life at the end of life., 1-, 3-, and 6-months after randomization
Other Outcome Measures: Key Implementation Factors, Qualitative interviews after individual participation. Interviews will be guided by the Consolidated Framework for Implementation Research (CFIR) to explore the factors associated with implementation, including aspects of the intervention, inner and outer settings, individuals, and processes of care. Individual constructs within these domains were chosen to fit this specific intervention and context., 6-months after randomization|Key Implementation Outcomes, Qualitative interviews after individual participation. Interviews will also explore three key implementation outcomes (acceptability, fidelity, penetration) that will guide future dissemination of the intervention., 6-months after randomization
Sponsor: University of Washington
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 950
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: STUDY00005369
Start Date: 2019-04-17
Primary Completion Date: 2022-10-31
Completion Date: 2023-01-31
First Posted: 2018-10-26
Results First Posted:
Last Update Posted: 2021-12-08
Locations: Valley Medical Center, Renton, Washington, 98055, United States|UW Medicine - Harborview Medical Center, Seattle, Washington, 98104, United States|University of Washington Medical Center - Northwest, Seattle, Washington, 98133, United States|University of Washington Medical Center - Montlake, Seattle, Washington, 98195, United States
Study Documents:

NCT Number: NCT04635852
Study Title: Fentanyl Buccal Tablet for the Relief of Episodic Breathlessness in Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04635852
Acronym: EFFENDYS
Study Status: COMPLETED
Brief Summary: "Episodic breathlessness (or dyspnea) is one form of chronic refractory breathlessness characterized by a severe worsening of breathlessness intensity or unpleasantness beyond usual fluctuations in the patient's perception. Episodes are time-limited (seconds to hours) and occur intermittently, with or without underlying continuous breathlessness. Episodes may be predictable or unpredictable, depending on whether any trigger(s) can be identified. There is a range of known triggers which can interact (e.g. exertion, emotions, comorbidities or external environment). One episode can be caused by one or more triggers." (definition by an international expert consensus \[Simon et al. 2013\]). Approximately half of patients with cancer complain about breathlessness with the highest prevalence in pulmonary malignancies. Episodic breathlessness is reported by 81% of breathless cancer patients with significant impairment on quality of life and limitations on activity. Although episodic breathlessness show some similar characteristics like episodes of pain (breakthrough cancer pain, BTCP; median duration 30minutes), they are often shorter: 91% last less than 20minutes (min). Other evidence supports these findings with duration between 2-15minutes which is a real challenge for the treatment of episodic breathlessness. In the majority of cases, episodic breathlessness occur 1-4 times per day and peak intensity is rated moderate or severe.

There is evidence for the effectiveness of opioids for the relief of chronic refractory breathlessness. There is no evaluated and proven

standard treatment for the relief of episodic breathlessness at the moment but immediate-release morphine (IRM) as solution or tablet is most frequently used in clinical practice to treat episodic breathlessness. Time to onset of action of IRM is about 20-30min for pain. Fentanyl is a potent opioid and shows good evidence for the treatment of BTCP through its quick onset of action (5-15min) and short duration of action (50-60min). Because of its pharmacodynamic properties fentanyl might be appropriate and effective for the relief of episodic breathlessness. However, the efficacy of fentanyl for the relief of breathlessness and time to onset is unknown.

This pilot study aims to evaluate relative efficacy, feasibility and time to onset of two different opioids (fentanyl and morphine) in order to improve the management of episodic breathlessness.
Study Results: NO
Conditions: Cancer|Dyspnea, Paroxysmal
Interventions: DRUG: Fentanyl|DRUG: Immediate release morphine
Primary Outcome Measures: Time to onset of meaningful breathlessness relief, To determine the time to onset of meaningful breathlessness relief of fentanyl buccal tablet (FBT) in comparison to immediate-release morphine (IRM), minutes (by stop watch) from drug application of FBT/IRM up to breathlessness relief
Secondary Outcome Measures: Breathlessness intensity, Breathlessness intensity measured by NRS (range 0-10), at 0, 3, 5, 10, 15, 20, 30, 45 and 60 minutes after application of FBT/IRM|Numbers of rescue medication doses, If adequate breathlessness relief was not reached after 30 min, the patient could use his standard rescue medication., Numbers of rescue medication doses through study completion, assessed at day 10 (final visit)|Patient's & investigator's satisfaction, Patient's and investigator's satisfaction of breathlessness relief and route of application regarding ease of administration (4-point verbal rating scale: 0 = poor/unsatisfied and 4 = excellent/very satisfied)., through study completion, day 10 (e.g. final visit)|Preferences of study drugs, FBT or IRM or both/none, through study completion, day 10 (e.g. final visit)
Other Outcome Measures: Number of (serious) adverse events (AE/SAE; Safety of FBNT/IRM), Counts of adverse events, through study completion, day 10 (e.g. final visit)|Severity of AE/SAE (Safety of FBNT/IRM), CTCAE tool v4.03 (National Cancer Institute Common Terminology Criteria), through study completion, day 10 (e.g. final visit)|Oxygen saturation (Safety of FBNT/IRM), finger clip pulse oximetry (Contec Medical Systems Co., China), through study completion, day 10 (e.g. final visit)|Patient's vigilance (Safety of FBNT/IRM), Glasgow Coma Scale (GCS), through study completion, day 10 (e.g. final visit)|Respiratory rate (Safety of FBNT/IRM), breaths per minute, through study completion, day 10 (e.g. final visit)|Enrollment rate (Feasibility of study procedures), Ratio of patients screened to patient with informed consent, day 10 (e.g. final visit)|Completion rate (Feasibility of study procedure), Ratio of patients that were randomly assigned to the experimental vs active comparator arm to

patients that completed the study, day 10 (e.g. final visit)|Drop outs (Feasibility of study procedures), Counts of drop out per visit (TPh+EPh), day 10 (e.g. final visit)|Reasons for rejection of study participation of screened patient (Feasibility of study procedures), List of reasons/ free text responses, day 10 (e.g. final visit)|Acceptability of study procedures, closed questions: 4-point verbal rating scale between 0=poor/unsatisfied and 4=excellent/very satisfied, and yes/no; reports by patients, investigators and clinical team, day 10 (e.g. final visit)|Acceptability of measurement tools, closed questions: 4-point verbal rating scale between 0=poor/unsatisfied and 4=excellent/very satisfied, and yes/no; reports by patients, investigators and clinical team, day 10 (e.g. final visit)|Acceptability of rescue procedures, closed questions: 4-point verbal rating scale between 0=poor/unsatisfied and 4=excellent/very satisfied, and yes/no; reports by patients, investigators and clinical team, day 10 (e.g. final visit)
Sponsor: University of Cologne
Collaborators: Teva Branded Pharmaceutical Products R&D, Inc.
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: Uni-Koeln-1412|2011-005797-32|DRKS00004353
Start Date: 2013-03
Primary Completion Date: 2014-11
Completion Date: 2014-12
First Posted: 2020-11-19
Results First Posted:
Last Update Posted: 2020-11-19
Locations: University Hospital Göttingen Center of Palliative Medicine, Göttingen, Hessen, 37075, Germany|Study Center Palliative Medicine, Cologne, NRW, 50937, Germany|Hospital Essen- Mitte, Departement of Palliative Medicine, Essen, NRW, 45136, Germany
Study Documents:

NCT Number: NCT03650205
Study Title: Ivabradine to Prevent Anthracycline-induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT03650205
Acronym: IPAC
Study Status: UNKNOWN
Brief Summary: Anthracyclines are associated with cardiotoxic effects. Previous studies suggest that enalapril, and or carvedilol, protect against cardiovascular effects of these drugs.

Ivabradine selectively reduces heart rate through inhibition of the

cardiac pace maker IF channel, thus prolonging the duration of spontaneous depolarization in the sinus node. Additionally, ivabradine might preserve myocardial perfusion without negative inotropic effect and probably maintain cardiac contractility despite the reduction of heart rate.

Ivabradine has been shown to improve outcome in patients with heart failure and angina. The aim of this study is to evaluate whether ivabradine might prevent anthracycline-induced cardiotoxicity.
Study Results: NO
Conditions: Neoplasms|Heart Failure|Cardiotoxicity|Chemotherapy Effect|Oncology
Interventions: DRUG: Ivabradine|DRUG: Placebo
Primary Outcome Measures: Ventricular function, Reduction in global longitudinal strain of at least 10% (GLS), 365 days after randomization
Secondary Outcome Measures: Composite endpoint of mortality or major cardiovascular outcomes, Composite endpoint of mortality or major cardiovascular outcomes (defined as acute myocardial infarction, heart failure, inappropriate sinus tachycardia and arrhythmia), 365 days after randomization|Left ventricular dysfunction, Incidence of left ventricular (LV) dysfunction defined as reduction of LV ejection fraction by 10%., 365 days after randomization|Incidence of myocardial injury, Levels of NT-proBNP and high-sensitivity cardiac troponin T, 90 days after randomization|Incidence of myocardial injury, Levels of NT-proBNP and high-sensitivity cardiac troponin T, 180 days after randomization|Incidence of myocardial injury, Levels of NT-proBNP and high-sensitivity cardiac troponin T, 365 days after randomization|Diastolic dysfunction, Assessment by echocardiography the incidence of diastolic dysfunction using the following parameters: peak E-wave velocity, peak A-wave velocity, mitral valve (MV) E/A ratio, MV deceleration time, pulsed-wave tissue doppler imaging e' velocity, Mitral E/e', left atrium maximum volume index, pulmonary vein(PV) systole(S) wave, PV diastole (D) wave, continuous wave (CW) doppler: tricuspid regurgitation, systolic jet velocity; Color M- mode., 365 days after randomization|Ventricular function, Reduction in global longitudinal strain of at least 10% (GLS), 180 days after randomization
Other Outcome Measures: Composite endpoint of mortality or major cardiovascular outcomes, Composite endpoint of mortality or major cardiovascular outcomes (defined as acute myocardial infarction, heart failure, inappropriate sinus tachycardia and arrhythmia), yearly after randomization until 5 years|Left ventricular dysfunction, Incidence of left ventricular (LV) dysfunction defined as reduction of LV, 180 days after randomization|Incidence of myocardial injury, Levels of NT-proBNP and high-sensitivity cardiac troponin T, 90 days after randomization|Incidence of myocardial injury, Levels of NT-proBNP and high-sensitivity cardiac troponin T, 180 days after randomization|Diastolic dysfunction, Assessment by echocardiography the incidence of diastolic dysfunction using the following parameters: peak E-wave

velocity, peak A-wave velocity, mitral valve (MV) E/A ratio, MV deceleration time, pulsed-wave tissue doppler imaging e' velocity, Mitral E/e', left atrium maximum volume index, pulmonary vein(PV) systole(S) wave, PV diastole (D) wave, continuous wave (CW) doppler: tricuspid regurgitation, systolic jet velocity; Color M- mode., 180 days after randomization|Adverse events, bradycardia, hypertension, atrial fibrillation, luminous phenomena, syncope, hypotension, erythema, rash, diplopia, vertigo, urticaria, 180 days after randomization|Adverse events, bradycardia, hypertension, atrial fibrillation, luminous phenomena, syncope, hypotension, erythema, rash, diplopia, vertigo, urticaria, 365 days after randomization|Heart rate variability, Assessment of heart variability through 24-hour holter the following parameters: mRR - ms, SDNN - ms, SDANN - ms, SDNNi - ms, rMSSD-ms, NN50, pNN50., 180 days after randomization|Oxygen consumption (VO2), Measurement of VO2 by cardiopulmonary exercise test, 180 days after randomization|Ventilatory equivalents for oxygen (VE/VO2) and for carbon dioxide (VE/VCO2), Measurement of ventilatory equivalents for oxygen (VE/VO2) and for carbon dioxide (VE/VCO2) by cardiopulmonary exercise test, 180 days after randomization|Left Ventricular Dimensions, LV diastolic diameter, LV diastolic diameter, LV diastolic diameter, yearly after randomization until 5 years|Left ventricular geometry and mass, LV mass, Septal thickness, Posterior wall thickness, yearly after randomization until 5 years|Subgroup analyses regarding the primary outcome, Type of cancer, gender, age, 365 days after randomization
Sponsor: University of Sao Paulo
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 160
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 42559415520020065
Start Date: 2019-01-22
Primary Completion Date: 2021-10-01
Completion Date: 2021-12-01
First Posted: 2018-08-28
Results First Posted:
Last Update Posted: 2019-04-02
Locations: Instituto do Cancer do Estado de Sao Paulo, Sao Paulo, SP, 01246000, Brazil
Study Documents:

NCT Number: NCT04827563
Study Title: Dyspnea and Cardiotoxicity in Multiple Myeloma Patients Who Receive Carfilzomib

Study URL: https://beta.clinicaltrials.gov/study/NCT04827563
Acronym:
Study Status: RECRUITING
Brief Summary: This study will explore why some multiple myeloma patients who receive carfilzomib (an anti-cancer medication) experience shortness of breath while others do not. The purpose of this research is to gather information on the effectiveness of the EndoPAT device, which is FDA-approved to assess the health of a patient's blood vessels. These assessments will help doctors leading the study determine the reasons why patients may develop shortness of breath (dyspnea) when being treated with carfilzomib and ways to better prevent this shortness of breath.
Study Results: NO
Conditions: Multiple Myeloma|Shortness of Breath|Dyspnea|Cardiotoxicity
Interventions: DEVICE: EndoPAT|DEVICE: Blood Pressure Cuff|DIAGNOSTIC_TEST: Echocardiogram|OTHER: Quality of Life Assessment|OTHER: Blood Tests
Primary Outcome Measures: Endothelial Function and Dyspnea Associations in Multiple Myeloma Patients, The association between baseline endothelial function and dyspnea in myeloma patients treated with carfilzomib. These associations will be assessed by comparing endothelial function within two cohorts: patients with abnormal baseline endothelial function, and patients with normal baseline endothelial function. Baseline endothelial function will be measured using EndoPat, an FDA-approved device used for health tests. Dyspnea rates will be assessed by participant-reported outcomes using the FACIT Dyspnea-10 Raw Dyspnea Score and Common Terminology Criteria for Adverse Events V5., 2 months
Secondary Outcome Measures: Cardiovascular Toxicities Associated with Changes in Carfilzomib-Induced Endothelial Function, The association between changes in carfilzomib-induced endothelial function and frequency of cardiovascular toxicities stratified by patients with abnormal and normal baseline endothelial function.Cardiovascular toxicities in this study will be defined as new or worsening symptomatic heart failure, hypertension, myocardial ischemia, stroke, pulmonary hypertension, arrhythmias and thromboembolic events that will be measured per CTCAE V5., 2 months|The Affects of Carfilzomib Dose/Dosing Schedule on the Incidence of Dyspnea, The affects of carfilzomib dose/dosing schedule on how often participants experience dyspnea (shortness of breath) will be assessed by participant reported outcomes using the FACIT Dyspnea-10 (raw dyspnea score) and data collected on adverse events (side effects) using CTCAE V5., 2 months|Changes in Cardiovascular Physiology and Risk Factors Associated with Endothelial Function, To determine whether changes in endothelial function are associated with cardiovascular physiological changes and cardiovascular risk factors within participants receiving carfilzomib. These associations will be measured by: hemodynamics (using the average 24-hour ambulatory blood pressure reported by participants after treatment using home blood pressure monitoring),

echocardiography using echocardiogram, and data collected on patient's vascular and cardiovascular health at baseline., 2 months
Other Outcome Measures:
Sponsor: University of Chicago
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 50
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IRB20-1768
Start Date: 2021-03-22
Primary Completion Date: 2023-08-01
Completion Date: 2024-08-01
First Posted: 2021-04-01
Results First Posted:
Last Update Posted: 2023-04-28
Locations: University of Chicago, Chicago, Illinois, 60637, United States
Study Documents:

NCT Number: NCT00687349
Study Title: Improving Clinician Communication Skills (ICCS)
Study URL: https://beta.clinicaltrials.gov/study/NCT00687349
Acronym: ICCS
Study Status: COMPLETED
Brief Summary: This research study is a randomized trial to evaluate a training program that is designed to improve the communication skills of clinicians. The training program focuses on care for patients with serious illnesses and their family members, and assesses effectiveness using patient and family outcomes. The long term goal of this research is to improve communication skills of doctors and nurses, thereby improving patient and family outcomes.
Study Results: NO
Conditions: Advanced Cancer|Chronic Obstructive Pulmonary Disease (COPD)|Restrictive Lung Disease|Congestive Heart Failure|End Stage Liver Disease
Interventions: BEHAVIORAL: Training Program Intervention
Primary Outcome Measures: Patient and family ratings on the "End-of-Life domain" of the Quality of Communication Questionaire (QOC), 4/1/2007-3/31/2012
Secondary Outcome Measures: Patient symptoms of depression as assessed by the PHQ-8 (Memorial Symptom Assessment scale), 4/01/2007-3/31/2012|Patient-, family-, and nurse-assessed ratings of the quality of end-of-life care provided by study clinicians using Quality of End-of-Life Care questionaire, 4/01/2007-3/31/2012
Other Outcome Measures:
Sponsor: University of Washington

Collaborators: National Institute of Nursing Research (NINR)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 6086
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 31466-G|R01NR009987
Start Date: 2007-04
Primary Completion Date: 2013-02
Completion Date: 2013-03
First Posted: 2008-05-30
Results First Posted:
Last Update Posted: 2014-09-16
Locations: Medical University of South Carolina, Charleston, South Carolina, 29425, United States|University of Washington; Harborview Medical Center, Seattle, Washington, 98104, United States|Veteran's Affairs Puget Sound HCS, Seattle, Washington, 98108, United States|University of Washington; UW Medical Center, Seattle, Washington, 98195, United States
Study Documents:

NCT Number: NCT00067249
Study Title: Women's Use of Alternative Medicine: A Multiethnic Study
Study URL: https://beta.clinicaltrials.gov/study/NCT00067249
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to examine socio-cultural factors of women's use of complementary and alternative medicine (CAM). The effects of socioeconomic status, social networks and acculturation on CAM use will be assessed among white, African-, Mexican-, and Chinese-American women.
Study Results: NO
Conditions: Uterine Fibroids|Osteoporosis|Urinary Tract Infection|High Blood Pressure|Heart Disease|Arthritis|Depression|Headaches
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Center for Complementary and Integrative Health (NCCIH)
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 3200
Funder Type: NIH
Study Type: OBSERVATIONAL

Study Design: Observational Model: |Time Perspective: p
Other IDs: F31AT001401-01
Start Date: 2001-04
Primary Completion Date:
Completion Date: 2001-09
First Posted: 2003-08-15
Results First Posted:
Last Update Posted: 2007-02-27
Locations:
Study Documents:

NCT Number: NCT02216149
Study Title: Effects of S-1 and Capecitabine on Coronary Artery Blood Flow
Study URL: https://beta.clinicaltrials.gov/study/NCT02216149
Acronym: FluoHeart
Study Status: TERMINATED
Brief Summary: Fluoropyrimidine chemotherapy agents , such as 5-fluorouracil and capecitabine, are occasionally associated with cardiac toxicity. Clinical fluoropyrimidine cardiotoxicity is infrequent, but subclinical toxicity may be much more common. Cardiac toxicity may be less frequent with S-1 as compared with 5-fluorouracil and capecitabine, but head-to-head comparisons are lacking. The purpose of the study is to compare 2 measures of subclinical coronary artery microvascular dysfunction, the coronary flow reserve and the coronary flow response to a cold pressor test, in a patient population who are being treated for adenocarcinoma of the gastrointestinal tract with one of 2 oxaliplatin-containing regimens, either with oxaliplatin plus S-1 or with oxaliplatin plus capecitabine.
Study Results: NO
Conditions: Esophagus Cancer|Stomach Cancer|Small Bowel Cancer|Colon Cancer|Rectum Cancer
Interventions: DRUG: S-1|DRUG: Capecitabine|DRUG: Oxaliplatin
Primary Outcome Measures: Frequency of coronary artery dysfunction, The frequency of subclinical coronary artery dysfunction is as assessed by comparing the coronary flow reserve during chemotherapy with the baseline coronary flow reserve, and the coronary flow response to a cold pressor test., 3 months
Secondary Outcome Measures: Coronary artery blood flow rate, The coronary artery blood flow rate is measured with ultrasound. The rates are compared with the baseline and between the groups., 3 months| Cardiac arrythmias during 24-hour electrocardiogram registration, Cardiac arrythmias detected with Holter cardiac recording., 3 months| Adverse events between the allocation groups, by CTCAE.4, 3 months| Response to chemotherapy, by RECIST 1.1, 3 months|Survival status, Survival from the first dose of study medication to study completion, 12 months
Other Outcome Measures:
Sponsor: Heikki Joensuu
Collaborators:

Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: HUS-01/2013|2013-003976-11
Start Date: 2015-01
Primary Completion Date: 2018-08
Completion Date: 2018-08
First Posted: 2014-08-13
Results First Posted:
Last Update Posted: 2018-08-28
Locations: Helsinki University Central Hospital, Helsinki, 00029, Finland
Study Documents:

NCT Number: NCT05797649
Study Title: Comparing N-terminal-proB-type Natriuretic Peptide With Other Criteria in Pleural Fluid Analysis
Study URL: https://beta.clinicaltrials.gov/study/NCT05797649
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: To assess the discriminative properties of pleural fluid (PF) N-terminal-proB-type-natriuretic-peptide (NTproBNP) levels in identifying heart failure (HF)-associated pleural effusions (PE).
Study Results: NO
Conditions: Pleural Effusion|Heart Failure|Malignant Neoplasm|Fluid Overload|Hypoalbuminemia|Renal Failure|Cirrhosis|Infections
Interventions:
Primary Outcome Measures: Comparison of the diagnostic performance of PF NTproBNP level in the diagnosis of HF-associated pleural effusions with other conventional biochemical criteria, Pleural fluid NTproBNP will be measured in patients with pleural effusion of various aetiologies including malignancy, pleural infection, heart failure and other causes of volume overload. The sensitivity and specificity of an elevated pleural fluid NTproBNP level in successfully identifying a pleural effusion due to underlying heart failure will be measured and compared against existing classification criteria for pleural effusion such as Light's Criteria, pleural-serum protein gradient or albumin gradient., 24 months
Secondary Outcome Measures: To measure the PF NTproBNP level in patients with pleural effusion of various aetiologies, 24 months| Correlation of clinical factors that may affect the levels of pleural fluid NTproBNP such as echocardiographic features, presence of comorbidities, nutritional status, serum albumin level, levels of inflammatory markers and presence of infection, Clinical data of patients admitted to the hospital with pleural effusion will be

measured and recorded. Statistical analysis will then be performed to evaluate for degree of correlation between the presence or severity of a clinical parameter, echocardiogram results e.g. severe valvular stenosis, or, e.g. presence of medical comorbidities or presence of concomitant infection, and the levels of NTproBNP identified in the patient's pleural fluid detected within same admission., 24 months|To correlate the PF NTproBNP levels with the echocardiographic features and prognosis of patients with heart failure, 24 months
Other Outcome Measures:
Sponsor: Chinese University of Hong Kong
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 300
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NTProBNPPleuralEffusion1
Start Date: 2023-12-01
Primary Completion Date: 2025-11-30
Completion Date: 2025-11-30
First Posted: 2023-04-04
Results First Posted:
Last Update Posted: 2023-04-04
Locations:
Study Documents:

NCT Number: NCT04704349
Study Title: Latest Imaging SPECT System Evaluation Phase 1
Study URL: https://beta.clinicaltrials.gov/study/NCT04704349
Acronym: LISSE1
Study Status: COMPLETED
Brief Summary: Monocentric study for the evaluation of a whole body CZT scintigraphy system.
Study Results: NO
Conditions: Rheumatic Disease|Neoplasms|Parathyroid Diseases|Pulmonary Embolism|Heart Diseases|Thyroid Diseases|Kidney Diseases|Dementia|Parkinsonian Disorders
Interventions: RADIATION: Scintigraphy
Primary Outcome Measures: Rate of images with a score greater than or equal to 4, Rate of images obtaining a score greater than or equal to 4 in visual image quality analysis on a 5-point LIKERT scale., Day 0
Secondary Outcome Measures: collimator performance, Physical measurements of collimator performance on test object., Day 0
Other Outcome Measures:
Sponsor: Centre Hospitalier Régional d'Orléans
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: NA
Enrollment: 68
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: OTHER
Other IDs: CHRO-2019-12
Start Date: 2020-10-05
Primary Completion Date: 2021-01-27
Completion Date: 2021-01-27
First Posted: 2021-01-11
Results First Posted:
Last Update Posted: 2021-11-03
Locations: CHR d'Orleans, Orléans, 45067, France
Study Documents:

NCT Number: NCT03051191
Study Title: Pathogenic Mechanisms of Cancer and Cardiovascular Diseases
Study URL: https://beta.clinicaltrials.gov/study/NCT03051191
Acronym:
Study Status: COMPLETED
Brief Summary: Subjects with cardiovascular diseases (CVD) have higher incidence of cancers compared to general population. The investigators hypothesized that shared molecular mechanism play a pivotal role in the pathogenesis of CVD including heart failure (HF) and cancers. To address this hypothesis, the investigators are going to explore the expression pattern of micro RNA (miRNA) and cell free DNA (cfDNA) derived from host, gut microbiota and gut microbiota composition extensively in patients with or without CVD, non-ischemic HF (NIHF), and cancers. The participants will be recruited from the outpatient clinic in Sakakibara Heart Institute or Japanese Foundation for Cancer Research. By comparing the expression pattern of miRNA, cfDNA, or gut microbiota composition, the investigators are seeking to find the pathogenic mechanisms shared by those diseases.
Study Results: NO
Conditions: Pathogenesis|Cardiovascular Diseases|Cancer
Interventions: DIAGNOSTIC_TEST: micro RNA
Primary Outcome Measures: miRNA, Expression pattern of miRNA in blood, At enrollment|Cell free DNA from host, Quantity of cell free DNA derived from host in blood, At enrollment|Cell free DNA from microbiota, Expression pattern of cell free DNA distinct from microbiota in blood, At enrollment|bacterial composition in stool, the bacterial composition analyzed by shot gun analysis of 16s rRNA genes in stool, At enrollment
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Sakakibara Heart Institute
Collaborators: Japanese Foundation for Cancer Research
Sex: ALL

Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 66
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SHIP02
Start Date: 2017-01-01
Primary Completion Date: 2019-12-01
Completion Date: 2019-12-01
First Posted: 2017-02-13
Results First Posted:
Last Update Posted: 2020-10-22
Locations: Sakakibara Heart Institute, Fuchu, 183-0003, Japan|The Cancer Institute Hospital for Japanese Foundation for Cancer Research, Tokyo, 135-8550, Japan
Study Documents:

NCT Number: NCT00668291
Study Title: Primary Pigmented Nodular Adrenocortical Disease (PPNAD) and the CARNEY Complex (CNC)
Study URL: https://beta.clinicaltrials.gov/study/NCT00668291
Acronym: EVACARNEY
Study Status: COMPLETED
Brief Summary: Cohort CNC-PPNAD will be investigated with clinical, genetic, biological and imaging work-up every year during 3 years. Cohort L-MC will be investigated clinically at inclusion and a PERKAR1A genotype will be performed.
Study Results: NO
Conditions: Primary; Complex|Pigmented Nodular Adrenocortical Disease, Primary, 1|Periorificial Lentiginosis|Cardiac Myxoma
Interventions:
Primary Outcome Measures: To assess the clinical manifestations of the CARNEY Complex (CNC) and/or the primary pigmented nodular adrenocortical disease (PPNAD), 6 months
Secondary Outcome Measures: Genotype/phenotype correlation. To determine the frequency of PRKAR1A germline mutation in patients with isolated cardiac myxoma or isolated lentiginosis., 6 months
Other Outcome Measures:
Sponsor: Assistance Publique - Hôpitaux de Paris
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 133
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: P060251
Start Date: 2008-01

Primary Completion Date: 2015-05
Completion Date: 2016-01
First Posted: 2008-04-29
Results First Posted:
Last Update Posted: 2016-07-06
Locations: Hôpital Cochin, Paris, 75679, France
Study Documents:

NCT Number: NCT05138991
Study Title: Reproducibility and Accuracy of a Portable System for Early Detection of Cardiac Dysfunction in Childhood Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT05138991
Acronym:
Study Status: RECRUITING
Brief Summary: The clinical trial compares the reproducibility and accuracy of cardiac tonometry-based portable systems that may detect early cardiac dysfunction (SphygmoCor® Xcel and Oscar 2™ ambulatory blood pressure monitor) at home and in the clinic to currently available screening tests for heart failure including echocardiogram (echo) and cardiovascular magnetic resonance (CMR). The SphygmoCor® Xcel and Oscar 2™ systems may help detect cardiac dysfunction earlier than other available screening tests because it can be self-administered outside of the clinic. This study aims to test the accuracy and practicality of these devices in the clinic setting and at home.
Study Results: NO
Conditions: Hematopoietic and Lymphoid Cell Neoplasm|Malignant Solid Neoplasm
Interventions: PROCEDURE: Echocardiogram Recording|OTHER: Questionnaire Administration|PROCEDURE: Stress Cardiac Magnetic Resonance Imaging|DEVICE: Wireless Synchronized Cardiac Function Monitoring Device
Primary Outcome Measures: Accuracy of ejection fraction (EF) in the clinic setting, and determine its reproducibility at home., Validate the accuracy of ejection fraction, as measured using a tonometry-based system (SphygmoCor® Xcel), in the clinic setting, and determine the reproducibility (Oscar 2™) at home., Up to 2 years
Secondary Outcome Measures: Cost-effectiveness of tonometry-based screening in the clinic setting and at home., Will apply the sensitivity and specificity of echo, CMR, and the Oscar 2™ ABPM system (clinic, home-based) to compare the number of asymptomatic cardiac dysfunction cases identified via each method. Screening costs for echo and CMR, including costs of clinical services, will be obtained from the 2020 Centers for Medicare \& Medicaid Services (CMS)., Up to 2 years
Other Outcome Measures:
Sponsor: City of Hope Medical Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT

Phases: NA
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING
Other IDs: 21466|NCI-2021-11335|21466|P30CA033572|R21CA261797
Start Date: 2022-06-22
Primary Completion Date: 2024-11-15
Completion Date: 2024-11-15
First Posted: 2021-12-01
Results First Posted:
Last Update Posted: 2022-07-28
Locations: City of Hope Medical Center, Duarte, California, 91010, United States
Study Documents:

NCT Number: NCT01171508
Study Title: Circadian Disturbances After Breast Cancer Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT01171508
Acronym: CIRCA
Study Status: COMPLETED
Brief Summary: The purpose of this study is to investigate circadian disturbances after breast cancer surgery by means of monitoring sleep and heart-rate variability, by measuring a metabolite of melatonin in urine and by questionnaires and a sleep-diary.
Study Results: NO
Conditions: Circadian Rhythm Disorders|Anxiety|Breast Cancer
Interventions: DEVICE: Wrist-Actigraph - Octagonal Basic Motionlogger, Ambulatory monitoring Inc, New York, USA|DEVICE: Polysomnograph - Embla A10 (Medcare, Reykjavik, Iceland)|DEVICE: Holter monitor - Medilog AR12 (Oxford Instruments, Oxford, England)|PROCEDURE: Urine 6-sulphatoxymelatonin (aMT6s)|OTHER: Karolinska Sleepiness Scale|OTHER: Visual Analog Scale and 10 point-scales to measure fatigue, general well-being, subjective sleep and pain|OTHER: Sleep-diary
Primary Outcome Measures: Preoperative sleep architecture of breast cancer patients, Sleep architecture measured by Polysomnography (awake, stadium I-IV, REM sleep, sleep latency, awakenings)., 1 day preoperatively|Postoperative sleep architecture of breast cancer patients (early phase), Sleep architecture measured by Polysomnography (awake, stadium I-IV, REM sleep, sleep latency, awakenings), The first postoperative night|Postoperative sleep architecture of breast cancer patients (late phase), Sleep architecture measured by Polysomnography (awake, stadium I-IV, REM sleep, sleep latency, awakenings), The 14th postoperative night|Sleep quality, fatigue, well-being and pain., Fatigue, generel well-being, subjective sleep and pain scores on a Visual Analog Scale - questionnaires filled out daily. Sleepiness measured by Karolinska Sleepiness Scale. A sleep-diary recording sleep quantity of day and night sleep., 1 day preoperatively till 14 days postoperatively|Preoperative melatonin levels and amplitude, Excretion

of aMT6s in urine. Urine will be collected from 23-07, quantified and 2 samples will be taken to measure aMT6s., 1 day preoperatively| Postoperative melatonin levels and amplitude (early phase), Excretion of aMT6s in urine. Urine will be collected from 23-07, quantified and 2 samples will be taken to measure aMT6s., The first postoperative night|Postoperative melatonin levels and amplitude, Excretion of aMT6s in urine. Urine will be collected from 23-07, quantified and 2 samples will be taken to measure aMT6s., The 14th postoperative night|Sleep architecture, Actigraphy (total minutes asleep, sleep effectiveness, sleep latency, awakenings). A wrist actigraph wil be worn from 1 day preoperatively and taken off on the 14th postoperative day., 1 day preoperatively till 14 days postoperatively
Secondary Outcome Measures: Preoperative heart-rate variability of breast cancer patients, Heart-rate variability measured by Holter monitor and a following analysis of frequency domain parameters., 1 day preoperatively|Postoperative heart-rate variability of breast cancer patients (early phase), Heart-rate variability measured by Holter monitor and a following analysis of frequency domain parameters., The first postoperative night|Postoperative heart-rate variability of breast cancer patients (late phase), Heart-rate variability measured by Holter monitor and a following analysis of frequency domain parameters., The 14th postoperative night
Other Outcome Measures:
Sponsor: Melissa Voigt Hansen
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 12
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: MVH-02
Start Date: 2011-02
Primary Completion Date: 2011-11
Completion Date: 2011-11
First Posted: 2010-07-28
Results First Posted:
Last Update Posted: 2013-03-08
Locations: Herlev Hospital, Copenhagen, 2730, Denmark
Study Documents:

NCT Number: NCT00779571
Study Title: The Female Health Dietary Intervention Study
Study URL: https://beta.clinicaltrials.gov/study/NCT00779571
Acronym: FEMIN
Study Status: COMPLETED
Brief Summary: This study has two phases:

1. In phase 1 of the study (8 weeks),the effect of two different low

calorie diets on manifestations of PCOS, including risk factors for the metabolic syndrome and cardiovascular risk profile will be compared.
2. In phase 2 the long term effect (next 44 weeks) on sustained weight-loss and the above mentioned parameters will be compared and evaluated.
Study Results: NO
Conditions: Polycystic Ovary Syndrome|Morbid Obesity
Interventions: BEHAVIORAL: Crispbread
Primary Outcome Measures: Weight loss, One year
Secondary Outcome Measures: Improvement of PCOS, diabetes type 2- and coronary heart disease-risk factors, one year
Other Outcome Measures:
Sponsor: The Hospital of Vestfold
Collaborators: Oslo University Hospital
Sex: FEMALE
Age: ADULT
Phases: NA
Enrollment: 61
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 86-814d 6.2008.453
Start Date: 2008-10
Primary Completion Date: 2011-09
Completion Date: 2012-02
First Posted: 2008-10-24
Results First Posted:
Last Update Posted: 2014-10-10
Locations: Kvinneklinikken, Rikshospitalet-Radiumhospitalet HF, Oslo, Norway
Study Documents:

NCT Number: NCT02674204
Study Title: STOP Heart Disease in Breast Cancer Survivors Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT02674204
Acronym: STOP
Study Status: TERMINATED
Brief Summary: The purpose of this study is to to examine the effects of atorvastatin, a type of statin, on changes to the heart among women undergoing breast cancer treatment. Atorvastatin may reduce or eliminate the harmful effects of chemotherapy treatment to the heart tissue of breast cancer patients.
Study Results: YES
Conditions: Breast Cancer|Heart Disease|Cardiotoxicity|Myocardial Dysfunction
Interventions: DRUG: Atorvastatin|DRUG: Placebo
Primary Outcome Measures: Change in Global Circumferential Strain (GCS) Measured by Cardiac MRI (CMRI), baseline to 12 months post

initiation of statin intervention
Secondary Outcome Measures: Change in Global Longitudinal Strain as Measured by CMRI, Baseline to 12 months of follow-up|Change in Peak Left Ventricular Twist as Measured by CMRI, Baseline to 12 months of follow-up|Change in Peak Left Ventricular Torsion as Measured by CMRI, Baseline to 12 months of follow-up|Change in Left Ventricular Untwisting Rate as Measured by CMRI, Baseline to 12 months of follow-up|Change in Left Ventricular Ejection Fraction as Measured by CMRI, Baseline to 12 months of follow-up|Change in Left Ventricular End Diastolic Volume as Measured by CMRI, Baseline to 12 months of follow-up|Change in Left Ventricular End Systolic Volume as Measured by CMRI, Baseline to 12 months of follow-up|Change in Cardiac Output as Measured by CMRI, Baseline to 12 months of follow-up|Change in Left Ventricular Mass as Measured by CMRI, Baseline to 12 months of follow-up|Change in Left Ventricular Concentricity as Measured by CMRI, Baseline to 12 months of follow-up|Change in Native T1 as Measured by CMRI, Baseline to 12 months of follow-up|Change in Post Contrast T1 as Measured by CMRI, Baseline to 12 months of follow-up|Change in Extracellular Volume as Measured by CMRI, Baseline to 12 months of follow-up|Change in Native T2 as Measured by CMRI, Baseline to 12 months of follow-up
Other Outcome Measures:
Sponsor: Cedars-Sinai Medical Center
Collaborators: California Breast Cancer Research Program
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 2
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: TREATMENT
Other IDs: IIT2015-12-Goodman-STOP
Start Date: 2016-05-05
Primary Completion Date: 2018-05-25
Completion Date: 2018-05-25
First Posted: 2016-02-04
Results First Posted: 2019-03-25
Last Update Posted: 2019-05-15
Locations: Cedars-Sinai Medical Center, Los Angeles, California, 90048, United States
Study Documents: Study Protocol and Statistical Analysis Plan|Informed Consent Form

NCT Number: NCT03645317
Study Title: Avoiding Cardiac Toxicity in Lung Cancer Patients Treated With Curative-intent Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT03645317
Acronym: ACCOLADE
Study Status: UNKNOWN

Brief Summary: Radiotherapy plays a major role in the treatment of lung cancer and recent advances in radiotherapy have led to better cure rates. However, the radiotherapy dose needed to destroy the cancer cells can unfortunately also damage the surrounding organs, such as the heart. The precise mechanism of damage and which areas of the heart are more sensitive to radiation is not currently known. This project uses the analysis of large amounts of existing radiotherapy treatment data to determine this. Establishing detailed radiotherapy dose limits for the heart and the heart's sub-structures will lead to the delivery of heart-sparing radiotherapy, where possible, in lung cancer patients treated in Yorkshire and Greater Manchester. The investigators estimate that this should lead to an improvement in one-year survival of approximately 10%.
Study Results: NO
Conditions: Lung Cancer
Interventions: DIAGNOSTIC_TEST: Blood tests & cardiac imaging
Primary Outcome Measures: The effect of radiation dose to the heart assessed using blood test (full blood count), The effect of radiation dose to the heart assessed using full blood count measurement at the following time points (before radiotherapy, within 7 days post-radiotherapy and at 4 months post-radiotherapy), 4 months (duration of each participant on study)|The effect of radiation dose to the heart assessed using blood test (lipids & cholesterol - LDL & HDL levels), The effect of radiation dose to the heart assessed using lipid \& cholesterol (LDL \& HDL) measurements at the following time points (before radiotherapy, within 7 days post-radiotherapy and at 4 months post-radiotherapy), 4 months (duration of each participant on study)|The effect of radiation dose to the heart assessed using blood test (troponin), The effect of radiation dose to the heart assessed using troponin measurement at the following time points (before radiotherapy, within 7 days post-radiotherapy and at 4 months post-radiotherapy), 4 months (duration of each participant on study)|The effect of radiation dose to the heart assessed using blood test (C-reactive protein), The effect of radiation dose to the heart assessed using C-reactive protein measurement at the following time points (before radiotherapy, within 7 days post-radiotherapy and at 4 months post-radiotherapy), 4 months (duration of each participant on study)|The effect of radiation dose to the heart assessed using blood test (brain natriuretic peptide), The effect of radiation dose to the heart assessed using brain natriuretic peptide measurement at the following time points (before radiotherapy, within 7 days post-radiotherapy and at 4 months post-radiotherapy), 4 months (duration of each participant on study)|The effect of radiation dose to the heart assessed using cardiac imaging (cardiac ultrasound), The effect of radiation dose to the heart assessed using cardiac ultrasound scans at the following time points (before radiotherapy and at 4 months after radiotherapy). The following components of the cardiac ultrasound measured during the study: parasternal long axis, parasternal short axis, apical 2/4/5 chambers, apical long axis, subcostal and parasternal notch., 4 months (duration of each participant on study)|The effect of radiation dose

to the heart assessed using cardiac imaging (cardiac CT), The effect of radiation dose to the heart assessed using cardiac CT scans at the following time points (before radiotherapy and at 4 months after radiotherapy). The following components of the cardiac CT scan measured during the study: coronary calcium score (Agaston/Volume) - CAC-RDS 0, CAC-RDS 1, CAC-RDS 2, CAC-RDS 3, CAC-RADS classification., 4 months (duration of each participant on study)|The effect of radiation dose to the heart assessed using cardiac imaging (12-lead ECG), The effect of radiation dose to the heart assessed using 12-lead ECG at the following time points (before radiotherapy and at 4 months after radiotherapy). The following components of the ECG measured during the study: heart rate, rhythm, P wave, QRS complex, QT interval, ST segment \& PR interval., 4 months (duration of each participant on study)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Prof Corinne Faivre-Finn
Collaborators: The Leeds Teaching Hospitals NHS Trust|University of Manchester|University of Leeds|Manchester University NHS Foundation Trust
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: BASIC_SCIENCE
Other IDs: M401
Start Date: 2019-06-12
Primary Completion Date: 2022-04-01
Completion Date: 2022-07-01
First Posted: 2018-08-24
Results First Posted:
Last Update Posted: 2021-08-02
Locations: Leeds Teaching Hospitals NHS Trust, Leeds, LS9 7TF, United Kingdom|The Christie NHS Foundation Trust, Manchester, M20 4BX, United Kingdom
Study Documents:

NCT Number: NCT01730417
Study Title: Phase I Study of the Safety, Distribution, and Radiation Dosimetry of Ultratrace Iobenguane 123I-mIBG
Study URL: https://beta.clinicaltrials.gov/study/NCT01730417
Acronym: mIBG
Study Status: COMPLETED
Brief Summary: The goal of this proposal is to produce and test high specific activity Ultratrace iobenguane I 123 in normal human volunteers.
Study Results: NO

Conditions: Neuroendocrine Tumors|Heart Failure
Interventions: DRUG: no carrier added metaiodobenzylguanidine
Primary Outcome Measures: Radiation dosimetry, Radiation dosimetry was measured by imaging at several time points. Blood and urine samples were also collected to correlate with imaging parameters. Side effects were also assessed after drug administration., 2 weeks
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Bennett Chin
Collaborators: National Cancer Institute (NCI)|Molecular Insights Pharmaceuticals
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 12
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: Pro00019124 (MIP-CA130394-01)|5R44CA130394-03
Start Date: 2009-11
Primary Completion Date: 2011-06
Completion Date: 2011-07
First Posted: 2012-11-21
Results First Posted:
Last Update Posted: 2012-11-21
Locations: Duke University Medical Center, Durham, North Carolina, 27710, United States
Study Documents:

NCT Number: NCT04318405
Study Title: Real Life Study on Iron Isomaltoside 1000 in the Treatment of ID in CKD, Heart Failure, ObGyn, IBD, Cancer and Elective Surgery (Real-CHOICE).
Study URL: https://beta.clinicaltrials.gov/study/NCT04318405
Acronym: Real-CHOICE
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Real-CHOICE - designed as a prospective, longitudinal, observational, non-interventional study - will investigate the attitude of patients and physicians towards IV (intravenous) iron therapy in general and IIM (iron isomaltoside 1000) treatment particularly before and after IIM treatment in iron deficient patients with or without anemia in the real-world clinical setting after commercial availability of this product in Switzerland.
Study Results: NO
Conditions: Iron-Deficiency Anemia|Iron-Deficiency
Interventions: DRUG: Iron isomaltoside 1000
Primary Outcome Measures: Attitude of patients towards IV iron treatment evaluated with questionnaire., Rate of patients with stability or positive change in attitude.

Questionnaire comprises the following questions:

1. I am hesitant to be treated with IV iron.
2. I would consider IV iron treatment due to the physician´s choice.
3. I would consider IV iron treatment due to its safety compared to other iron treatment options.
4. I would consider IV iron treatment due to its efficacy compared to other iron treatment options., Change from baseline taking into account baseline (BL) and follow-up (FU) answers. Follow-up at the latest 12 weeks after observed dosing and before a potential subsequent dosing (if available based on clinical routine follow-up). Secondary Outcome Measures: Effectiveness of treatment with IIM., Iron deficiency anemia (IDA): Hb (Hemoglobin) increase ≥ 1 g/dL., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM., Iron deficiency without anemia (IDNA): Maintenance of baseline Hb-level and/or Hb above lower limit of normal (LLN)., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Attitude of patients towards IIM treatment evaluated with questionnaire., Taking into account baseline (BL) and follow-up (FU) answers.

Questionnaire comprises the following questions:

1. I am hesitant to be treated with IIM.
2. I would consider IIM treatment due to the physician´s choice.
3. I would consider IIM treatment due to its safety compared to other iron treatment options.
4. I would consider IIM treatment due to its efficacy compared to other iron treatment options.
5. I would consider IIM treatment due to its specific dosing and administration schedule., Complete observation time-frame (the total observation period of this study will amount to 90 months).|Attitude of physicians towards IIM and IV iron treatment evaluated with questionnaire., Questionnaire comprises the following questions:

1. I am hesitant to treat with IV iron.
2. I would consider IV iron treatment due to the patient´s desire.
3. I would consider IV iron treatment due to its safety compared to other iron treatment options.
4. I would consider IV iron treatment due to its efficacy compared to other iron treatment options.

And:

1. I am hesitant to treat with IIM.
2. I would consider IIM treatment due to the patient´s desire.
3. I would consider IIM treatment due to its safety compared to other iron treatment options.

4. I would consider IIM treatment due to its efficacy compared to other iron treatment options.
5. I would consider IIM treatment due to its specific dosing and administration schedule., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Patient and disease profiles at baseline., Evaluation of kind of iron deficiency., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Patient and disease profiles at baseline., Institution of diagnosis of IDA/IDNA., Baseline.|Patient and disease profiles at baseline., Etiology of iron deficiency., Baseline.|Patient and disease profiles at baseline., Method of iron need determination., Baseline.|Calculation of iron need based on IIM simplified dosing scheme., Evaluation of dosing intensity of IIM., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Calculation of iron need based on IIM simplified dosing scheme., Calculated iron need., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Calculation of iron need based on IIM simplified dosing scheme., Determined iron need., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Calculation of iron need based on IIM simplified dosing scheme., Difference between administered IIM dose and calculated iron need., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Treatment sequence before IIM., Dose intensities of administration., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Treatment sequence before IIM., Dose intervals of administration., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Reason(s) for selection of IIM., Reasons for treatment choice of IIM in current patient populations. Reasons could be: efficacy, safety profile, quality of life, patient's preference, physician's preference, comorbidities, convenient dosing, other., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Treatment with IIM., Dose intensity of administration., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Treatment with IIM., Mode of administration., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Treatment with IIM., Duration of infusion., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Treatment satisfaction of physician and patient upon treatment., Rate of physicians and patients with stability or positive change in satisfaction upon IIM treatment., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: whole blood count changes., Red blood cell count, Complete observation time-frame (the total observation period of this study per patient will amount to 3

months).|Effectiveness of treatment with IIM: whole blood count changes., White blood cell count, Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: whole blood count changes., Hemoglobin, Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: whole blood count changes., Hematocrit, Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: whole blood count changes., Platelets, Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: total Hb increase., Hemoglobin, Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: serum ferritin increase., Serum ferritin, Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: serum ferritin increase., Transferrin saturation (TfS), Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: serum ferritin increase., Soluble transferrin receptor (sTfR), Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: serum ferritin increase., Phosphate level, Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Effectiveness of treatment with IIM: CRP (C-reactive protein) status., CRP status., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).|Safety and tolerability of treatment with IIM, including frequency and severity of treatment-emergent AEs (Adverse Events) / ADRs (Adverse Drug Reactions)., Number of patients with:

* Treatment-emergent adverse events (maximum grade per patient),
* Grade 3/4 treatment-emergent adverse drug reactions,
* Grade 3/4 treatment-emergent serious adverse events,
* Treatment-emergent serious adverse drug reactions,
* Pre-treatment adverse events,
* Pre-treatment serious adverse events,
* Follow-up adverse events,
* Follow-up serious adverse events., Complete observation time-frame (the total observation period of this study per patient will amount to 3 months).

Other Outcome Measures:
Sponsor: Pierre Fabre Pharma AG
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:

Enrollment: 324
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NIS-PFM-2019-2654
Start Date: 2020-06-02
Primary Completion Date: 2023-05-01
Completion Date: 2023-05-01
First Posted: 2020-03-24
Results First Posted:
Last Update Posted: 2023-03-31
Locations: 21, Basel, Switzerland|9, Basel, Switzerland|1, Bern, Switzerland|15, Biel, Switzerland|19, Brugg, Switzerland|18, Gossau, Switzerland|11, Kreuzlingen, Switzerland|12, Kreuzlingen, Switzerland|8, Kreuzlingen, Switzerland|5, Liestal, Switzerland|20, Opfikon, Switzerland|16, Rheinfelden, Switzerland|13, Sankt Gallen, Switzerland|7, Sion, Switzerland|6, Spreitenbach, Switzerland|17, St. Gallen, Switzerland|14, Steinach, Switzerland|10, Wettingen, Switzerland|3, Wohlen, Switzerland|2, Zürich, Switzerland|4, Zürich, Switzerland
Study Documents:

NCT Number: NCT03946852
Study Title: Abdominal Regional Perfusion in Donation After Cardiac Death for Multi-Organ Transplantation
Study URL: https://beta.clinicaltrials.gov/study/NCT03946852
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: The main purpose of this study is to increase the pool of organs available for donation by performing ARP to recondition donation after cardiac death (DCD) organs prior to transplantation. We will compare the outcomes of our ARP DCD liver transplants with historical data to determine the efficacy of this treatment compared to transplantation with standard DCD and donation after brain death (DBD) organs. We will also analyze biological samples from donors and recipients and compare them with outcome data in an effort to determine if any biological markers are able to predict the quality/ success of the grafts.
Study Results: NO
Conditions: Liver Transplant; Complications|Ischemia Reperfusion Injury|Cirrhosis|Liver Cancer|Liver Metastases|End Stage Liver Disease
Interventions: DEVICE: Abdominal Regional Perfusion
Primary Outcome Measures: Primary non-function, Graft failure requiring re-transplantion, 1 week|Early allograft dysfunction, Transient non-functioning of the liver transplant but with usual recovery to full functioning liver, 1 week|Ischemic Cholangiopathy, Non-anastomotic biliary stricture without other identifiable etiology, 1 week to 12 months post transplant
Secondary Outcome Measures: Overall patient survival, Patient Mortality at any time post transplant, 1 and 5 years|Graft survival,

Need for retransplant secondary to graft failure of any cause, or death, 5 years
Other Outcome Measures: Biliary anastomotic stricture, Imaging or biochemical evidence of anastomotic stricture requiring intervention, 1 year|Biliary Anastomotic leak, Imaging or endoscopic evidence of bile leak requiring antibiotics or percutaneous drainage, 30 days|Length of ICU stay, Duration of post-operative stay in ICU, 30 days|Overall Length of stay, Overall duration of stay in hospital post-transplant, 30 days|Re-operation rate, Frequency of return to the operating room for any reason, 30 days
Sponsor: London Health Sciences Centre
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 113712
Start Date: 2019-06
Primary Completion Date: 2021-06
Completion Date: 2026-06
First Posted: 2019-05-13
Results First Posted:
Last Update Posted: 2019-05-13
Locations:
Study Documents:

NCT Number: NCT00001452
Study Title: Defining the Genetic Basis for the Development of Primary Pigmented Nodular Adrenocortical Disease (PPNAD) and the Carney Complex
Study URL: https://beta.clinicaltrials.gov/study/NCT00001452
Acronym:
Study Status: COMPLETED
Brief Summary: Lentiginosis refers to groups of diseases marked by the presence of pigmented spots on the skin. These conditions are most commonly associated with multiple tumors and changes in hormone producing glands. The cause of these diseases is unknown, but researchers suggest there may be a level of inheritance involved in their development. Meaning to say that some of these diseases may "run in the family" and be passed down form generation to generation.

Primary pigmented nodular adrenocortical disease (PPNAD) is a pituitary-independent, primary adrenal form of hypercortisolism characterized by;

1. Resistance to suppression by the drug dexamethasone

2. The body is unable to secrete cortisol in a normal rhythm
3. Distinct microscopic changes of both adrenal glands

PPNAD can be associated with tumors (myxomas) of the skin, heart, breast, tumors (swannomas) of the nerve sheaths, pigmented spots (nevi and lentigines) of the skin, growth hormone (GH) producing tumors of the pituitary gland, and tumors of the testicles, ovaries, and thyroid gland. In the presence of these associations the condition is referred to as the Carney Complex. Presently there are no tests for screening of PPNAD and the Carney Complex. In addition, it is unknown how these conditions are genetically transferred from generation to generation.

This study proposes to use standard methods of clinical testing for endocrine and nonendocrine diseases and genetic testing in order to;

1. Define the genetic basis for PPNAD and/or the Carney Complex.
2. Determine the molecular changes associated with the development of the tumors.
3. Identify carriers of the disease.
4. Determine the prognosis for carriers and affected individuals.
5. Provide sufficient data for genetic counseling of families with PPNAD and/or Carney Complex.\<TAB\>
Study Results: NO
Conditions: Cushing's Syndrome|Pituitary Adenoma|Carney Complex|Primary Pigmented Nodular Adrenocortical Disease|Peutz-Jeghers Syndrome
Interventions: DRUG: oCRH
Primary Outcome Measures: Genotype and clinical phenotype correlation in patients with PPNAD, Carney Complex, Peutz-Jeghers Syndrome and related conditions., Genotype and clinical phenotype correlation in patients with PPNAD, Carney Complex, Peutz-Jeghers Syndrome and related conditions., This is an ongoing project
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 1387
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 950059|95-CH-0059
Start Date: 1995-12-14
Primary Completion Date:
Completion Date:
First Posted: 1999-11-04
Results First Posted:

Last Update Posted: 2023-07-11
Locations: National Institutes of Health Clinical Center, Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT02054052
Study Title: Intrapleural Bevacizumab Injection for Malignant Effusion in Lung Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02054052
Acronym:
Study Status: COMPLETED
Brief Summary: Malignant pleural or pericardial effusion is common in lung cancer, and intrapleural drugs injection is important in the treatment. Non- cytotoxic drugs include those with a sclerosing effect that produces pleurodesis, which is easy to cause severe chest pain despite of no influence on the following chemotherapy. Tumor angiogenesis is important in producing MPE. Bevacizumab has been administrated locally in treating optic nerve sickness successfully by anti-VEGF mechanism. So we hypothesize that intrapleural bevacizumab is also effective in treating MPE.
Study Results: NO
Conditions: Non-small Cell Lung Cancer|Malignant Pleural Effusion
Interventions: DRUG: Bevacizumab
Primary Outcome Measures: Lung cancer symptom, Evaluated by lung cancer symptom scale 21-30 days after the treatment
Secondary Outcome Measures: response rate, Evaluate response rate 21-30 days after the treatment|Time to progression, 1 year after the treatment of MPE.|Overall survival, 1 year after the treatment of MPE|Number of Participants with Adverse Events, one months after the treatment of MPE
Other Outcome Measures:
Sponsor: Haihong Yang, MD, Pricipal investigator
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 22
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: GZTO1401
Start Date: 2014-01
Primary Completion Date: 2019-03
Completion Date: 2019-03
First Posted: 2014-02-04
Results First Posted:
Last Update Posted: 2019-03-29
Locations: The First Affliliated Hospital of Guangzhou MC, Guangzhou, Guangdong, 510120, China

Study Documents:

NCT Number: NCT01586104
Study Title: Intensity-Modulated Radiation Therapy in Treating Younger Patients With Lung Metastases
Study URL: https://beta.clinicaltrials.gov/study/NCT01586104
Acronym:
Study Status: COMPLETED
Brief Summary: This pilot clinical trial studies intensity-modulated radiation therapy (IMRT) in treating younger patients with lung metastases. Specialized radiation therapy that delivers a high dose of radiation directly to the tumor may kill more tumor cells and cause less damage to normal tissue.
Study Results: NO
Conditions: Adult Rhabdomyosarcoma|Lung Metastases|Metastatic Ewing Sarcoma/Peripheral Primitive Neuroectodermal Tumor|Previously Treated Childhood Rhabdomyosarcoma|Recurrent Adult Soft Tissue Sarcoma|Recurrent Childhood Rhabdomyosarcoma|Recurrent Ewing Sarcoma/Peripheral Primitive Neuroectodermal Tumor|Recurrent Wilms Tumor and Other Childhood Kidney Tumors|Stage IV Adult Soft Tissue Sarcoma|Stage IV Wilms Tumor|Stage V Wilms Tumor|Unspecified Adult Solid Tumor, Protocol Specific|Unspecified Childhood Solid Tumor, Protocol Specific
Interventions: RADIATION: intensity-modulated radiation therapy
Primary Outcome Measures: Feasibility of delivering cardiac-sparing IMRT with central quality control in 20 subjects, Feasibility of delivering whole lung IMRT will be demonstrated by obtaining QARC central quality control approval of institutional IMRT plans for the 20 subjects enrolled onto the study., 1-5 years|Dosimetric advantages of whole lung IMRT treatment over standard whole lung irradiation, Compare treatment plans and different organ dose-volume histograms such as lungs, heart, thyroid gland, liver etc., 1-5 years|Short-term efficacy (lung-metastases free survival) and acute tolerance of whole lung IMRT, At a minimum period of six months after IMRT, Estimated using Kaplan-Meier survival curves (six months after IMRT)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Ann & Robert H Lurie Children's Hospital of Chicago
Collaborators: Northwestern University|National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: Lung IMRT
Start Date: 2011-02
Primary Completion Date: 2013-09
Completion Date: 2015-09

First Posted: 2012-04-26
Results First Posted:
Last Update Posted: 2013-09-24
Locations: Children's Healthcare of Atlanta - Egleston, Atlanta, Georgia, 30322, United States|Ann & Rober H Lurie Children's Hospital of Chicago, Chicago, Illinois, 60611, United States|Riley Hospital for Children, Indianapolis, Indiana, 46202-5225, United States|Dana-Farber Cancer Institute, Boston, Massachusetts, 02115, United States|Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States|Children's Hospital of Pittsburgh of UPMC, Pittsburgh, Pennsylvania, 15224, United States|M D Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT03186404
Study Title: Statins for the Primary Prevention of Heart Failure in Patients Receiving Anthracycline Pilot Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03186404
Acronym: SPARE-HF
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Anthracycline (AC) chemotherapy has substantially reduced the mortality rate from several common cancers globally. Unfortunately, AC treatment is associated with up to 19% risk of heart failure (HF). Current standard of care for preventing AC induced HF (AIHF) is cardiac surveillance followed by initiation of treatment once HF is diagnosed. With this approach 89% of patients fail to recover heart function and 46% will experience adverse cardiac events. Therefore there is a need for effective preventive therapy to reduce the risk of AIHF. Based on small human studies, animal studies, and our own pilot data, statins are an ideal class of drug for this purpose.

We will conduct a pilot double blinded, placebo controlled, randomized controlled trial to assess whether pre-treatment with statins before AC can prevent heart dysfunction. Eligible patients with cardiovascular risk factors scheduled to receive AC will be recruited. They will be randomized to statin therapy or placebo and followed until the end of cancer treatment. Primary outcome is the difference in cardiac MRI-determined left ventricular ejection fraction between pre-AC and end of treatment.
Study Results: NO
Conditions: Cancer|Heart Failure|Cardiotoxicity
Interventions: DRUG: Atorvastatin|DRUG: Placebo oral tablet
Primary Outcome Measures: Cardiac MRI measured LVEF within 4 weeks of anthracycline completion, Cardiac MRI LVEF at the end of treatment will be measured before cancer treatment and within 4 weeks after completion of anthracycline-based treatment. The pre-treatment measurement will facilitate a baseline adjusted comparison between placebo and statin treated groups., Within 4 weeks of cancer therapy completion

Secondary Outcome Measures:
Other Outcome Measures: Cardiac MRI measured LV end diastolic volume (LVEDV) and end systolic volume (LVESV) at the end of treatment, these measures will be obtained at the same time as the LVEF measures with pre-treatment measurements facilitating a baseline adjusted comparison between placebo and statin treated groups, Within 4 weeks of anthracycline completion|The incidence of cardiotoxicity, defined by LVEF fall \>10% from pre-cancer treatment assessment to \<53%, From start of anthracycline therapy to upto 4 weeks of anthracycline completion|Interruption of study drug due to side effects or permanent cessation of study drug or cancer treatment due to cardiac dysfunction, as defined by reduction in drug dose or delay of cancer treatment by more than 1 week or permanent cessation, From start of anthracycline therapy to upto 4 weeks of anthracycline completion|Troponin I, Maximal increase in troponin I, Maximal increase in Troponin I between pre-anthracycline therapy to within 4 weeks of anthracycline completion|BNP, Maximal increase in BNP, From start of anthracycline therapy to within 4 weeks of cancer therapy completion|Myocardial strain, Maximal change in myocardial strain, From start of anthracycline therapy to within 4 weeks of cancer therapy completion|MRI tissue characterization parameters, Maximal change in myocardial tissue characterization parameters as measured by cardiac MRI from pre-anthracycline treatment to within 4 weeks of anthracycline completion, Within 4 weeks of anthracycline completion
Sponsor: University Health Network, Toronto
Collaborators: Mount Sinai Hospital, Canada|Unity Health Toronto|Sunnybrook Health Sciences Centre|Scarborough General Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 112
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: SPARE HF Pilot
Start Date: 2018-05-10
Primary Completion Date: 2021-12-21
Completion Date: 2023-12
First Posted: 2017-06-14
Results First Posted:
Last Update Posted: 2022-02-08
Locations: Toronto General Hospital, Toronto, Ontario, M5G 2N2, Canada
Study Documents:

NCT Number: NCT03838627
Study Title: Feasibility and Agreement of Remote Evaluation of Resting Heart Rate and Heart Rate Variability in Survivors of Hodgkin Lymphoma Treated With Chest Radiation (PILOT STUDY-SURVIVOR)

Study URL: https://beta.clinicaltrials.gov/study/NCT03838627
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Primary Objective The objective is to determine the feasibility and agreement of remote evaluation of resting heart rate and HRV using the commercially available WHOOP® wrist monitor, compared to in-office measurements using AtCor Medical SphygmoCor HRV Software, in a cohort of 40 St. Jude Life Study participants with a history of mantle radiation for management of Hodgkin lymphoma.

Elucidating the mechanisms that contribute to adverse cardiovascular outcomes and reduced quality of life among the growing population of childhood cancer survivors is paramount. Cancer, certain cancer drugs, radiation therapy, cancer-associated lifestyle disturbances, and cancer-independent comorbidities combine to predispose cancer survivors to autonomic dysfunction (AD). Reduced heart rate variability (HRV) has been described in various cancer cohorts. Furthermore, these markers of AD have been implicated in adverse outcomes in oncology patients, including increased mortality, exercise limitation, and fatigue. However, data are largely derived from small studies with methodological limitations, and the contribution of AD to overall morbidity and mortality in cancer survivors is not well understood.

The objective is to determine the feasibility and agreement of remote evaluation of resting heart rate and HRV using the commercially available WHOOP® wrist monitor, compared to in-office measurements using AtCor Medical SphygmoCor HRV Software, in a cohort of 40 St. Jude Life Study participants with a history of mantle radiation for management of Hodgkin lymphoma.
Study Results: NO
Conditions: Hodgkin Disease
Interventions:
Primary Outcome Measures: The number of patients who wear, return and have sufficient data for analysis of resting heart rate and HRV after removal of noise by WHOOP® HRV software data analysis algorithms., Feasibility will be considered adequate if 30 of 40 participants have at least 3 hours of HRV data from the home wearing period., 48 hours| The degree of agreement between measurements of continuous HRV parameters derived from the two methods will be assessed using linear regression, Pearson's correlation coefficient and Bland Altman analysis., A mean discrepancy of \<20 msec for SDNN measured by the two methods will be considered acceptable agreement., 10 minute electrocardiogram recording
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: St. Jude Children's Research Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases:
Enrollment: 34
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: WHOOPHPP|NCI-2021-05183
Start Date: 2019-02-05
Primary Completion Date: 2021-01-19
Completion Date: 2023-06-30
First Posted: 2019-02-12
Results First Posted:
Last Update Posted: 2023-01-25
Locations: Kirsten Ness, Memphis, Tennessee, 38105, United States
Study Documents: Study Protocol and Informed Consent Form

NCT Number: NCT03604627
Study Title: Study of Coronary Calcium Score as a Marker of Post-radiation Vascular Dysplasia in Adults Treated During Childhood for Cancer With Mediastinal Irradiation
Study URL: https://beta.clinicaltrials.gov/study/NCT03604627
Acronym: COROCAN
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: To measure coronary calcium score in adults treated during childhood or adolescence for irradiation cancer in the heart and / or anthracycline area and compare them to determine whether irradiation of the heart area is associated with increased calcium score after adjustment for other cardiovascular risk factors (age, sex, smoking, dyslipidemia, obesity, diabetes, high blood pressure and renal failure).
Study Results: NO
Conditions: Childhood Cancer
Interventions: OTHER: Coronal calcium score measurement
Primary Outcome Measures: Incidence of a calcium score, Incidence of a calcium score measured by the Agatston score\> 0 in the study population of adults treated during childhood or adolescence for cancer with irradiation of the heart area and / or treatment with anthracyclines, Up to 24 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Gustave Roussy, Cancer Campus, Grand Paris
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 300
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 2017-A02256-47|2017/2610

Start Date: 2018-06-14
Primary Completion Date: 2023-09
Completion Date: 2025-06
First Posted: 2018-07-27
Results First Posted:
Last Update Posted: 2023-05-17
Locations: Gustave Roussy, Villejuif, Val De Marne, 94805, France|Hôpital Bichat, Paris, France|Hôpital Trousseau, Paris, France
Study Documents:

NCT Number: NCT05036252
Study Title: Study of Cardiopulmonary Exercise Testing in Women Who Have HER2-Positive Breast Cancer With Mild Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT05036252
Acronym:
Study Status: RECRUITING
Brief Summary: The purpose of this study is to find out how much oxygen is used during a cardiopulmonary exercise test (CPET) in women who have mild cardiotoxicity after standard treatment for HER2-positive breast cancer, and to see whether the results of this test can be used to predict how well participants' heart and lungs will work if they continue to receive this kind of treatment.
Study Results: NO
Conditions: Breast Cancer|HER2-positive Breast Cancer|HER2-positive Metastatic Breast Cancer|Breast Cancer Stage I|Breast Cancer Stage II|Breast Cancer Stage III|Breast Cancer Stage IV|Cardiotoxicity
Interventions: DIAGNOSTIC_TEST: Cardiopulmonary Exercise Test|DIAGNOSTIC_TEST: Echocardiogram|DIAGNOSTIC_TEST: Echocardiography
Primary Outcome Measures: Baseline VO2peak in participants with HER2-positive breast cancer, The primary purpose is to evaluate baseline VO2peak in patients with HER2-positive solid tumors and left ventricular systolic dysfunction, At baseline
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 30
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 21-271
Start Date: 2021-08-27
Primary Completion Date: 2023-08-27
Completion Date: 2023-08-27
First Posted: 2021-09-05
Results First Posted:
Last Update Posted: 2022-09-16

Locations: Memorial Sloan - Kettering Cancer Center, New York, New York, 10021, United States
Study Documents:

NCT Number: NCT01944826
Study Title: The TAKO-TSUBO And Cancer Registry
Study URL: https://beta.clinicaltrials.gov/study/NCT01944826
Acronym: TTAC
Study Status: UNKNOWN
Brief Summary: Prospective, multicenter, observational registry collecting data from subjects with Tako-Tsubo (stress-induced) cardiomyopathy (TTC). Uniform, complete, and accurate data will be collected on the subject's medical history, during index hospitalization for TTC, and during follow-up.

The objectives are to evaluate the prevalence and incidence of cancer in patients with TTC, to document the underlying causes of death during hospital stay and during follow-up, to determine the long-term prognosis, and to identify possible predictors of short and long-term mortality.
Study Results: NO
Conditions: Tako-Tsubo Cardiomyopathy|Stress-induced Cardiomyopathy|Acute Coronary Syndrome
Interventions: OTHER: Registry of patients with Tako-Tsubo cardiomyopathy
Primary Outcome Measures: prevalence and incidence of cancer in patients with TTC, 5 years
Secondary Outcome Measures: causes of death during hospital stay and during follow-up, 5 years
Other Outcome Measures: possible predictors of short and long-term mortality in patients with TTC, 5 years
Sponsor: Deutsches Herzzentrum Muenchen
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 800
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: TTAC
Start Date: 2011-02
Primary Completion Date: 2016-02
Completion Date: 2016-02
First Posted: 2013-09-18
Results First Posted:
Last Update Posted: 2013-09-18
Locations: Deutsches Herzzentrum München, Munich, Bavaria, 80636, Germany
Study Documents:

NCT Number: NCT04361552
Study Title: Tocilizumab for the Treatment of Cytokine Release Syndrome in Patients With COVID-19 (SARS-CoV-2 Infection)
Study URL: https://beta.clinicaltrials.gov/study/NCT04361552
Acronym:
Study Status: WITHDRAWN
Brief Summary: This phase III trial compares the effect of adding tocilizumab to standard of care versus standard of care alone in treating cytokine release syndrome (CRS) in patients with SARS-CoV-2 infection. CRS is a potentially serious disorder caused by the release of an excessive amount of substance that is made by cells of the immune system (cytokines) as a response to viral infection. Tocilizumab is used to decrease the body's immune response. Adding tocilizumab to standard of care may work better in treating CRS in patients with SARS-CoV-2 infection compared to standard of care alone.
Study Results: NO
Conditions: Cerebrovascular Accident|Chronic Obstructive Pulmonary Disease|Chronic Renal Failure|Coronary Artery Disease|Diabetes Mellitus|Malignant Neoplasm|SARS Coronavirus 2 Infection
Interventions: OTHER: Best Practice|BIOLOGICAL: Tocilizumab
Primary Outcome Measures: 7-day length of invasive mechanical ventilation (MV), The 7-day length of invasive MV for each arm will be estimated with 95% confidence intervals (CIs) using the exact binomial distribution. Their difference by the arms will be tested by Cochran-Mantel-Haenszel (CMH) test stratified by the age group and Sequential Organ Failure Assessment (SOFA) score at significance level of 0.05., Up to 7 days|30-day mortality rate, Defined as death within 30-day after randomization. The 30-day mortality rate for each arm will be estimated with 95% CIs using the exact binomial distribution. Their difference by the arms will be tested CMH test stratified by the age group and SOFA score at significance level of 0.05., Up to 30-day after randomization
Secondary Outcome Measures: Rate of intensive care (ICU) transfer, The rate of ICU transfer for each arm will be estimated with 95% CIs using the exact binomial distribution. Their difference by the arms will be tested CMH test stratified by the age group and SOFA score at significance level of 0.05., Up to 2 years|Rate of invasive mechanical ventilation, The rate of invasive mechanical ventilation for each arm will be estimated with 95% CIs using the exact binomial distribution. Their difference by the arms will be tested CMH test stratified by the age group and SOFA score at significance level of 0.05., Up to 2 years|Rate of tracheostomy, The rate of tracheostomy for each arm will be estimated with 95% CIs using the exact binomial distribution. Their difference by the arms will be tested CMH test stratified by the age group and SOFA score at significance level of 0.05., Up to 2 years|Length of ICU stay, Will first be described by median and inter-quartile, and then compared between two arms by Wilcoxon Sum-Rank test, Up to 2 years|Length of hospital stay, Up 2 years
Other Outcome Measures:

Sponsor: Emory University
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: STUDY00000419|NCI-2020-02314|WINSHIP4998-20|P30CA138292
Start Date: 2020-04-07
Primary Completion Date: 2020-06-02
Completion Date: 2020-06-02
First Posted: 2020-04-24
Results First Posted:
Last Update Posted: 2020-06-18
Locations: Emory University Hospital/Winship Cancer Institute,
Atlanta, Georgia, 30322, United States
Study Documents:

NCT Number: NCT05411705
Study Title: Efficacy and Safety of rhTPO's Prophylactic Treatment of
CTIT in Patients With High Risk of Cardiac Injury
Study URL: https://beta.clinicaltrials.gov/study/NCT05411705
Acronym: Circular
Study Status: RECRUITING
Brief Summary: To assess the efficacy and safety of an optimised
dosing regimen of rhTPO's prophylactic treatment of cancer treatment-
induced thrombocytopenia(CTIT) and to explore the cardioprotective
effect of rhTPO in cancer patients with high risk of treatment-induced
cardiac injury.
Study Results: NO
Conditions: Cancer Treatment Induced Thrombocytopenia
Interventions: DRUG: rhTPO|DRUG: Control
Primary Outcome Measures: Proportion of patients whose platelet count
is ≥ 75×10^9/L after 2 cycles cancer treatment., Efficacy was defined
as treatment without salvage therapy to increase platelet counts.,
After 2 cycles cancer treatment (month 1.5~month 2, depends on
chemotherapy regimen), each cycle is 14, 21 or 28 days
Secondary Outcome Measures: Proportion of patients receiving salvage
treatment to increase platelet counts., Salvage treatment including
platelet infusion, rhIL-11, etc., during 3 cycles cancer treatment
period(each cycle is 14, 21 or 28 days)|Changes in cTnT/cTnI, 1,3 and
6 months after initial treatment|Changes in NT-proBNP, 1,3 and 6
months after initial treatment|Changes in LVEF, LVEF will be assessed
by echocardiography, 1,3 and 6 months after initial treatment|Changes
in neutrophile granulocyte count, during 3 cycles cancer treatment
period(each cycle is 14, 21 or 28 days)|Incidence of adverse events,
treatment-related adverse events, from study start date to the end of

follow-up, up to 6 months
Other Outcome Measures:
Sponsor: The First Affiliated Hospital of Dalian Medical University
Collaborators: Shenyang Sunshine Pharmaceutical Co., LTD.
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 165
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: FJ-KS-KY-2022-28(X)
Start Date: 2022-06-06
Primary Completion Date: 2023-11
Completion Date: 2024-06
First Posted: 2022-06-09
Results First Posted:
Last Update Posted: 2023-01-04
Locations: Anqing Municipal Hospital, Anqing, Anhui, 246003, China|
Cancer Hospital Chinese Academy of Medical Sciences, Beijing, Beijing,
100021, China|Penking University Shougang Hospital, Beijing, Beijing,
100144, China|Chinese PLA General Hospital, Beijing, Beijing, 100853,
China|The Fourth Hospital of Hebei Medical University, Shijiazhuang,
Hebei, 050011, China|Harbin Medical University Cancer Hospital,
Harbin, Heilongjiang, 150081, China|Henan Provincial People's
Hospital, Zhengzhou, Henan, 450003, China|Henan Cancer Hospital,
Zhengzhou, Henan, 450008, China|Union Hospital Tongji Medical College,
Huazhong University of Science and Technology, Wuhan, Hubei, 430022,
China|Tongji Hospital Tongji Medical College of Huazhong University of
Science & Technology, Wuhan, Hubei, 430030, China|Jilin Cancer
Hospital, Changchun, Jilin, 130012, China|China-japan Union Hospital
Of Jilin University, Changchun, Jilin, 130033, China|The First
Affiliated Hospital of Dalian Medical University, Dalian, Liaoning,
116011, China|Liaoning Cancer Hospital & Institute, Shenyang,
Liaoning, 110801, China|Shaanxi Provincial cancer Hospital, Xi'an,
Shaanxi, 710065, China|Shandong Cancer Hospital, Jinan, Shandong,
250117, China|Tianjin Medical University Cancer Tnstitute & Hospital,
Tianjin, Tianjin, 300181, China|Cancer hospital of the University
Chinese Academy of Sciences, Hangzhou, Zhejiang, 11008795, China
Study Documents:

NCT Number: NCT02610426
Study Title: Whole Exome Sequencing in Finding Causative Variants in
Germline DNA Samples From Patients With Congestive Heart Failure
Receiving Therapy for Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02610426
Acronym:
Study Status: RECRUITING
Brief Summary: This research trial studies whole exome sequencing in

finding causative variants in germline deoxyribonucleic acid (DNA) samples from patients with congestive heart failure receiving therapy for breast cancer. Studying samples of germline DNA in the laboratory from patients with congestive heart failure receiving therapy for breast cancer may help doctors learn more about changes that occur in DNA and identify biomarkers related to congestive heart failure.
Study Results: NO
Conditions: Breast Carcinoma
Interventions: OTHER: Laboratory Biomarker Analysis
Primary Outcome Measures: Identification of rare coding variants of large effect that predict the risk of CHF, Assessed by burden analysis., Baseline
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Cancer Institute (NCI)
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 162
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NCI-2013-02291|NCI-2013-02291|ECOG-E5103T3|E5103T3|E5103T3|U10CA180820
Start Date: 2014-03-25
Primary Completion Date: 2100-01-01
Completion Date: 2100-01-01
First Posted: 2015-11-20
Results First Posted:
Last Update Posted: 2023-05-06
Locations: Eastern Cooperative Oncology Group, Boston, Massachusetts, 02215, United States
Study Documents:

NCT Number: NCT05753254
Study Title: Effect on Markers of Cardiovascular, Reproductive and Cancer Risk From Firefighting Training
Study URL: https://beta.clinicaltrials.gov/study/NCT05753254
Acronym: BIOBRAND3
Study Status: NOT_YET_RECRUITING
Brief Summary: Epidemiological studies based on Danish registries have observed that Danish male firefighters have more cardiovascular disease, infertility diagnose and a trend to increased risk of cancer than other Danish employed males. Firefighting activities include a combination of stressors such as strenuous work under heat, smoke and soot known to be able to affect cardiovascular and reproductive health, with smoke and soot also being known to increase the risk of cancer.

The training facilities of real-fire extinguishing exercises in Denmark operate using wood or natural gas fire, which will have differential gradients of smoke, soot and possibly heat. The investigators will use different training conditions to create gradients of the different stressors and investigate health effects thereof. With this approach, the investigators expect to be able to evaluate the individual contribution of the different stressors in markers of cardiovascular, cancer and reproductive health risk. The project will include approx. 35 young conscript participants on a firefighting course, followed in four sessions, three firefighting training sessions under different fire conditions (no fire, wood fire and gas fire) and one control scenario.
Study Results: NO
Conditions: Reactive Hyperemia|Micro RNA|Heart Rate Variability|DNA Strand Breaks|Oxidative Stress|Heat Stress
Interventions: OTHER: Firefighting training exercises with no fire|OTHER: Firefighting training exercises under wood fire|OTHER: Firefighting training exercises under gas fire
Primary Outcome Measures: Change in reactive hyperemia index - afternoon, Reactive hyperemia index (RHI) measured with the device EndoPAT 2000. A reactive hyperemia is induced by a blood cuff on the upper arm and the peripheral vasodilation response is assessed in the small digital vessels of a fingertip with a portable device connected to a computer, with RHI determined by an algorithm from the device, with lower index values corresponding to a worsen situation., Baseline afternoon measurement, afternoon measurement immediately after firefighting without fire, afternoon measurement immediately after firefighting under wood fire and afternoon measurements immediately after firefighting under gas fire|Change in reactive hyperemia index - morning, Reactive hyperemia index (RHI) measured with the device EndoPAT 2000. A reactive hyperemia is induced by a blood cuff on the upper arm and the peripheral vasodilation response is assessed in the small digital vessels of a fingertip with a portable device connected to a computer, with RHI determined by an algorithm from the device, with lower index values corresponding to a worsen situation., Baseline morning measurement, morning measurement in subsequent day after firefighting without fire, morning measurement in subsequent day after firefighting under wood fire and morning measurement in subsequent day after firefighting under gas fire|Change in Heart Rate Variability pNN50 at rest - afternoon, Heart rate variability (HRV) measured with the device EndoPAT 2000. The HRV is calculated using the initial 5.5 complete minutes before the cuff is applied. pNN50 is the proportion of successive NN intervals differing by more than 50 milliseconds divided by the total number of N intervals (given in percentage)., Baseline afternoon measurement, afternoon measurement immediately after firefighting without fire, afternoon measurement immediately after firefighting under wood fire and afternoon measurements immediately after firefighting under gas fire|Change in Heart Rate Variability pNN50 at rest - morning, Heart rate variability (HRV) measured with the device EndoPAT 2000. The HRV is calculated using the

initial 5.5 complete minutes before the cuff is applied. pNN50 is the proportion of successive NN intervals differing by more than 50 milliseconds divided by the total number of N intervals (given in percentage)., Baseline morning measurement, morning measurement in subsequent day after firefighting without fire, morning measurement in subsequent day after firefighting under wood fire and morning measurement in subsequent day after firefighting under gas fire|Change in Heart Rate Variability RMSSD at rest - afternoon, Heart rate variability (HRV) measured with the device EndoPAT 2000. The HRV is calculated using the initial 5.5 complete minutes before the cuff is applied. RMSSD is the square root of the mean squared differences of successive NN intervals (given in milliseconds), Baseline afternoon measurement, afternoon measurement immediately after firefighting without fire, afternoon measurement immediately after firefighting under wood fire and afternoon measurements immediately after firefighting under gas fire|Change in Heart Rate Variability RMSSD at rest - morning, Heart rate variability (HRV) measured with the device EndoPAT 2000. The HRV is calculated using the initial 5.5 complete minutes before the cuff is applied. RMSSD is the square root of the mean squared differences of successive NN intervals (given in milliseconds), Baseline morning measurement, morning measurement in subsequent day after firefighting without fire, morning measurement in subsequent day after firefighting under wood fire and morning measurement in subsequent day after firefighting under gas fire|Change in Heart Rate Variability ratio LF/HF at rest - afternoon, Heart rate variability (HRV) measured with the device EndoPAT 2000. The HRV is calculated using the initial 5.5 complete minutes before the cuff is applied. Ratio of low frequency and high frequency bands, Baseline afternoon measurement, afternoon measurement immediately after firefighting without fire, afternoon measurement immediately after firefighting under wood fire and afternoon measurements immediately after firefighting under gas fire|Change in Heart Rate Variability ratio LF/HF at rest - morning, Heart rate variability (HRV) measured with the device EndoPAT 2000. The HRV is calculated using the initial 5.5 complete minutes before the cuff is applied. Ratio of low frequency and high frequency bands, Baseline morning measurement, morning measurement in subsequent day after firefighting without fire, morning measurement in subsequent day after firefighting under wood fire and morning measurement in subsequent day after firefighting under gas fire|Changes in levels of 8-oxodG excretion in first morning urine, Oxidized nucleobase 8-oxodG will be measured in urine samples by High-performance liquid chromatography (HPLC) as marker of oxidative stress, together with creatinine, for adjusting for urine concentration. Data will be reported as nanomol 8-oxodG per millimol creatinine., Baseline, before firefighting without fire, day after firefighting without fire, before firefighting under wood fire, day after firefighting under wood fire, before firefighting under gas fire, day after firefighting under gas fire|Changes in levels of DNA strand breaks in peripheral blood mononuclear cells, DNA strand breaks will be measured by comet assay, and reported as number of lesions per

10\^6 base pairs, transformed from percentage of DNA in tail using the calibration curve from the well-establish relationship between ionizing radiation dose and yield of strand breaks in DNA., Baseline, before firefighting without fire, day after firefighting without fire, before firefighting under wood fire, day after firefighting under wood fire, before firefighting under gas fire, day after firefighting under gas fire|Changes in core temperature, Core body temperature will be assessed by an ingestible pill thermometer with data recorded and reported as time series during the period in transit., Baseline day, during the day of firefighting without fire, during the day of firefighting under wood fire and during the day of firefighting under gas fire.|Changes in scrotal temperature, Scrotal temperature will be assessed by skin sensor placed in the scrotum of male participants and reported as scrotal skin temperature time series., Baseline day, during the day of firefighting without fire, during the day of firefighting under wood fire and during the day of firefighting under gas fire.|Changes in scrotal thermoregulation, Core body temperature will be assessed by an ingestible pill thermometer and scrotal temperature will be assessed by skin sensor placed in the scrotum of male participants, to assess the thermoregulation of the scrotum during firefighting exercises. Time series of core body temperature and scrotal skin temperature will be analysed for eventual thermoregulation disruption., Baseline day, during the day of firefighting without fire, during the day of firefighting under wood fire and during the day of firefighting under gas fire.|Changes in levels of circulating micro RNA, Circulating micro RNA candidates will be measured by RNA extraction from serum samples, reverse transcribed into complementary DNA (cDNA) and analysed with quantitative polymerase chain reaction (qPCR)., Baseline, before firefighting without fire, day after firefighting without fire, before firefighting under wood fire, day after firefighting under wood fire, before firefighting under gas fire, day after firefighting under gas fire|Changes in urinary potency of AhR activation, The aryl hydrocarbon receptor (AhR) activation will be assessed in vitro using urine samples on the PAH CALUX (Chemical Activated LUciferase gene eXpression bioassay) reporter assay. The smoke and soot exposures are complex mixtures of compounds with potential toxic effect. Routine measurements of PAHs are usually quantified for a target list of 16 common soot elements and even less chemical species for urinary metabolites, but many other compounds are present in both soot and metabolites mixtures. The toxicity of PAHs is primarily caused through the binding to AhR, and induction of AhR related genes and subsequent toxic pathways. The outcome will be measured in the form of benzo\[a\]pyrene equivalence., Baseline, before firefighting without fire, day after firefighting without fire, before firefighting under wood fire, day after firefighting under wood fire, before firefighting under gas fire, day after firefighting under gas fire|Changes in potency of AhR activation from skin deposits, The aryl hydrocarbon receptor (AhR) activation will be assessed in vitro using wipe samples on the PAH CALUX (Chemical Activated LUciferase gene eXpression

bioassay) reporter assay. The smoke and soot exposures are complex mixtures of compounds with potential toxic effect. Routine measurements of PAHs are usually quantified for a target list of 16 common soot elements, but many other compounds are present in soot mixtures. The toxicity of PAHs is primarily caused through the binding to AhR, and induction of AhR related genes and subsequent toxic pathways. The outcome will be measured in the form of benzo\[a\]pyrene equivalence., Baseline, before firefighting without fire, immediately after firefighting without fire, before firefighting under wood fire, immediately after firefighting under wood fire, before firefighting under gas fire, immediately after firefighting under gas
Secondary Outcome Measures: Changes in levels of follicle-stimulating hormone in serum, Follicle-stimulating hormone (FSH) will be measured in serum samples, Baseline, before firefighting without fire, day after firefighting without fire, before firefighting under wood fire, day after firefighting under wood fire, before firefighting under gas fire, day after firefighting under gas fire|Changes in levels of serum inhibin B, Inhibin B hormone will be measured in serum samples, Baseline, before firefighting without fire, day after firefighting without fire, before firefighting under wood fire, day after firefighting under wood fire, before firefighting under gas fire, day after firefighting under gas fire|Changes in urinary levels of PAH metabolites excretion, The internal dose of polycyclic aromatic hydrocarbons (PAHs), that would have the contribution from different exposure routes, will be assessed in first morning urine samples and measured for 7 isomer hydroxyl-PAH compounds and 5 nitro-PAH compounds, measured by high-performance liquid chromatography (HPLC), Baseline, before firefighting without fire, day after firefighting without fire, before firefighting under wood fire, day after firefighting under wood fire, before firefighting under gas fire, day after firefighting under gas fire|Changes in levels of PAHs in skin wipes from the neck, Skin wipes will be sampled to determine the PAH composition of deposited soot on the neck area. The wipes will be analysed for the 16 US Environmental Protection Agency priority list of PAH compounds by HPLC., Baseline, before firefighting without fire, immediately after firefighting without fire, before firefighting under wood fire, immediately after firefighting under wood fire, before firefighting under gas fire, immediately after firefighting under gas| Changes in FEV1 spirometric measurements, Lung function will be measured by spirometry using the Spirometer device EasyOne Air. Forced Expiratory Volume at 1 second (FEV1)., Baseline, immediately after firefighting without fire, immediately after firefighting under wood fire and immediately after firefighting under gas fire|Changes in FVC spirometric measurements, Lung function will be measured by spirometry using the Spirometer device EasyOne Air. Forced Vital capacity (FVC)., Baseline, immediately after firefighting without fire, immediately after firefighting under wood fire and immediately after firefighting under gas fire|Changes in PEF spirometric measurements, Lung function will be measured by spirometry using the Spirometer device EasyOne Air. Peak Expiratory Flow (PEF)., Baseline, immediately after

firefighting without fire, immediately after firefighting under wood fire and immediately after firefighting under gas fire|Changes in FEV1/FVC ratio from spirometric measurements, Lung function will be measured by spirometry using the Spirometer device EasyOne Air. Forced Expiratory Volume at 1 second (FEV1) and Forced Vital Capacity (FVC) ratio is calculated from device output., Baseline, immediately after firefighting without fire, immediately after firefighting under wood fire and immediately after firefighting under gas fire|Changes in blood troponin levels, Cardiac troponin levels using ELISA immunoassays will be assessed in serum samples., Baseline, before firefighting without fire, day after firefighting without fire, before firefighting under wood fire, day after firefighting under wood fire, before firefighting under gas fire, day after firefighting under gas fire|Changes in work load measured by muscle activity, Muscle activity will be assessed to control for body workload through electromyography (EMG) using the portable device Nexus10. Bipolar surface EMG electrodes are applied to the skin over the muscles in 3 relevant body regions (shoulder, leg and back). The signals are collected with a data logger and reported as work load during a working day., Baseline day, firefighting without fire day, firefighting under wood fire day and firefighting under gas fire day
Other Outcome Measures:
Sponsor: National Research Centre for the Working Environment, Denmark
Collaborators: University of Copenhagen|University Hospital Bispebjerg and Frederiksberg|Rigshospitalet, Denmark
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 35
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: BASIC_SCIENCE
Other IDs: 72403|FFIKA WP4.3|AMFF 16-2022-03|H-21068847
Start Date: 2023-03
Primary Completion Date: 2024-06
Completion Date: 2024-06
First Posted: 2023-03-03
Results First Posted:
Last Update Posted: 2023-03-03
Locations: The National Research Centre for the Working Environment, Copenhagen, 2100, Denmark
Study Documents:

NCT Number: NCT04473703
Study Title: Cardiac Adverse Reactions Related to Immune Checkpoint Inhibitor in NSCLC Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04473703
Acronym:
Study Status: NOT_YET_RECRUITING

Brief Summary: This is a prospective, open label, single arm study. A total of 300 patients with primary non-small cell lung cancer treated with PD-1/PD-L1 immune checkpoint inhibitors(ICIs) are expected to included . All patients will follow up for at least 1 year. Patients with cardiac adverse reactions after PD-1/PD-L1 immune checkpoint inhibitor treatment at admission or during the subsequently follow-up period will randomly assigned a random number to each patient by computer random sequence. Patients with odd random number will treat with RASI (renin-angiotensin system inhibitors) , and those with even random number will treat with ARNI (angiotensin-receptor-neprilysin inhibitor) .
Study Results: NO
Conditions: Adverse Reactions|Immune Checkpoint Inhibitor|Non-Small Cell Lung Cancer Patients|Cardiac Event
Interventions: DRUG: renin-angiotensin system inhibitors or angiotensin-receptor-neprilysin inhibitor
Primary Outcome Measures: Major Adverse Cardiovascular Events, a) Primary Outcome is Major Adverse Cardiovascular Events (MACE) related to ICIs, includes: cardiovascular death, myocardial infarction(nonfatal), stroke(nonfatal), heart failure that caused readmission, 1 year
Secondary Outcome Measures: Common Terminology Criteria for Adverse Events (CTCAE), Common Terminology Criteria for Adverse Events (CTCAE) related to ICIs, includes: arrhythmia, cardiogenic chest pain, valvular heart disease, cardiomyopathy, myocardial pericardial disease, 1 year|All cause of death, every reason that cause patient's death after ICIs treatment, 1 year|examination indexes, The examination indexes that related to myocardial damage, 1 year
Other Outcome Measures:
Sponsor: Shanghai Chest Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 300
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SHXKYY202005
Start Date: 2020-08-01
Primary Completion Date: 2022-08-01
Completion Date: 2023-08-01
First Posted: 2020-07-16
Results First Posted:
Last Update Posted: 2020-07-16
Locations:
Study Documents:

NCT Number: NCT03553654

Study Title: Low-dose CT-based Method for Detection of Subclinical Anthracycline-induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT03553654
Acronym:
Study Status: COMPLETED
Brief Summary: Prospective single arm study to evaluate a low-dose CT-based protocol for early detection of myocardial dysfunction in 50 cancer patients undergoing anthracycline-based chemotherapy.
Study Results: NO
Conditions: Neoplasms
Interventions: DIAGNOSTIC_TEST: low dose CT
Primary Outcome Measures: cardiomyopathy, Cardiomyopathy is defined as a decrease in the left ventricular ejection fraction by echocardiography of greater than 10 percentage points, to a value \< 53% (normal reference value for 2D echocardiography)., 12 months after completion of chemotherapy
Secondary Outcome Measures: Change in CT-based left ventricular strain parameters, Change in CT-based left ventricular strain parameters before and after the chemotherapy, 12 months after completion of chemotherapy|Change in left ventricular global longitudinal strain based on echocardiography, Change in left ventricular global longitudinal strain between baseline and post-chemotherapy., 12 months after completion of chemotherapy|Change in echocardiographic left ventricular ejection fraction, left ventricular ejection fraction change between baseline and post-chemotherapy., 12 months after completion of chemotherapy
Other Outcome Measures:
Sponsor: University of California, San Diego
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 19
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 160252
Start Date: 2018-01-09
Primary Completion Date: 2021-12-12
Completion Date: 2021-12-12
First Posted: 2018-06-12
Results First Posted:
Last Update Posted: 2022-11-03
Locations: University of California San Diego Medical Center, San Diego, California, 92037, United States
Study Documents:

NCT Number: NCT01143454
Study Title: Characterization of Patients With Uncommon Presentations

and/or Uncommon Diseases Associated With the Cardiovascular System
Study URL: https://beta.clinicaltrials.gov/study/NCT01143454
Acronym:
Study Status: RECRUITING
Brief Summary: Background:

- Researchers are interested in studying individuals who have known or suspected metabolic or genetic diseases that put them at a high risk for heart diseases or diseases of their blood vessels. To improve the results of the study, both affected and nonaffected individuals will be asked to provide blood and other samples and will undergo tests to evaluate heart and lung function. Nonaffected individuals will include relatives of affected individuals and healthy nonrelated volunteers.

Objectives:

- To study individuals who have or are at risk for cardiovascular diseases, as well as their unaffected relatives and healthy volunteers.

Eligibility:

- Individuals between 1 and 100 years of age. Participants may be healthy volunteers, individuals with cardiovascular diseases, or unaffected relatives of individuals with cardiovascular diseases.

Design:

* Participants will have some or all of the following tests, as directed by the study researchers:
* Photography of the face and full body
* Body measurements
* Radiography, including chest or limb x-rays
* Metabolic stress testing to study heart and muscle function
* Echocardiography to study heart function
* Magnetic resonance imaging (MRI) studies, including cardiovascular MRI, angiography, and contrast MRI, to study heart function and performance
* Computed tomography (CT) angiogram to obtain images of the heart and lungs
* Positron emission tomography (PET) imaging to study possible fat infiltration of the heart
* Six-minute walk test to study heart, lung, and muscle function and performance
* Vascular ultrasound to study blood vessel walls
* Blood, tissue, and other specimens will be collected for research and testing, and will be taken either as part of the clinical study or during surgical procedures.
* Follow-up studies may be performed under separate research protocols.

Study Results: NO
Conditions: Cardiomyopathy|Li-Fraumeni Syndrome|Parkinson's Disease|Atherosclerosis|Cardiovascular Capacity
Interventions: DRUG: 11C-Acetate|DRUG: 13N-Amonia
Primary Outcome Measures: Disease Diagnosis, This protocol will complement the aims of the Undiagnosed Diseases Program (UDP), which may admit some of its subjects through this protocol, to provide answers to subjects with conditions associated with cardiovascular features that may have long eluded diagnosis and to advance medical knowledge about rare and uncommon human diseases., Ongoing
Secondary Outcome Measures: Understanding disease pathophysiolgy, to assist in the understanding of disease pathophysiology and in the generation of diagnoses in subjects with uncommon presentations of diseases with cardiovascular consequences., Ongoing|Potential genetic counseling, Determining molecular etiology of diseases encountered on this protocol, Ongoing
Other Outcome Measures:
Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 5000
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 100126|10-H-0126
Start Date: 2010-07-21
Primary Completion Date:
Completion Date:
First Posted: 2010-06-14
Results First Posted:
Last Update Posted: 2023-07-11
Locations: National Institutes of Health Clinical Center, Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT01328054
Study Title: A Study in Cancer Patients to Evaluate the Effect of Lapatinib on the QTc Interval
Study URL: https://beta.clinicaltrials.gov/study/NCT01328054
Acronym:
Study Status: COMPLETED
Brief Summary: This study will estimate the effect of lapatinib on cardiac repolarization (QTc interval duration) in subjects with advanced solid tumors. The study treatment period will occur over five days and an End of Study visit will be conducted on Day 8 (or no later than 3 days beyond Day 8). Subjects will receive placebo that mimics lapatinib for 2 days as three separate doses given 12 hours apart (8 tablets/dose) and lapatinib (2000mg) for 2 days as three separate

doses given 12 hours apart (8 tablets/dose). Subjects will not know when they are receiving placebo vs. lapatinib. Digital 12-lead ECG recordings will be extracted from continuous ECG recordings obtained via a Holter monitor to measure QTc interval duration. Triplicate ECG measurements of QTc interval will be taken at pre-specified times at Day 1 (Baseline) and pre-dose and up to 24 hours after the third dose of placebo or lapatinib on Study Days 2 and 4. Pharmacokinetic sampling will occur immediately following each pre-specified QTc measurement in subjects dosed with placebo or lapatinib. Subjects who complete participation in this study, if they are eligible, will be offered the option to continue treatment with lapatinib, either alone or in combination with other oncology drugs in pre-selected anticancer regimens, in a continuation protocol, EGF111767.
Study Results: YES
Conditions: Cancer
Interventions: DRUG: lapatinib|DRUG: placebo matching lapatinib
Primary Outcome Measures: Treatment Difference in Duration of Cardiac Ventricular Depolarization and Repolarization Interval (QT) in Fridericia-corrected QT Interval (QTcF) Values Between Placebo and Lapatinib 2000mg, A Holter monitor is an ambulatory portable device used for continuously monitoring the cardiovascular system. Three replicate electrocardiograms (ECGs) were collected at 30, 15, and 0 minutes prior to the administration of study treatment (trt) on Days 1 and 3 and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hr post-dose on Days 2 and 4. The 3 readings at each time point (TP) were averaged prior to any analysis. BL is the average of the pre-dose QTcF values (triplicate) taken on Day 1 for PBO and on Day 3 for LAP. Mean change from BL was calculated by subtracting the BL values from individual QTcF for each TP. BL adjusted mean difference in absolute QTcF between LAB and PBO (trt difference) with the corresponding 90% confidence interval (CI) was estimated for each TP (pre-dose and 1, 2, 3, 4, 6, 8, 10, 12, and 24-hr post-dose). Trt difference analysis was performed by a repeated measures analysis of variance adjusted for trt group, TP, and trt group*TP interaction., Baseline (BL) (Day1) and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24-hours (hr) post-dose on Day 2 for placebo (PBO). Baseline (Day 3) and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24-hours post-dose on Day 4 for lapatinib (LAP).
Secondary Outcome Measures: Change From Baseline in the Holter ECG Parameters of QT Interval, Corrected QT Interval (QTc), Bazett Corrected QTc Interval (QTcB), Individual-corrected QT Interval (QTcI), RR Interval, PR Interval, and QRS Duration at Indicated Time Points, A Holter monitor is an ambulatory portable device for continuously monitoring the cardiovascular system. Change from Baseline in QT interval, QTc interval, QTcB interval, QTcI interval, RR interval, PR interval, and QRS duration at each time point for lapatinib was assessed in comparison with time-matched placebo. Three replicate ECGs were collected at 30, 15, and 0 minutes prior to the administration of study treatment on Days 1 and 3 and pre-dose and 1, 2, 3, 4, 6, 8, 10, and 24 hours post dose on Days 2 and 4. The three readings at each time point were averaged prior to any analysis.

Baseline is the average of the pre-dose ECGs (triplicate) taken on Day 1 for placebo and Day 3 for lapatinib. Change from Baseline was calculated by subtracting the Baseline values from individual post-Baseline values for each time point., Baseline (Day1) and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24-hours post-dose on Day 2 for placebo. Baseline (Day 3) and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24-hours post-dose on Day 4 for lapatinib.|Number of Participants With 12-lead Holter ECG Findings at the Indicated Time Points, The number of participants with 12-lead Holter ECG findings of normal (NL), abnormal not clinically significant (Abn NCS), and abnormal clinically significant (Abn CS) are reported. Abnormal ECG findings or change in ECG morphological patterns were based on the ECG interpretations provided by the ECG core lab. Three replicate 12-lead Holter ECGs were collected at -30, -15, and 0 minutes prior to the administration of study treatment on Days 1 (Baseline for placebo) and 3 (Baseline for lapatinib) and pre-dose and 1, 2, 3, 4, 6, 8, 10,12, and 24 hours post dose on Days 2 and 4. The three readings at each time point were averaged prior to any analysis. Baseline is the pre-dose ECGs (triplicate) taken on Day 1 for placebo and on Day 3 for lapatinib., Baseline (Day1) and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24-hours post-dose on Day 2 for placebo. Baseline (Day 3) and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24-hours post-dose on Day 4 for lapatinib.|Number of Participants With the Worst-case Post-Baseline 12-lead Holter ECG Findings With Significant ST, T Wave, and U Wave Abnormalities, Abnormal ECG findings or change in ECG morphological patterns were based on the ECG interpretations provided by the ECG core lab. Three replicate Holter ECGs were collected at 30, 15, and 0 minutes prior to the administration of study treatment on Days 1 (Baseline for placebo) and 3 (Baseline for lapatinib) and pre-dose and 1, 2, 3, 4, 6, 8, 10, and 24 hours post dose on Days 2 and 4. The three readings at each time point were averaged prior to any analysis. Baseline is the pre-dose ECGs (triplicate) taken on Day 1 for placebo and Day 3 for lapatinib. The number of participants with the worst-case post-Baseline 12-lead Holter ECG findings with significant ST, T wave, and U wave abnormalities were analyzed., Baseline (Day1) and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24-hours post-dose on Day 2 for placebo. Baseline (Day 3) and pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, and 24-hours post-dose on Day 4 for lapatinib.|Number of Participants With Any Adverse Event (AE) or Serious Adverse Event (SAE), An AE is defined as any untoward medical occurrence in a participant temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity or is a congenital anomaly/birth defect, or is an important medical eventsthat jeopardizes the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition, new primary cancers, liver events, cardiac dysfunction, pneumonitis, and laboratory abnormalities., From the start of study

treatment until follow-up (within approximately 28 days following the last dose of study medication [up to end of Study Week 4])|Mean Albumin, and Hemoglobin at the Indicated Time Points, Blood samples were collected for the measurement of albumin and hemoglobin at Baseline; Days 5 and 8-11. Baseline is defined as the most recent, non-missing value from a central laboratory prior to or on the first study treatment dose date., Baseline; Day 5 and end of study visit on Day 8-11|Mean Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), and Aspartate Aminotransferase (AST) at the Indicated Time Points, Blood samples were collected for the measurement of ALP, ALT, and AST at Baseline; Days 5 and 8-11. Baseline is defined as the most recent, non-missing value from a central laboratory prior to or on the first study treatment dose date., Baseline; Day 5 and end of study visit on Day 8-11|Mean Direct Bilirubin, Total Bilirubin, and Creatinine at the Indicated Time Points, Blood samples were collected for the measurement of direct bilirubin, total bilirubin, and creatinine at Baseline; Days 5 and 8-11; Baseline is defined as the most recent, non-missing value from a central laboratory prior to or on the first study treatment dose date., Baseline; Day 5 and end of study visit on Day 8-11|Mean Calcium, Chloride, Carbon Dioxide (CO2), Potassium, Sodium, Magnesium and Urea at the Indicated Time Points, Blood samples were collected for the measurement of calcium, chloride, CO2, potassium, sodium, magnesium and urea at Baseline; at Days 5 and 8-11. Baseline is defined as the most recent, non-missing value from a central laboratory prior to or on the first study treatment dose date., Baseline; Day 5 and end of study visit on Day 8-11|Mean Total Neutrophils (ANC [Absolute Neutrophil Count]), Platelets and Leukocyte Count at the Indicated Time Points, Blood samples were collected for the measurement of total neutrophils (ANC), platelets, and leukocyte count at Baseline; Days 5 and 8-11. Baseline was defined as the most recent, non-missing value from a central laboratory prior to or on the first study treatment dose date., Baseline; Day 5 and end of study visit on Day 8-11|Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at the Indicated Time Points, Blood pressure measurements included SBP and DBP and were obtained at Baseline; on Day 2 (at pre-dose, 4, 8, 12 and 24 hours post dose), and on Day 4 (at pre-dose, 4, 8, 12 and 24 hours post dose). Baseline is defined as the most recent, non-missing value prior to or on the first study treatment dose date. Change from Baseline was calculated as the post-Baseline value minus the Baseline value., Baseline; on Day 2 (at pre-dose, 4, 8, 12 and 24 hours post-dose), and on Day 4 (at pre-dose, 4, 8, 12 and 24 hours post-dose)|Change From Baseline in Heart Rate at the Indicated Time Points, Heart rate were measured at Baseline; on Day 2 (at pre-dose, 4, 8, 12 and 24 hours post dose), and on Day 4 (at pre-dose, 4, 8, 12 and 24 hours post dose. Baseline is defined as the most recent, non-missing value prior to or on the first study treatment dose date. Change from Baseline was calculated as the post-Baseline value minus the Baseline value., Baseline; on Day 2 (at pre-dose, 4, 8, 12 and 24 hours post dose), and on Day 4 (at pre-dose, 4, 8, 12 and 24 hours post dose|Number of Participants With 12-lead ECG

Findings at Indicated Time Points, The number of participants with the 12-lead ECG findings normal (NL), abnormal not clinically significant (Abn NCS), and abnormal clinically significant (Abn CS) are reported. Clinical significance was based on the medical and scientific judgement of the investigator or qualified designee. A single safety 12-lead ECG was performed using a standard 12-lead ECG machine at Baseline; on Day 1 (at pre-dose); on Day 2 (at pre-dose, 4, 8, 12 and 24 hours post-last- dose); on Day 4 (at pre-dose, 4, 8, 12 and 24 hours post-last-dose); at the End of Study visit (Day 8-11); and at the post-treatment Follow-up visit (if applicable)., BL;Day 1 (at pre-dose);Day 2 (at pre-dose, 4, 8, 12 and 24 hr post dose);Day 4 (at pre-dose, 4, 8, 12 and 24 hr post dose);End of Study visit (Day 8-11); and Follow-up (within approx 28 days following last dose of study trt [up to end of Study Week 4])|Mean Area Under the Plasma Drug Concentration-time Curve (AUC) From Time Zero (Pre-dose) to the Last Time of Quantifiable Concentration (AUC[0-t]) and From Time Zero (Pre-dose) to 24 Hours Post Dose (AUC[0-24]) for Lapatinib, AUC is defined as the area under the lapatinib concentration-time curve as a measure of drug exposure. AUC(0-t) and AUC(0-24) were determined from the plasma concentration-time data using the linear trapezoidal rule for increased concentrations and the logarithmic trapezoidal rule for decreased concentrations. For PK analysis, one blood sample was collected on Day 1 for placebo Baseline. The 24 hour blood sample on Day 2 also served for lapatinib Baseline. Pre-dose blood samples were collected 30 minutes prior to the administration of study medication on Day 2 (placebo) and Day 4 (lapatinib). Serial blood samples were collected on Day 2 (for placebo) and on Day 4 (for lapatinib) at the following post-last-dose time points 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours., Day 1 pre-dose; on Day 2 (at pre-dose, then 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post-last-dose), and on Day 4 (at pre-dose, then 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post-last-dose)|Mean Maximum Plasma Concentration (Cmax) and Observed Plasma Concentration at 24 Hours Post-dose (C24) of Lapatinib, The first occurrence of Cmax and C24 was determined directly from the raw concentration-time data. For PK analysis, one blood sample was collected on Day 1 for placebo Baseline. The 24 hour blood sample on Day 2 also served for lapatinib Baseline. Pre-dose blood samples were collected 30 minutes prior to the administration of study medication on Day 2 (placebo) and Day 4 (lapatinib). Serial blood samples were collected on Day 2 (for placebo) and on Day 4 (for lapatinib) at the following post-last-dose time points 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours., Day1 pre-dose; on Day 2 (at pre-dose, then 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post-dose), and on Day 4 (at pre-dose, then 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post-dose)|Median Time to Cmax (Tmax) and the Time Prior to the First Quantifiable (Non-zero) Lapatinib Plasma Concentration (Tlag) Following the Last (3rd) Lapatinib Dose, For each participant, the time at which Cmax was observed (tmax) was determined directly from the raw concentration-time data. For each participant, the time prior to the first quantifiable (non-zero) concentration (tlag) was determined directly from the raw concentration-time data. Since all

participants received 2 doses of study medication prior to the collection of the first (pre-dose) blood sample on Day 4, tlag was expected to be zero. For PK analysis, one blood sample was collected on Day 1 for placebo Baseline. The 24 hour blood sample on Day 2 also served for lapatinib Baseline. Pre-dose blood samples were collected 30 minutes prior to the administration of study medication on Day 2 (placebo) and Day 4 (lapatinib). Serial blood samples were collected on Day 2 (for placebo) and on Day 4 (for lapatinib) at the following post-last-dose time points 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours., Day 1 pre-dose; on Day 2 (at pre-dose, then 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post-dose), and on Day 4 (at pre-dose, then 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post-dose)
Other Outcome Measures:
Sponsor: GlaxoSmithKline
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 58
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: SINGLE (PARTICIPANT)|Primary Purpose: TREATMENT
Other IDs: 114271
Start Date: 2011-12
Primary Completion Date: 2015-03
Completion Date: 2015-03
First Posted: 2011-04-04
Results First Posted: 2016-01-28
Last Update Posted: 2016-06-08
Locations: GSK Investigational Site, Detroit, Michigan, 48202, United States|GSK Investigational Site, Lebanon, New Hampshire, 03756, United States|GSK Investigational Site, Durham, North Carolina, 27710, United States|GSK Investigational Site, Salt Lake City, Utah, 84112, United States
Study Documents:

NCT Number: NCT02423356
Study Title: Strain Echocardiography to Predict Cardiotoxicity in Patients Receiving Chemotherapy Containing Doxorubicin
Study URL: https://beta.clinicaltrials.gov/study/NCT02423356
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to investigate the heart functioning of patients being treated with with doxorubicin chemotherapy who have sarcoma, lymphoma or breast cancer in order to better predict risk of developing symptomatic heart failure.
Study Results: NO
Conditions: Breast Neoplasms|Lymphoma|Sarcoma
Interventions: PROCEDURE: Echocardiogram

Primary Outcome Measures: Composite cardiotoxicity, Transthoracic echocardiograms with strain imaging, Up to 28 days prior to beginning chemotherapy, during chemotherapy (specifically, at the visit that will administer doxorubicin to a cumulative total of at least 225mg/m2), 6 months after starting chemotherapy, and 12 months after starting chemotherapy
Secondary Outcome Measures: Serum cardiac biomarkers as predictors of composite cardiotoxicity, Blood draw to measure Troponin and BNP levels, Up to 28 days prior to beginning chemotherapy, during chemotherapy (specifically, at the visit that will administer doxorubicin to a cumulative total of at least 225mg/m2), 6 months after starting chemotherapy, and 12 months after starting chemotherapy
Other Outcome Measures: Pharmacogenomic biomarkers as predictors of composite cardiotoxicity (exploratory), Blood draw for genotyping, During chemotherapy (up to 12 months)
Sponsor: Daniel Rushing
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 12
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IUCRO-0483
Start Date: 2015-04-23
Primary Completion Date: 2018-02-01
Completion Date: 2018-02-01
First Posted: 2015-04-22
Results First Posted:
Last Update Posted: 2018-08-21
Locations: Indiana University Health Hospital, Indianapolis, Indiana, 46202, United States|Indiana University Melvin and Bren Simon Cancer Center, Indianapolis, Indiana, 46202, United States
Study Documents:

NCT Number: NCT02509156
Study Title: Stem Cell Injection in Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT02509156
Acronym: SENECA
Study Status: COMPLETED
Brief Summary: The primary purpose of this study is to examine the safety and feasibility of delivering allogeneic human mesenchymal stem cells (allo-MSCs) by transendocardial injection to cancer survivors with left ventricular (LV) dysfunction secondary to anthracycline-induced cardiomyopathy (AIC).

The secondary purpose of this study is to obtain preliminary evidence for therapeutic efficacy of allo-MSCs delivered by transendocardial injection to cancer survivors with LV dysfunction secondary to AIC.

Study Results: YES
Conditions: Cardiomyopathy Due to Anthracyclines
Interventions: BIOLOGICAL: Allo-MSCs|BIOLOGICAL: Placebo
Primary Outcome Measures: Proportion of Major Adverse Cardiac Events (MACE), Proportion of adjudicated events including death, hospitalization for worsening heart failure, and/or other exacerbation of heart failure (non-hospitalization)., Baseline to 12 months|Proportion of Other Significant Clinical Events, Proportion of other significant adjudicated clinical events including: non-fatal stroke, non-fatal MI, coronary artery revascularization, ventricular tachycardia/fibrillation, pericardial tamponade, infectious myocarditis, hypersensitivity reaction, neoplasm, and/or other potential deleterious late effects., Baseline to 12 months|Subjects With Events Precluding Their Receipt of Product, Number and percent of subjects with events between randomization and study product injection (SPI) that preclude the subject from receiving product., Randomization to SPI|Subjects Who Receive Less Than 20 Injections During SPI, Number and percent of subjects who receive less than 20 injections during SPI, During SPI procedure|Subjects Who Did Not Receive the Study Product (Either 100 Million Cells or Placebo), Number and percent of subjects who did not receive the study product (either 100 million cells or placebo), During SPI procedure|Subjects Who Have at Least One Cardiac MRI Endpoint Measure That is Uninterpretable, Number and percent of subjects who have at least one cardiac MRI endpoint measure that is uninterpretable due to issues related to the device, including, but not limited to, inability to undergo the procedure., Baseline to 12 months|Subjects Who Fail to Complete Follow-up, Number and percent of subjects who fail to complete follow up, Baseline to 12 months
Secondary Outcome Measures: Change From Baseline in Left Ventricular Ejection Fraction (LVEF), Change in left ventricular ejection fraction as assessed via cardiac MRI., Baseline to 12 months|Change From Baseline in Left Ventricular Ejection Fraction (LVEF)-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in Global Strain (HARP MRI), Change in global circumferential strain as assessed via cardiac MRI, Baseline to 12 months|Change From Baseline in Global Strain (HARP MRI)-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the

change per six months) for each treatment arm from the model., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in Regional Strain (HARP MRI), Change in regional longitudinal strain as assessed via cardiac MRI, Baseline to 12 months|Change From Baseline in Regional Strain (HARP MRI)-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in Left Ventricular End Diastolic Volume Index (LVEDVI), Change in left ventricular end diastolic volume index as measured via cardiac MRI, Baseline to 12 months|Change From Baseline in Left Ventricular End Diastolic Volume Index (LVEDVI)-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in Left Ventricular End Systolic Volume Index (LVESVI), Change in left ventricular end systolic volume index as assessed via cardiac MRI, Baseline to 12 months|Change From Baseline in Left Ventricular End Systolic Volume Index (LVESVI)-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in Left Ventricular Sphericity Index, Change in Left Ventricular Sphericity Index as assessed by cardiac MRI. Sphericity index is the ratio of the long and short axis measurements of the left ventricle., Baseline to 12 months|Change From Baseline in Left Ventricular Sphericity Index-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model.

Sphericity index is the ratio of the long and short axis measurements of the left ventricle., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in Area of Injury, Change in the scar percent (scar mass normalized to left ventricular mass) as assessed via cardiac MRI., Baseline to 12 months|Change From Baseline in Area of Injury-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in Exercise Tolerance (Six Minute Walk Test), Change in the distance walked (in meters) as measured by the six minute walk test. Two walk tests were completed at each endpoint visit (separated by 30 min). The average distance of the two walk tests will be used for analysis., Baseline to 12 months|Change From Baseline in Exercise Tolerance (Six Minute Walk Test)-Trajectory, Change in the distance walked (in feet) as measured by the six minute walk test. Two walk tests were completed at each endpoint visit (separated by 30 min). The average distance of the two walk tests will be used for analysis. The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in Minnesota Living With Heart Failure Questionnaire Score, Change in the quality of life summary score as measured by the Minnesota Living with Heart Failure Questionnaire. Minimum and maximum scores for scale are 0 and 105 respectively. Lower scores indicative of better outcome., Baseline to 12 months|Change From Baseline in Minnesota Living With Heart Failure Questionnaire Score-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model.

Minimum and maximum scores for scale are 0 and 105 respectively. Lower scores indicative of better outcome., Assessed as a trajectory (baseline, 6 months, and 12 months)|Change From Baseline in N-Terminal Pro-Brain Natriuretic Peptide (NT-proBNP), Change in N-Terminal pro-Brain Natriuretic Peptide (NT-proBNP) as measured via laboratory blood

draw, Baseline to 12 months|Change From Baseline in N-Terminal Pro-Brain Natriuretic Peptide (NT-proBNP)-Trajectory, The change in this measure over time is assessed using a repeated measures linear regression model of trajectory (change over time). If there is no interaction between change over time and treatment a single calculated value is the slope (the change per six months) from the model. If there is an interaction, the p-value for interaction is presented along with two calculated values representing the slope (the change per six months) for each treatment arm from the model., Assessed as a trajectory (baseline, 6 months, and 12 months)|Cumulative Days Alive and Out of Hospital for Heart Failure, Days alive and out of hospital for heart failure during the study evaluation period. Subjects were allotted a visit window extending 30 days past their anticipated 12-month visit (i.e., 395 days)., Baseline to End of 12 Month Visit Window (i.e. 395 days after intervention)
Other Outcome Measures:
Sponsor: The University of Texas Health Science Center, Houston
Collaborators: National Heart, Lung, and Blood Institute (NHLBI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 46
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: HSC-SPH-15-0443|5UM1HL087318
Start Date: 2016-08
Primary Completion Date: 2019-11
Completion Date: 2020-04-20
First Posted: 2015-07-27
Results First Posted: 2020-09-15
Last Update Posted: 2020-11-05
Locations: Stanford University School of Medicine, Stanford, California, 94305, United States|University of Florida-Department of Medicine, Gainesville, Florida, 32610, United States|University of Miami-Interdiciplinary Stem Cell Institute, Miami, Florida, 33101, United States|Indiana Center for Vascular Biology and Medicine, Indianapolis, Indiana, 46202, United States|University of Louisville, Louisville, Kentucky, 40202, United States|Minneapolis Heart Institute Foundation, Minneapolis, Minnesota, 55407, United States|Texas Heart Institute, Houston, Texas, 77030, United States
Study Documents: Informed Consent Form|Study Protocol and Statistical Analysis Plan

NCT Number: NCT05261256
Study Title: Cardiac Impairments Following Pediatric Cardiotoxic Anti-cancer Treatment
Study URL: https://beta.clinicaltrials.gov/study/NCT05261256

Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: This study aims at investigating the feasibility of recruitment and application of a method regarding early detection of subclinical changes in cardiac health after completion of acute cancer treatment during childhood and adolescence.
Study Results: NO
Conditions: Cardiovascular Diseases|Pediatric Cancer
Interventions: DIAGNOSTIC_TEST: Exercise stress echocardiography
Primary Outcome Measures: Feasibility Criteria 1 - Recruitment Rate, The number of children, adolescents and young adults with a history of pediatric cancer who agree to participate compared to the total number approached for this study., Throughout study completion, an average of 2 years|Feasibility Criteria 2 - Acceptance, Number of finished and discontinued exercise stress echocardiographies., Throughout study completion, an average of 2 years|Feasibility Criteria 3 - Data Quality, Number of evaluable examination data., During the procedure|Feasibility Criteria 4 - Practicability, Difference between scheduled and required time frame for the single examination., During the procedure|Feasibility Criteria 5 - Participants' Feedback, Feedback questionnaire with multiple choice options and free text answers., During the procedure
Secondary Outcome Measures: Reference Values of Healthy Peers, Assessment of reference values from age- and gender-matched healthy peers (matched pairs)., Throughout study completion, an average of 2 years|Analysis of Echocardiography Marker 1, Deformation Parameters in % (global longitudinal strain and circumferencial strain), During the procedure|Analysis of Echocardiography Marker 2, Ejection Fraction (EF) in %, During the procedure|Analysis of Echocardiography Marker 3, M-Mode Parameter, During the procedure|Analysis of Echocardiography Marker 4, Tricuspid Annular Plane Systolic Excursion (TAPSE) in millimeter, During the procedure|Analysis of Echocardiography Marker 5, Left ventricle end diastolic volume (LVEDV) in ml/m², During the procedure|Cardiorespiratory Fitness, Submaximal oxygen uptake VO2peak (ml/kg/min), During the procedure|Physical Activity Level post-therapy, For participants with a history of pediatric cancer: Physical activity questionnaire ActiOn post-therapy for the assessment of the amount of moderate-to-vigorous physical activity., During the procedure|Physical Activity Level in Healthy Control Subjects, For healthy control subjects: Physical activity questionnaire from the KiGGS study (German Health Interview and Examination Survey for Children and Adolescents)., During the procedure
Other Outcome Measures:
Sponsor: Technical University of Munich
Collaborators: Ludwig-Maximilians - University of Munich
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 80
Funder Type: OTHER

Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: German Heart Foundation
Start Date: 2022-02-01
Primary Completion Date: 2023-10-31
Completion Date: 2023-12-31
First Posted: 2022-03-02
Results First Posted:
Last Update Posted: 2022-03-02
Locations: Institute of Preventive Pediatrics, Department of Sport and Health Sciences, Technical University of Munich, Germany, Munich, 80992, Germany
Study Documents:

NCT Number: NCT02368054
Study Title: Hemodynamic Stability of Bupivacaine With and Without Adrenaline for Paracervical Block for Cervical Conization
Study URL: https://beta.clinicaltrials.gov/study/NCT02368054
Acronym: HSBAPCB
Study Status: COMPLETED
Brief Summary: Cervical conization is done for pre-cancer disease. The procedure is performed with local anesthesia and general anesthesia. Local anesthesia is given by paracervical block, and several different local anesthetics is being used including bupivacaine with and without adrenaline. Adrenaline might reduce local bleeding and reduce toxicity of bupivacaine by reducing absorption, but might affect cardiovascular function. This study will examine this effect.
Study Results: NO
Conditions: Cervical Intraepithelial Neoplasia
Interventions: DRUG: Bupivacaine|DRUG: Adrenaline
Primary Outcome Measures: Changes in Cardiac Output as measured by LiDCOplus monitor., After paracervical Block., 0-10 minutes
Secondary Outcome Measures: Changes in Stroke Volume as measured by LiDCOplus monitor., After paracervical block., 0-10 minutes|Changes in Heart Rate as measured by LiDCOplus monitor., After paracervical block., 0-10 minutes|Changes in Total Peripheral Resistance as measured by LiDCOplus monitor., After paracervical Block., 0-10 minutes
Other Outcome Measures:
Sponsor: Helse Fonna
Collaborators:
Sex: FEMALE
Age: ADULT
Phases: PHASE4
Enrollment: 34
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT

Other IDs: 49024|2014-004504-29|2014/1909/REK-vest
Start Date: 2015-05
Primary Completion Date: 2016-02
Completion Date: 2016-02
First Posted: 2015-02-20
Results First Posted:
Last Update Posted: 2016-08-19
Locations: Kirurgisk Klinikk-Anestesi, Haugesund, Rogaland, 5504, Norway
Study Documents:

NCT Number: NCT02615054
Study Title: Assessment for Long-Term Cardiovascular Impairment Associated With Trastuzumab Cardiotoxicity in HER2-Positive Breast Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT02615054
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This is for participants with a history of HER2-positive breast cancer and were treated with chemotherapy that increases the risk of abnormal heart function. Strain (a marker of heart function) is a new method of monitoring heart function in cancer patients and is measured with an ultrasound. Exercise testing is another method that can be used to monitor for abnormal heart function in cancer patients. The purpose of this study is to see if strain and exercise testing can be used to detect for late signs of heart damage from chemotherapy.
Study Results: NO
Conditions: Trastuzumab Cardiotoxicity|HER2-Positive Breast Cancer Survivors
Interventions: DEVICE: 2D Echocardiogram|DEVICE: Cardiopulmonary exercise testing and post-CPET cardiac function
Primary Outcome Measures: cardiac function, Exercise capacity will be assessed by CPET, and echocardiographic images will be obtained immediately after CPET to evaluate contractile reserve., 2 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 58
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 15-258
Start Date: 2015-11
Primary Completion Date: 2023-11
Completion Date: 2023-11

First Posted: 2015-11-25
Results First Posted:
Last Update Posted: 2022-12-02
Locations: Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States
Study Documents:

NCT Number: NCT05731375
Study Title: Mitochondrial dysfUnction: a Key Player in Doxorubicin-induced Skeletal and Cardiac muscLE Damage
Study URL: https://beta.clinicaltrials.gov/study/NCT05731375
Acronym: MUSCLE
Study Status: NOT_YET_RECRUITING
Brief Summary: The goal of this observational study is to demonstrate the ability of using non-invasive Phosphorus (31P) Magnetic Resonance Spectroscopy (MRS) to monitor changes of in-vivo markers of mitochondrial function in skeletal and cardiac muscles in muscles in large B- or T-cell lymphoma patients during treatment with (R-)CHOP. The main question it aims to answer is:

• Can 31P-MRS be used to monitor changes of in vivo markers of mitochondrial function in skeletal and cardiac muscles in large B- or T-cell lymphoma patients during treatment with (R-)CHOP?

To be able to answer this main question, participants will undergo 31P-MRS imaging of the calf muscles and of the heart 3 times during the study period.
Study Results: NO
Conditions: Doxorubicin Induced Cardiomyopathy|Chemotherapeutic Toxicity|B-cell Lymphoma|T-cell Lymphoma
Interventions: DIAGNOSTIC_TEST: 31-MRS at 7 Tesla (T)
Primary Outcome Measures: Changes in skeletal and cardiac muscle mitochondrial function, Assessed through 31P-MRS imaging. Parameters include:

* PCr recovery rate (in seconds)
* PCr/ATP ratio, Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)
Secondary Outcome Measures: Adherence rates to the study protocol, Measured as:

* recruitment/retention rates
* completion of study measurements within timeframes, Baseline to 18 weeks.|Changes in physical fitness (Maximum short exercise capacity (Watt)), Assessed through Steep Ramp test, Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Changes in hand grip strength (kg), Assessed through Hand Grip Strength Test, Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Changes in leg strength (kg), Assessed through hypothetical 1-repetition max leg press, Baseline,

halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Changes in skeletal muscle area in cm2, Assessed through routine CT-scans, Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Changes in subjective physical activity levels (min/week moderate-to-vigorous physical activity), Physical activity levels will be assessed subjectively using the Short QUestionnaire to ASsess Health-enhancing physical activity (SQUASH), Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Changes in objective physical activity levels (min/week moderate-to-vigorous physical activity), Participants are provided with a Fitbit Inspire HR and are asked to wear these as much as possible during the whole study period. The Fitbit continuously registers the heart rate. Based on this, physical activity levels will be calculated., Throughout the whole study, but of particular interest are the 9th week after baseline and 18th week post-baseline|Changes in health-related Quality of Life, Measured using the core EORTC Quality of life questionnaire (QLQ-C30). The results of the questionnaire can be used to calculate a summary score, global health status, functional subscales and symptom subscales. For the summary score, global health status and functional subscales, a higher score is a better outcome, whilst for the symptom subscales, a lower score is a better outcome. All scores range from 0 to 100.

* Global health status
* Summary score

Functional scales:

* Physical functioning
* Role functioning
* Emotional functioning
* Cognitive functioning
* Social functioning

Symptom scales:

* Fatigue
* Nausea and vomiting
* Pain
* Dyspnoea
* Insomnia
* Appetite loss
* Constipation
* Diarrhoea
* Financial difficulties, Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Changes in lymphoma specific symptoms, Measured using the add-on of the abovementioned EORTC QLQ-C30, which is specifically developed for non-Hodgkin lymphoma patients (EORTC QLQ-NHL-HG29). A higher score depicts worse outcomes. All scores range from 0 to 100., Baseline, halfway (R-)CHOP

treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)| Changes in fatigue, The EORTC provides several questionnaires to asses the quality of life of cancer patients. To assess fatigue the EORTC developed a specific fatigue questionnaire (QLQ-FA12). This questionnaire can be used to assess different dimensions of fatigue. A lower score depicts a better outcome. All scores range from 0 to 100.

Fatigue dimensions:

* Physical fatigue
* Emotional fatigue
* Cognitive fatigue, Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Changes in skeletal muscle end-exercise pH, Assessed through 31P-MRS imaging., Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Changes in skeletal muscle delta PCr during recovery after exercise in mM, Assessed through 31P-MRS imaging., Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)

Other Outcome Measures: Changes in weight (kg), As measured by investigator during study visit., Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)|Height (cm), As measured by investigator during study visit., Baseline, halfway (R-)CHOP treatment (+/- 9 weeks), after (R-)CHOP treatment (+/- 18 weeks)
Sponsor: UMC Utrecht
Collaborators: Julius Clinical
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 12
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NL83538.041
Start Date: 2024-04
Primary Completion Date: 2025-12
Completion Date: 2025-12
First Posted: 2023-02-16
Results First Posted:
Last Update Posted: 2023-02-16
Locations: Diakonessenhuis, Utrecht, 3582 KE, Netherlands|UMC Utrecht, Utrecht, 3584CX, Netherlands
Study Documents:

NCT Number: NCT00247975
Study Title: Ability of L-carnitine to Prevent Heart Damage in Breast Cancer Patients Receiving Anthracycline Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT00247975
Acronym:

Study Status: TERMINATED
Brief Summary: Breast cancer is very common and afflicts 1 in 9 North American women. The treatment of breast cancer often requires the use of chemotherapy including "anthracyclines". Anthracyclines can damage the heart resulting in heart failure and even death. Clinicians and researchers are continually seeking methods that will reduce the toxic effects of anthracycline treatment.

L-carnitine is a substance that is produced naturally in the body and is required for normal heart function. Animal studies have suggested that L-carnitine protects the heart from the effects of anthracyclines, however this has not been verified in humans.

This study will assess the potential role of L-carnitine in the prevention of anthracycline induced heart damage. The investigators will enroll 144 patients into this study. Patients will be randomly assigned to L-carnitine therapy or to standard care (no L-carnitine therapy). Patients in the L-carnitine group will receive oral and intravenous L-carnitine prior to and after their anthracycline therapy. Patients will undergo regular follow up and testing to assess heart function. The investigators believe that patients treated with L-carnitine will benefit and have fewer complications associated with anthracycline treatment.
Study Results: NO
Conditions: Heart Failure
Interventions: DRUG: L-carnitine
Primary Outcome Measures: To compare the effects of L-carnitine therapy versus placebo on left ventricular (LV) ejection fraction (EF) as a marker of anthracycline induced cardiotoxicity, 1 year
Secondary Outcome Measures: To compare the effects of L-carnitine therapy versus placebo on: other potential markers of anthracycline induced cardiotoxicity such as LV volume, LV systolic and diastolic function, troponin T (TnT) and NT-pro-brain natriuretic peptide (BNP), 1 year|"Anthracycline-induced cardiotoxicity" and clinical cardiac outcomes, 1 year|Serum L-carnitine levels, 4 months|To assess: the safety of L-carnitine, 1 year|the predictive value of serum biomarkers (TnT, BNP, and L-carnitine levels) for cardiotoxicity and cardiac outcome (ejection fraction, LV volumes, congestive heart failure, and cardiac death), 1 year|the effect of anthracyclines on plasma L-carnitine levels, 4 months|the correlation of L-carnitine levels with serum TnT and BNP levels, 4 months
Other Outcome Measures:
Sponsor: Ottawa Heart Institute Research Corporation
Collaborators: Canadian Institutes of Health Research (CIHR)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 36
Funder Type: OTHER
Study Type: INTERVENTIONAL

Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: CIHR #: 126541
Start Date: 2006-03
Primary Completion Date: 2010-10
Completion Date: 2011-10
First Posted: 2005-11-02
Results First Posted:
Last Update Posted: 2022-08-16
Locations: University of Ottawa Heart Institute, Ottawa, Ontario, K1Y 4W7, Canada
Study Documents:

NCT Number: NCT02177175
Study Title: Carvedilol for the Prevention of Anthracycline/Anti-HER2 Therapy Associated Cardiotoxicity Among Women With HER2-Positive Breast Cancer Using Myocardial Strain Imaging for Early Risk Stratification
Study URL: https://beta.clinicaltrials.gov/study/NCT02177175
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to find out the effects, good and/or bad, of a beta blocker (carvedilol) on heart function during treatment with anti-HER2 medication(s) including trastuzumab (Herceptin).
Study Results: YES
Conditions: Breast Cancer
Interventions: DRUG: Carvedilol|OTHER: placebo
Primary Outcome Measures: Maximum Change in LVEF at 3 Months, Value at 3 months minus value at baseline, 3 months|Maximum Change in LVEF at 6 Months, Value at 6 months minus value at baseline, 6 months|Maximum Change in LVEF at 9 Months, Value at 9 months minus value at baseline, 9 months|Maximum Change in LVEF at 12 Months, Value at 12 months minus value at baseline, 12 months
Secondary Outcome Measures: Incidence of Abnormal LVEF at 12 Months, The study is designed to detect an intergroup difference of absolute difference of 10 percentage points (simple difference) in the change in LVEF between the experimental and control group. Ten percent is the change in LVEF that is associated with differing degrees of left ventricular dysfunction, and long-term studies among non-cancer patients have shown that outcomes differ among groups of patients who have LVEF differing by 10%., 12 months
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 82

Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: 14-099
Start Date: 2014-06-24
Primary Completion Date: 2021-06-24
Completion Date: 2021-06-24
First Posted: 2014-06-27
Results First Posted: 2022-06-07
Last Update Posted: 2022-07-12
Locations: Memorial Sloan Kettering West Harrison, Harrison, New York, 10604, United States|Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT03444259
Study Title: Prospective Project to Identify Biomarkers of Morbidity and Mortality in Cardiovascular Interventional Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT03444259
Acronym: CAREBANK
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The objective of CAREBANK study is to establish definitive relationships with human cardiac samples and clinical phenotypes in patients undergoing cardiac procedures. Specifically, the investigators aim at comparing atrial phenotypes from atrial fibrillation patients and controls. The work consists of three broad categories: A) role of atrial cardiomyopathy in atrial fibrillation; B) genetic defects predisposing to atrial fibrillation; and C) the role of inflammation in atrial fibrillation.
Study Results: NO
Conditions: Atrial Fibrillation|Coronary Artery Disease|Aortic Valve Stenosis|Aortic Valve Disease|Mitral Valve Disease|Cardiac Arrythmias|Cardiac Tumor|Cardiac Surgery
Interventions: PROCEDURE: Cardiac surgery
Primary Outcome Measures: Atrial fibrillation, Occurrence of atrial fibrillation, postoperatively until 5 years follow-up
Secondary Outcome Measures: Stroke, Occurrence of stroke, postoperatively until 5 years follow-up|Transient ischemic attack, Occurrence of Transient ischemic attack, postoperatively until 5 years follow-up|Myocardial infarction, Occurrence of Myocardial infarction, postoperatively until 5 years follow-up|Target vessel revascularization, Occurrence of Target vessel revascularization, postoperatively until 5 years follow-up|All-cause Mortality, All-cause Mortality, postoperatively until 5 years follow-up|Post-pericardiotomy syndrome, Occurrence of Post-pericardiotomy syndrome, postoperatively until 1 years follow-up
Other Outcome Measures:
Sponsor: University of Turku

Collaborators: Brigham and Women's Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1001
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: T273/2015
Start Date: 2016-02-01
Primary Completion Date: 2025-12-31
Completion Date: 2025-12-31
First Posted: 2018-02-23
Results First Posted:
Last Update Posted: 2022-11-02
Locations: Turku University Hospital, Turku, 20520, Finland
Study Documents:

NCT Number: NCT02652975
Study Title: Anticancer Treatment of Breast Cancer Related to Cardiotoxicity and Dysfunctional Endothelium
Study URL: https://beta.clinicaltrials.gov/study/NCT02652975
Acronym: ABCDE
Study Status: COMPLETED
Brief Summary: Several cytotoxic regimens are related to endothelial cell damage and vascular toxicity. Endothelial dysfunction is implicated in the pathogenesis of all known cardiovascular diseases (CVD) and closely related to the metabolic syndrome. Both CVD and diabetes contributes importantly to total mortality and to breast cancer (BC) specific mortality.

In the epidemiological part of the project, the investigators will determine the prevalence and incidence of cardiovascular and metabolic morbidity/mortality in early BC patients compared to the Danish background population.

In the clinical part, the investigators will study the changes of endothelial function and metabolic parameters in BC patients receiving chemotherapy.

With increasing number of BC survivors, long-term consequences of curative cancer treatment should be studied. The investigators hypothesize that cytotoxic therapy worsens metabolic parameters possibly through endothelial dysfunction. If this is true, the next step will be to evaluate how strict metabolic control will affect prognosis.
Study Results: NO
Conditions: Breast Neoplasms|Endothelial Dysfunction|Cardiovascular Disease|Metabolic Syndrome
Interventions: PROCEDURE: Venous occlusion plethysmography|PROCEDURE:

SphygmoCor|PROCEDURE: 24hour blood pressure|PROCEDURE: DEXA scan|
BIOLOGICAL: Laboratory blood samples
Primary Outcome Measures: Changes in endothelial dysfunction evaluated using plethysmography., Measured before start of chemotherapy (week 0), immediately after ended chemotherapy (week 18) and one year after ended chemotherapy (week 70).|Changes in aortic pressure evaluated using applanation tonometry (SphygmoCor), Measured before start of chemotherapy (week 0), immediately after ended chemotherapy (week 18) and one year after ended chemotherapy (week 70).|Changes in blood pressure evaluated by 24 hour blood pressure measurements., Measured before start of chemotherapy (week 0), immediately after ended chemotherapy (week 18) and one year after ended chemotherapy (week 70).|Changes in metabolic measurements using the blood samples listed in descriptive field., P-Kolesterol, P-Kolesterol HDL, P-Kolesterol LDL, P-Triglyceride, P-Glukose, P-Progesteron, P-Testosteron, P-Von Willebrand-faktor, P-Natrium, P-Kalium, P-Kreatinin and P-Østradiol., Measured before start of chemotherapy (week 0), immediately after ended chemotherapy (week 18) and one year after ended chemotherapy (week 70).|Changes in body composition using DEXA scans, Measured before start of chemotherapy (week 0), immediately after ended chemotherapy (week 18) and one year after ended chemotherapy (week 70).|Changes in risk of cardiovascular death within 10 years using the SCORE-system., The SCORE-system is a well- established and validated method using age, gender, smoking status, systolic blood pressure and plasma cholesterol for risk stratification., Measured before start of chemotherapy (week 0), immediately after ended chemotherapy (week 18) and one year after ended chemotherapy (week 70).
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Aarhus
Collaborators: Danish Cancer Society
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 76
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: PREVENTION
Other IDs: ABCDE_AUH
Start Date: 2015-09
Primary Completion Date: 2018-06
Completion Date: 2018-06
First Posted: 2016-01-12
Results First Posted:
Last Update Posted: 2019-10-09
Locations: Aarhus University Hospital, Aarhus, Jutland, 8000, Denmark
Study Documents:

NCT Number: NCT03685175

Study Title: Using Hyperpolarized [1-13C]Pyruvate to Detect Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT03685175
Acronym: HPCardiotox
Study Status: ENROLLING_BY_INVITATION
Brief Summary: The anthracycline doxorubicin, first introduced in the 1960's, continues to be an effectively utilized antineoplastic drug. Even at relatively low cumulative doses there is risk of cardiotoxicity. However, the incidence of subclinical cardiotoxicity is not known, carrying a potential risk for late effects in cancer survivors. Doxorubicin has systemic toxicity that may contribute to cardiac metabolic stress, but the main cardiotoxic mechanism involves cardiac mitochondria. The primary goal of this study is to detect early changes in the mitochondrial metabolism in situ as a marker for subclinical doxorubicin induced cardiotoxicity. The problem of cardiovascular complications following chemotherapy for breast cancer goes far beyond anthracyclines alone. In addition, other agents such as trastuzumab, and pertuzumab and emerging novel therapies may also promote cardiovascular injury. The secondary objective is to test the hypothesis that cardiotoxicity due to other medical anticancer therapies and radiation therapy involving the heart field is associated with a signature of early impaired aerobic cardiac metabolism through pyruvate dehydrogenase.
Study Results: NO
Conditions: Breast Neoplasms
Interventions: DRUG: Formal study using hyperpolarized 13C-pyruvate injection|DRUG: Feasible study using hyperpolarized 13C-pyruvate injection
Primary Outcome Measures: Detect subclinical anthracycline induced cardiotoxicity using hyperpolarized carbon-13 pyruvate, Detect the correlation between cardiac carbon-13 pyruvate metabolism and cardiac mechanical function at baseline and after exposure to cardiotoxic therapy, 4 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Texas Southwestern Medical Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: EARLY_PHASE1
Enrollment: 110
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: STU 072016-058
Start Date: 2018-07-01
Primary Completion Date: 2023-08
Completion Date: 2023-08
First Posted: 2018-09-26

Results First Posted:
Last Update Posted: 2023-05-09
Locations: UT Southwestern - Advanced Imaging Research Center, Dallas, Texas, 75390, United States
Study Documents:

NCT Number: NCT01114659
Study Title: The Study of Polycystic Ovary Syndrome(PCOS) With Gene and Questionnaire
Study URL: https://beta.clinicaltrials.gov/study/NCT01114659
Acronym:
Study Status: COMPLETED
Brief Summary: Polycystic ovary syndrome (PCOS) is an extremely common disorder in women of reproductive age. Diagnosis of PCOS is principally based on clinical and physical findings. Diagnostic criteria and PCOS definitions used by clinicians and researchers are almost as heterogeneous as the syndrome. This first part of study is determine whether genetic polymorphisms influence hormonal and metabolic characteristics in Taiwanese patients with PCOS and controls. Furthermore, women with PCOS were reported with high risk of cardiovascular disease, the investigators planned to calculate the difference of carotid intima-media thickness (IMT) and B-type natriuretic peptide (BNP) between women with PCOS and normal control to determine the premature atherosclerosis of women with PCOS.
Study Results: NO
Conditions: Polycystic Ovary Syndrome
Interventions:
Primary Outcome Measures: The correlation of PCOS betwwen metabolic and cardiovascular disease., Participant were followed for 1 month in study period.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Taipei Medical University WanFang Hospital
Collaborators:
Sex: FEMALE
Age: CHILD, ADULT
Phases:
Enrollment: 169
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: WFH-PCOS-98076
Start Date: 2009-11
Primary Completion Date: 2010-08
Completion Date: 2010-10
First Posted: 2010-05-03
Results First Posted:
Last Update Posted: 2014-01-01
Locations: Taipei Medical University WanFang Hospital, Taipei, 116, Taiwan

Study Documents:

NCT Number: NCT01468675
Study Title: Health Information Technology (HIT) Enhanced Family History Documentation and Management in Primary Care
Study URL: https://beta.clinicaltrials.gov/study/NCT01468675
Acronym:
Study Status: COMPLETED
Brief Summary: We evaluated whether collection of risk factors to generate an electronic health record (EHR)-linked personalized health risk appraisal (HRA) for coronary heart disease (CHD), diabetes, breast and colorectal cancer (CRC) was associated with improved patient-provider communication, risk assessment, and breast cancer screening plans in the next year.
Study Results: YES
Conditions: Colorectal Cancer|Breast Cancer|Coronary Heart Disease|Diabetes
Interventions: OTHER: Intervention
Primary Outcome Measures: Number of Subjects Who Discussed Disease Risk With Primary Care Provider, 3 months following primary care visit
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Brigham and Women's Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 6075
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 2009P002762
Start Date: 2013-02
Primary Completion Date: 2014-12
Completion Date: 2014-12
First Posted: 2011-11-09
Results First Posted: 2016-12-21
Last Update Posted: 2017-04-28
Locations: Brigham and Women's Hospital, Boston, Massachusetts, 02120, United States
Study Documents:

NCT Number: NCT04400903
Study Title: Monitoring Heart Rate Variability for the Early Detection of Pancreatic Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT04400903
Acronym:
Study Status: TERMINATED
Brief Summary: This study examines heart rate monitoring variability

for the early detection of pancreatic cancer. Pancreatic cancer is a very difficult disease to detect early. This study is being done to observe the heart rate variability in patients with pancreatic cancer compared to undiagnosed individuals with increased risk of developing pancreatic cancer. This may help researchers determine if pancreatic occurrences/recurrences (chance of coming back) can be detected sooner through monitoring heart rate and activity.
Study Results: NO
Conditions: Pancreatic Ductal Adenocarcinoma|Stage I Pancreatic Cancer AJCC v8|Stage IA Pancreatic Cancer AJCC v8|Stage IB Pancreatic Cancer AJCC v8
Interventions: DEVICE: Activity Monitor|OTHER: Quality-of-Life Assessment|OTHER: Questionnaire Administration
Primary Outcome Measures: Magnitude of heart rate variability (HRV) decline (Stage I), As measured by root mean square of the successive differences (RMSSD) in pancreatic ductal adenocarcinoma (PDAC) patients and in high-risk participants., Up to 1 year after enrollment|Compliance statistics for wristband use (Stage II), Defined as the percentage of days during which data were collected during at least 70% of the hours., Until onset of PDAC, study withdrawal, or death, whichever occurs first, assessed up to 5 years after enrollment
Secondary Outcome Measures: Compliance statistics for wristband use for all participants (Stage I, II), Defined as the percentage of days during which data were collected for at least 70% of the hours., Up to 6 weeks and 6 months after enrollment and device activation|Effectiveness of virtual training (Stage I, II), Defined as the percentage of participants for whom high quality data are available within 3 days of set up. The pattern of missing data, and the percentage of participants able to collect data will be presented graphically. Will also associate the compliance with patient characteristics, regions and seasons to understand what may impact the compliance rate., Up to 1 week after enrollment and device activation|Magnitude of HRV change (Stage II), As measured by RMSSD, in participants at high-risk of developing PDAC., Up to 5 years post enrollment|Incidence of PDAC among high-risk participants (Stage II), Up to 5 years post enrollment|Time of PDAC diagnosis among high-risk participants who developed PDAC (Stage II), Up to 5 years post enrollment
Other Outcome Measures:
Sponsor: OHSU Knight Cancer Institute
Collaborators: Oregon Health and Science University|American Association for Cancer Research|National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 110
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: STUDY00021185|NCI-2020-03178|STUDY00021185|R01CA264133

Start Date: 2020-09-21
Primary Completion Date: 2022-09-30
Completion Date: 2022-09-30
First Posted: 2020-05-26
Results First Posted:
Last Update Posted: 2022-11-22
Locations: University of Nebraska Medical Center, Omaha, Nebraska, 68198-7680, United States|Laura and Isaac Perlmutter Cancer Center at NYU Langone, New York, New York, 10016, United States|OHSU Knight Cancer Institute, Portland, Oregon, 97239, United States
Study Documents:

NCT Number: NCT02080390
Study Title: Strain Imaging in Breast Cancer Patients Receiving Trastuzumab
Study URL: https://beta.clinicaltrials.gov/study/NCT02080390
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this research study is to evaluate the effects of the chemotherapeutic drug, Trastuzumab (Herceptin) on the heart. Trastuzumab (Herceptin) is used to treat specific types of breast cancer and is known to cause weakening of the heart. Unfortunately, little is know as to why this this happens. The investigators want to identify any factors that may lead to the early detection, treatment and prevention of the cardiotoxicity (heart problem) associated with this drug.
Study Results: NO
Conditions: Her 2 Positive Breast Cancer
Interventions: PROCEDURE: Transthoracic echocardiogram (ultrasound)
Primary Outcome Measures: Longitudinal Strain, Each transthoracic echocardiogram obtained during the patient's treatment will be assessed for longitudinal strain., Change in baseline longitudinal strain from beginning of study to end of study. Patients will be followed for a minimum of 1 year.|Left Ventricular Ejection Fraction, Left ventricular ejection fraction from all clinically indicated transthoracic echocardiograms will be compared from baseline through the end of the study., Change in ejection fraction from baseline to end of study. Patients will be followed for a minimum of 1 year.
Secondary Outcome Measures: Clinically evident congestive heart failure, Clinically evident congestive heart failure(symptoms of fluid overload such as shortness of breath, dyspnea on exertion, orthopnea or paroxysmal nocturnal dyspnea or physical findings of congestive heart failure such as jugular venous distension, rales on pulmonary exam, lower extremity edema)., From baseline to end of study. Patients will be followed for a minimum of 1 year.|Cardiac medication use, The type and dose of all cardiac medications will be followed from baseline to end of study., Baseline to end of study. Patients will be follwed for a minimum of 1 year.
Other Outcome Measures:
Sponsor: University of Florida

Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 25
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IRB201300763
Start Date: 2014-09
Primary Completion Date: 2016-10-28
Completion Date: 2019-02-14
First Posted: 2014-03-06
Results First Posted:
Last Update Posted: 2019-03-01
Locations: Univerisity of Florida, Gainesville, Florida, 32610, United States
Study Documents:

NCT Number: NCT00708903
Study Title: Study to Examine the Effect of HKI-272 on Rhythms of the Heart (Cardiac Repolarization)
Study URL: https://beta.clinicaltrials.gov/study/NCT00708903
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine whether HKI-272 affects the rhythms of the heart (cardiac repolarization).
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: neratinib|OTHER: Placebo|DRUG: Moxifloxacin
Primary Outcome Measures: QTc interval, 3 days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Puma Biotechnology, Inc.
Collaborators:
Sex: ALL
Age: ADULT
Phases: PHASE1
Enrollment: 60
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: DOUBLE|Primary Purpose: TREATMENT
Other IDs: 3144A1-105
Start Date: 2008-05
Primary Completion Date: 2008-07
Completion Date: 2008-07
First Posted: 2008-07-02
Results First Posted:
Last Update Posted: 2012-05-14

Locations: Tacoma, Washington, 98418, United States
Study Documents:

NCT Number: NCT00903890
Study Title: Cardiac Effects in Long-Term Survivors of Hodgkin's and Non-Hodgkin's Lymphoma
Study URL: https://beta.clinicaltrials.gov/study/NCT00903890
Acronym:
Study Status: COMPLETED
Brief Summary: This study is to inquire by mailed survey regarding the cardiac and general health of patients previously treated for Hodgkin's and non-Hodgkin's lymphoma with radiation therapy/ anthracycline chemotherapy.
Study Results: NO
Conditions: Hodgkin Disease|Lymphoma, Non-Hodgkin
Interventions: OTHER: Survey
Primary Outcome Measures: Measure changes in Cardiac ejection fraction score, Post Radiation Treatment|Measure changes in perfusion imaging score on the radionuclide cardiac profusion scan, Post Radiation
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Rochester
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 32
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ULYM07056
Start Date: 2008-08
Primary Completion Date: 2018-11
Completion Date: 2020-04-09
First Posted: 2009-05-19
Results First Posted:
Last Update Posted: 2021-03-05
Locations: University of Rochester Medical Center, Rochester, New York, 14642, United States
Study Documents:

NCT Number: NCT02809456
Study Title: Mitigation of Radiation Pneumonitis, Fibrosis and Heart Toxicity With Nicorandil in Lung Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02809456
Acronym:
Study Status: UNKNOWN
Brief Summary: This project will test the effect of nicorandil to mitigate the lung damage that can occur as a side effect of radiation therapy for lung cancer. Thousands of veterans develop lung cancer

every year, and are treated by radiation therapy. Studies of lung radiation injury in laboratory animals show that with nicorandil, investigators can significantly reduce the severity of lung fibrosis and heart toxicity.1,2 Nicorandil is FDA approved and in common use for treatment of angina. These studies will advance that work to human use. Successful mitigation of lung radiation damage and heart toxicity will improve the quality of life in veterans and non-veterans who are treated for lung cancer by radiation, and may also improve cure rates of radiation therapy for lung cancer.
Study Results: NO
Conditions: Radiation Pneumonitis
Interventions: DRUG: Nicorandil
Primary Outcome Measures: The rate of symptomatic radiation pneumonitis in patients with unresectable Stage II/III/ oligometastatic IV non-small cell lung carcinoma (NSCLC) who completed chemoradiation followed by nicorandil or not, Up to 2.5 years post-treatment
Secondary Outcome Measures: The quality of life (QOL) questionnaire, Baseline up to 2.5 years post-treatment|Biomarker analysis such as TGF-β, Serum surfactant proteins-A & -D, MMP1 and MMP7, Up to 97 days post-treatment|The overall survival in patients who received nicorandil versus observation, Up to 2.5 years post-treatment|Radiation pneumonitis (RP) score in patients who received nicorandil versus observation, Baseline up to 2.5 years post-treatment|The composite index (based on PFT, RP score and QOL) at the end of active treatment and 6 months after completion of treatment between patients who received nicorandil versus observation., Baseline up to 2.5 years post-treatment|Responses rates, Up to 2.5 years post-treatment
Other Outcome Measures:
Sponsor: Taipei Medical University WanFang Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: N201508038
Start Date: 2016-07
Primary Completion Date: 2019-07
Completion Date: 2019-12
First Posted: 2016-06-22
Results First Posted:
Last Update Posted: 2016-06-23
Locations:
Study Documents:

NCT Number: NCT02881203

Study Title: Breast Radiotherapy Audio Visual Enhancement for Sparing the Heart
Study URL: https://beta.clinicaltrials.gov/study/NCT02881203
Acronym: BRAVEHeart
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This study investigates the Breathe Well device to test whether it is superior to the existing treatment standard of the Varian Realtime Position Management (RPM) system in assisting patients with deep inspiration breath hold.
Study Results: NO
Conditions: Breast Cancer
Interventions: DEVICE: Breathe Well|DEVICE: RPM
Primary Outcome Measures: Accuracy of Breathe Well, The accuracy will be measured by comparing 'Breathe Well' and RPM measurements with images acquired of the breast during the radiation treatment using an electronic portal imaging device (EPID)., 2 years
Secondary Outcome Measures: Difference in set up times for Breathe Well vs RPM, The setup times for both systems, the 'Breathe Well' and the modified RPM system; will be measured for all fractions., 2 years|Patient comfort, To investigate patient comfort in using 'Breathe Well' via a patient survey., 2 years|Staff perception of Breathe Well, To investigate staff perception of 'Breathe Well' via a technology assessment survey., 2 years|To develop the use of EPID for real time MLC tracking during breast radiotherapy, 2 years|To compare actual and planned doses, Using dose reconstruction estimate the dose distribution delivered during radiotherapy and compare this with the planned dose., 2 years
Other Outcome Measures:
Sponsor: University of Sydney
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 45
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: BRAVEHeartV1
Start Date: 2018-09-15
Primary Completion Date: 2021-09-30
Completion Date: 2023-08
First Posted: 2016-08-26
Results First Posted:
Last Update Posted: 2021-12-16
Locations: Gillian Lamoury, St Leonards, New South Wales, 2065, Australia
Study Documents:

NCT Number: NCT01395303

Study Title: Polymorphisms in the Vitamin D System and Health
Study URL: https://beta.clinicaltrials.gov/study/NCT01395303
Acronym:
Study Status: COMPLETED
Brief Summary: Polymorphisms in the vitamin D system appear to affect the serum 25(OH)D levels. If so one would expect these polymorphisms to be associated with vitamin D related conditions and diseases, which will be tested in the present study including DNA analyses in 9700 subjects
Study Results: NO
Conditions: Infarction|Stroke|Diabetes|Fracture|Aortic Stenosis|Cancer|Death
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Tromso
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 9700
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UIT-ENDO-2011-2
Start Date: 2011-04
Primary Completion Date: 2016-07
Completion Date: 2016-08
First Posted: 2011-07-15
Results First Posted:
Last Update Posted: 2016-11-11
Locations: University of Tromsø, Tromsø, 9037, Norway
Study Documents:

NCT Number: NCT02641145
Study Title: Molecular Imaging of Primary Amyloid Cardiomyopathy
Study URL: https://beta.clinicaltrials.gov/study/NCT02641145
Acronym: MICA
Study Status: RECRUITING
Brief Summary: Cardiac amyloidosis is a major cause of early treatment-related death and poor overall survival in individuals with systemic light chain amyloidosis. This project will develop a novel approach to visualize cardiac amyloid deposits using advanced imaging methods. The long-term goal of this work is to identify the mechanisms of cardiac dysfunction, in order to guide the development of novel life-saving treatments.
Study Results: NO
Conditions: Amyloidosis, Primary|Cardiomyopathy
Interventions: RADIATION: F-18 florbetapir/C-11 acetate PET|DEVICE:

MRI|RADIATION: N-13 ammonia PET
Primary Outcome Measures: Change in F-18 florbetapir myocardial retention index from baseline to 6 months and 12 months, quantitative measure of F-18 florbetapir uptake by the heart muscle, Baseline, 6 and 12 months|Change in Serum oxidative stress markers from baseline to 6 months and 12 months, serum F-2 isoprostane and peroxynitrite levels, Baseline, 6 and 12 months|Change in Myocardial oxidative metabolism markers from baseline to 6 months, K mono and coronary flow reserve obtained by C-11 acetate PET/CT at rest and stress, Baseline and 6 months|Change in Magnetic resonance imaging markers from baseline to 6 months and 12 months, Extracellular volume index, T-1 mapping, late gadolinium enhancement, global strain, left ventricular mass, Baseline, 6 and 12 months
Secondary Outcome Measures: Change in Myocardial energy efficiency from baseline to 6 months, Myocardial energy efficiency, Kmono reserve, will be determined by C-11 acetate PET, Baseline and 6 months|Light Chain Toxicity, Study subject urine light chain's will be extracted and infused into zebrafish and isolated cardiomyocytes to study light chain toxicity, Baseline|Understand the role of gut microbiota and heavy metals in the pathogenesis of AL Amyloidosis, This will be tested using machine learning methods with 16S rRNA sequencing of salivary and stool samples in a 40-patient cohort with AL-amyloidosis compared to healthy controls from the NIH funded human microbiome project (HMP).This will also be used to test if the gut microbiome affects amyloid formation using a transgenic mouse model of AL amyloidosis that expresses the human LC in the gut and develops amyloid in the stomach., Baseline
Other Outcome Measures:
Sponsor: Brigham and Women's Hospital
Collaborators: National Institutes of Health (NIH)|National Heart, Lung, and Blood Institute (NHLBI)|American Heart Association
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 171
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 2015P002477|1R01HL130563-01A1
Start Date: 2016-04-01
Primary Completion Date: 2023-01-08
Completion Date: 2023-01-08
First Posted: 2015-12-29
Results First Posted:
Last Update Posted: 2022-10-25
Locations: Brigham and Womens' Hospital, Boston, Massachusetts, 02421, United States
Study Documents:

NCT Number: NCT05226416
Study Title: Analysis of Health Status of Comorbid Adult Patients With COVID-19 Hospitalised in Fourth Wave of SARS-CoV-2 Infection
Study URL: https://beta.clinicaltrials.gov/study/NCT05226416
Acronym: ACTIV4
Study Status: COMPLETED
Brief Summary: Depersonalized multi-centered registry initiated to analyze dynamics of non-infectious diseases after SARS-CoV-2 infection in population of Eurasian adult patients.
Study Results: NO
Conditions: COVID-19|Chronic Heart Failure|Diabetes Mellitus|Chronic Kidney Diseases|Ischemic Heart Disease|Arrythmia|Hypertensive Heart Disease|Overweight and Obesity|Oncology|Ischemic Stroke|Myocardial Infarction|Atrial Fibrillation|DVT|Stroke|Copd|Asthma|Pulmonary Embolism|Anemia|Myocarditis
Interventions:
Primary Outcome Measures: death for any cause, rate of lethal outcomes, From date of hospitalization until the date of first documented date of death from any cause, assessed up to 12 months| hospitalization for any cause, rate of hospitalization for any cause, 12 months after discharge
Secondary Outcome Measures: onset of any disease diagnosed 1 year after discharge, rate of patients with onset of any disease diagnosed 1 year after discharge, 1 year after discharge|rate of demand for medical care, number of patients seeking for health care after discharge, 1 year after discharge
Other Outcome Measures:
Sponsor: Eurasian Association of Therapists
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 3554
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ACTIV4
Start Date: 2022-02-21
Primary Completion Date: 2022-03-31
Completion Date: 2023-04-21
First Posted: 2022-02-07
Results First Posted:
Last Update Posted: 2023-05-09
Locations: Eurasian Association of Therapists, Moscow, 101000, Russian Federation
Study Documents:

NCT Number: NCT04574050
Study Title: SELF-BREATHE RCT for Chronic Breathlessness
Study URL: https://beta.clinicaltrials.gov/study/NCT04574050

Acronym:
Study Status: RECRUITING
Brief Summary: A feasibility RCT comprising two groups:

1. Intervention (SELF-BREATHE in addition to standard NHS care)
2. Control group (standard / currently available NHS care)
Study Results: NO
Conditions: Cancer|COPD|Asthma|Bronchiectasis Adult|Interstitial Lung Disease|Cystic Fibrosis|Chronic Heart Failure|Sickle Cell Disease|Renal Failure|Liver Failure|Post COVID-19|Dyspnea
Interventions: OTHER: SELF-BREATHE
Primary Outcome Measures: Feasibility: the number of patients recruited into this study over a 12-month period, The number of patients recruited into this study over a 12-month period, 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: King's College Hospital NHS Trust
Collaborators: King's College London
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: IRAS 285303|20/LO/1108
Start Date: 2020-01-11
Primary Completion Date: 2022-04-04
Completion Date: 2022-06-30
First Posted: 2020-10-05
Results First Posted:
Last Update Posted: 2021-09-09
Locations: King's College Hospital NHS Foundation TRUST, London, SE5 9RS, United Kingdom
Study Documents:

NCT Number: NCT00858039
Study Title: Cardiotoxicity of Adjuvant Trastuzumab
Study URL: https://beta.clinicaltrials.gov/study/NCT00858039
Acronym: CATS
Study Status: COMPLETED
Brief Summary: Trastuzumab (Herceptin®) increases the chances of cure in patients with Her-2 overexpressing early breast cancer. Unfortunately, both the chemotherapy drugs used in this setting (anthracyclines) and trastuzumab are known to cause cardiac dysfunction in a proportion of patients. Patients who develop heart problems when taking trastuzumab might have to stop this treatment, which could jeopardise their chances of cure. N-terminal pro-B-type natriuretic peptide (NT pro-BNP) is a cardiac biomarker that is

measured in the blood, the levels of which have been shown to indicate the presence of heart failure. Some early research has suggested that there may be a correlation between elevated NT pro-BNP and heart damage due to cancer chemotherapy and also trastuzumab. Troponin is another substance measured in the blood that can indicate heart damage. Finally, certain variations in an individual's genetic makeup (called polymorphisms) could put them at increased risk of heart damage from trastuzumab. Here we are studying whether any of these factors (NT pro-BNP levels, troponin levels, or certain genetic polymorphisms) can accurately predict who is at highest risk of trastuzumab-related cardiotoxicity.

The principal aim of this study is to evaluate the utility of NT pro-BNP as a predictive biomarker for the development of trastuzumab related cardiotoxicity (TRC). The investigators will also examine if single nucleotide polymorphisms in the HER2 gene or Fc-gamma-receptor genes predict for TRC.
Study Results: NO
Conditions: Breast Neoplasms|Heart Failure
Interventions:
Primary Outcome Measures: Cardiotoxicity (Cardiac death; grade 3/4 arrhythmia or ischaemia; NYHA Class 3 or 4 heart failure decline in LVEF by >10% to a level <55%; decline in LVEF by >5% to a level <50%), Until 6 months after completing trastuzumab
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Royal Prince Alfred Hospital, Sydney, Australia
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 220
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: X08-0296
Start Date: 2009-02
Primary Completion Date: 2013-07
Completion Date: 2014-06
First Posted: 2009-03-09
Results First Posted:
Last Update Posted: 2014-11-05
Locations: Royal Prince Alfred Hospital, Sydney, New South Wales, 2050, Australia|Royal North Shore Private Hospital, Sydney, New South Wales, 2065, Australia|Sydney Haematology Oncology Clinic, Sydney, New South Wales, 2077, Australia|Concord Hospital, Sydney, New South Wales, 2137, Australia|Liverpool Hospital, Sydney, New South Wales, 2170, Australia|Bankstown Hospital, Sydney, New South Wales, 2200, Australia|St George Private Hospital, Sydney, New South Wales, 2217, Australia|Sutherland Hospital, Sydney, New South Wales, 2232,

Australia|Macarthur Cancer Therapy Centre, Sydney, New South Wales, 2560, Australia|Nepean Cancer Care Centre, Sydney, New South Wales, 2750, Australia|Tweed Hospital, Tweed Heads, New South Wales, 2485, Australia|Royal Brisbane Hospital, Brisbane, Queensland, 4029, Australia|Andrew Love Cancer Centre, Geelong, Victoria, 3220, Australia|Warnambool Hospital, Warnambool, Victoria, Australia|The Mount Hospital, Perth, Western Australia, 6805, Australia
Study Documents:

NCT Number: NCT05656079
Study Title: To Evaluate the Cardiac Safety of Pegylated Liposomal Doxorubicin Concurrently Plus Trastuzumab and Pertuzumab in the Adjuvant Setting for Early-stage HER-2-positive Breast Cancer: a Multicenter, Randomized Controlled Clinical Study
Study URL: https://beta.clinicaltrials.gov/study/NCT05656079
Acronym: easy laugh
Study Status: RECRUITING
Brief Summary: To evaluate the safety and efficacy of pegylated liposomal doxorubicin/cyclophosphamide/trastuzumab/pertuzumab followed by docetaxel/ trastuzumab/pertuzumab compared with epirubicin/ cyclophosphamide followed by docetaxel/trastuzumab/pertuzumab in the adjuvant treatment of early breast cancer.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Pegylated liposomal doxorubicin|DRUG: Epirubicin|DRUG: Cyclophosphamid|DRUG: Trastuzumab|DRUG: Pertuzumab|DRUG: Docetaxel
Primary Outcome Measures: 1-year incidence of cardiotoxicity, 1-year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Shanghai Pudong Hospital
Collaborators: CSPC Ouyi Pharmaceutical Co., Ltd.
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 204
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: kazuma
Start Date: 2021-07-01
Primary Completion Date: 2024-09
Completion Date: 2025-09
First Posted: 2022-12-19
Results First Posted:
Last Update Posted: 2022-12-19
Locations: Shanghai Pudong Hospital, Shanghai, China
Study Documents:

NCT Number: NCT02101879
Study Title: Cardiotoxicity in Metastatic Her 2 Positive Patients Treated With Trastuzumab ,Pertuzumab and Taxanes
Study URL: https://beta.clinicaltrials.gov/study/NCT02101879
Acronym:
Study Status: UNKNOWN
Brief Summary: Approximately 15-25% of all breast cancers are human epidermal growth factor receptor 2 (HER2) positive and it has been well known that HER2 overexpression is associated with more aggressive phenotype and poor prognosis with resistance to certain chemotherapeutic agents.

Trastuzumab administration as an adjuvant and in metastatic HER2 positive breast cancer is associated with both symptomatic and asymptomatic cardiotoxicity. The incidence of trastuzumab-mediated cardiotoxicity were 27% with antracycline combination and 13% when it was administered with paclitaxel .

Pertuzumab, a recombinant humanized monoclonal antibody binding to the HER2 dimerization domain, prevents dimerization of HER2 with other HER receptors (HER3,HER1, and HER4) especially with HER3. Blocking HER2-HER3 dimerization is postulated to be the most clinically relevant action of pertuzumab and this can effectively block her2-mediated cell signaling.

Pertuzumab is indicated in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Treatment of breast cancer with pertuzumab plus trastuzumab plus docetaxel as first line treatment until disease progression might be complicated by cardiotoxicity in up to 14.5% of the Patients.

Cardinale et al showed that troponin I (TNI) positive identifies trastuzumab-treated patients who are at risk for cardiotoxicity and are unlikely to recover from cardiac dysfunction despite HF therapy.

There is very little data about the reversibility and identification of patients at risk for cardiotoxicity of the pertuzumab plus trastuzumab plus docetaxel regimen and of those who will not recover from cardiac dysfunction,this information is crucial. The usefulness of troponin I (TNI) and Brain natriuretic peptide (BNP) in the identification of patients at risk for PT cardiotoxicity and in the prediction of LVEF recovery has never been investigated.

based on this background , this study aim is to evaluate the cardiotoxicity of pertuzumab plus trastuzumab plus docetaxel regimen and the application of troponin I (TNI) and Brain natriuretic peptide (BNP) in this setting.

Study Results: NO
Conditions: Cardiotoxicity.|Anti Her2 Therapy.|Metastatic Breast Cancer
Interventions:
Primary Outcome Measures: To assesses blood levels of TNI and BNP during the first four cycles Trastuzumab&Pertuzumab and Taxanes treatment, Prior to every treatment cycle, blood samples will be taken for TNI \& BNP. Patients with elevated levels will be sent for LEVF evaluation. In cases with LEVF reduction of 15% or more from the baseline or LEVF less than 50% will be sent for Cardiological consult in order to consider ACEI or BB treatment, The patients will be followed until the end of therapy (an expected average of 18 months).| To evaluate the correlation between elevated TNI&BNP and decline of LVEF on echocardiography until end of treatment., Prior to every treatment cycle, blood samples will be taken for TNI \& BNP. Patients with elevated levels will be sent for LEVF evaluation. In cases with LEVF reduction of 15% or more from the baseline or LEVF less than 50% will be sent for Cardiological consult in order to consider ACEI or BB treatment, The patients will be followed until the end of therapy (an expected average of 18 months).
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Rambam Health Care Campus
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 20
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Cardiotoxicity
Start Date: 2014-05
Primary Completion Date: 2016-03
Completion Date: 2016-08
First Posted: 2014-04-02
Results First Posted:
Last Update Posted: 2014-05-02
Locations: Rambam MC, Haifa, Israel
Study Documents:

NCT Number: NCT02178579
Study Title: Prospective Observation of Cardiac Safety With Proteasome Inhibition
Study URL: https://beta.clinicaltrials.gov/study/NCT02178579
Acronym: PROTECT
Study Status: COMPLETED
Brief Summary: The purpose of this study is to better define and understand potential cardiac toxicities of proteasome inhibitors and to understand optimal management strategies to treat and prevent

cardiovascular events.
Study Results: NO
Conditions: Heart Failure|Multiple Myeloma
Interventions:
Primary Outcome Measures: Frequency of cardiac events of patients receiving PIs for MM., 18 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Vanderbilt University Medical Center
Collaborators: Takeda
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 95
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 140404
Start Date: 2014-11
Primary Completion Date: 2019-07-15
Completion Date: 2019-07-15
First Posted: 2014-07-01
Results First Posted:
Last Update Posted: 2020-09-14
Locations: University of Pennsylvania/Smilow Center for Translational Research, Philadelphia, Pennsylvania, 19104-5159, United States| Vanderbilt University Medical Center, Nashville, Tennessee, 37232, United States
Study Documents:

NCT Number: NCT01669239
Study Title: Study of Neoadjuvant Myocet®, Paclitaxel, Pertuzumab, and Trastuzumab in HER2-positive Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01669239
Acronym: Opti-HER
Study Status: COMPLETED
Brief Summary: This is a prospective, multicenter, single-arm, phase II study to evaluate the safety of neoadjuvant liposomal doxorubicin plus paclitaxel, trastuzumab, and pertuzumab in patients with HER2-positive breast cancer
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Liposomal Doxorubicin
Primary Outcome Measures: Rate of symptomatic (type A) and asymptomatic (type B) cardiac events during the study treatment period, Following 12 months after first dose of the study treatment
Secondary Outcome Measures: pCR in breast (pCRB), At the time of definitive surgery, an expected average of 23 weeks|pCR in breast and axilla (pCRBA), At the time of definitive surgery, an expected average of 23 weeks|Clinical objective response rate (cORR) in the breast and

axilla by RECIST criteria version 1.1, At the time of definitive surgery, an expected average of 23 weeks|Residual Cancer Burden (RCB) at surgery following the procedures of the MD Anderson Cancer Center, At the time of definitive surgery, an expected average of 23 weeks|Breast conservation rate at surgery, At the time of definitive surgery, an expected average of 23 weeks|Evaluation of serum biomarkers predictive of cardiotoxicity, Following 12 months after first dose of the study treatment|Percentage of patients with grade 3/4 neutropenia (assessed by CTCAE v.4), Following 12 months after first dose of the study treatment|Time of onset and time of recovery from symptomatic (type A) and asymptomatic (type B) cardiac events (assessed by CTCAE v.4), Following 12 months after first dose of the study treatment|Dose reductions due to treatment toxicity (assessed by CTCAE v.4), Following 12 months after first dose of the study treatment|Dose delays due to treatment toxicity (assessed by CTCAE v.4), Following 12 months after first dose of the study treatment|Number of patients with adverse events and serious adverse events (assessed by CTCAE v.4), Following 12 months after first dose of the study treatment
Other Outcome Measures:
Sponsor: SOLTI Breast Cancer Research Group
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 83
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: SOLTI-1002|2012-001201-24
Start Date: 2013-06
Primary Completion Date: 2016-01
Completion Date: 2016-01
First Posted: 2012-08-20
Results First Posted:
Last Update Posted: 2017-11-06
Locations: Hospital Clínic de Barcelona, Barcelona, Spain|Hospital Universitario Vall d´Hebron, Barcelona, Spain|Complejo Hospitalario San Pedro de Alcántara, Cáceres, Spain|Hospital Universitari Arnau de Vilanova de Lleida, Lleida, Spain|Hospital Universitario 12 de Octubre, Madrid, 28041, Spain|Centro Integral Oncológico Clara Campal, Madrid, Spain|Hospital Universitario Clínico San Carlos, Madrid, Spain|Hospital Universitario Puerta de Hierro de Majadahonda, Madrid, Spain|MD Anderson Cancer Center Madrid, Madrid, Spain|Hospital Universitario Virgen de la Arrixaca, Murcia, Spain|Hospital Son Llàtzer, Palma de Mallorca, Spain|Hospital Universitari Son Espases, Palma de Mallorca, Spain|Hospital Sant Joan de Reus, Reus, Spain|Hospital Sagrado Corazón USP, Sevilla, Spain|Hospital Universitario Virgen del Rocío, Sevilla, Spain|Hospital Virgen de la Macarena,

Sevilla, Spain|Fundación Instituto Valenciano de Oncología, Valencia, Spain|Hospital Arnau de Vilanova de Valencia, Valencia, Spain|Hospital Universitario Lozano Blesa, Zaragoza, Spain
Study Documents:

NCT Number: NCT05099679
Study Title: Pilot Study for Black Men With Prostate Cancer: Optimization Of Mental and Heart Health, the BOOM-Heart Study
Study URL: https://beta.clinicaltrials.gov/study/NCT05099679
Acronym:
Study Status: RECRUITING
Brief Summary: Pilot study to determine the feasibility of providing psychosocial and cardiac rehabilitation services to address socioeconomic health disparities and improve wellbeing for black men with prostate cancer.
Study Results: NO
Conditions: Prostate Cancer
Interventions: BEHAVIORAL: Cognitive behavioral therapy (supportive counseling)|BEHAVIORAL: Virtual Cardiac Rehabilitation
Primary Outcome Measures: Proportion of Completers, Proportion of screened eligible participants who complete the initial 2-hour psychosocial support session intake.

The pilot study is considered feasible if the primary endpoint is met in at least 50% of patients. We will evaluate the 95% CI of the feasibility rate., 12 weeks
Secondary Outcome Measures: Difference in Patient Health Questionnaire-9 (PHQ-9), 12 weeks|Difference of General Anxiety Disorder-7 (GAD-7) score, 12 weeks|Difference of Functional Assessment of Cancer Therapy-Prostate (FACT-P) score, 12 weeks
Other Outcome Measures:
Sponsor: Stanford University
Collaborators:
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 30
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IRB-60375|PROS0109|NCI-2022-02832
Start Date: 2021-11-18
Primary Completion Date: 2023-11
Completion Date: 2023-11
First Posted: 2021-10-29
Results First Posted:
Last Update Posted: 2023-06-23
Locations: Stanford University, Palo Alto, California, 94305, United States

Study Documents:

NCT Number: NCT00309439
Study Title: ALA and Prostate Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00309439
Acronym:
Study Status: UNKNOWN
Brief Summary: The problem is the lack of data from randomized controlled trials to throw light on the ALA-prostate cancer issue. There is therefore a need to acquire evidence from a randomized controlled study to illustrate the effect of ALA on a surrogate marker for prostate cancer, namely prostate specific antigen (PSA). Demonstration that atrial fibrillation recurrence was reduced after cardioversion and that there was no adverse effect of 1 years of ALA feeding on PSA would go a considerable way to providing the required evidence that ALA in the human diet has no adverse effect on the prostate and so allow its use for cardiovascular risk reduction. hypothesis: The effect of ALA on PSA levels over time will be no different from the control, so providing supportive data for the view that ALA is not cancer promoting.
Study Results: NO
Conditions: Atrial Fibrillation|Diet Therapy|Prostate Cancer
Interventions: PROCEDURE: ALA-rich diet
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Toronto
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment:
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE|Primary Purpose:
Other IDs: REB15636
Start Date:
Primary Completion Date:
Completion Date:
First Posted: 2006-03-31
Results First Posted:
Last Update Posted: 2012-06-13
Locations:
Study Documents:

NCT Number: NCT05378139
Study Title: Continuous Wireless Monitoring of Vital Signs and Automated Alerts in Hospitalized Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05378139

Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The primary aim of this study is to test and assess the implementation and effectiveness of continuous wireless vital signs monitoring with real-time alerts on:

The frequency of patients monitored with adequate data quality as adequate clinical user satisfaction in the initial versus the last part of the trial (primary outcome).
Study Results: NO
Conditions: Surgical Complication|Pulmonary Disease|Hematologic Diseases|Oncology|Cardiac Disease|Infections
Interventions: DEVICE: Vital signs measurements with new app
Primary Outcome Measures: Data quality, The number (frequency) of patients having adequate data quality (defined as at least 60% of the monitoring time with simultaneous recording of SpO2, respiratory rate, heart rate), 30 days|user satisfaction, Number of users with adequate clinical user satisfaction (defined as the nurse in charge of the patient at the end of monitoring answers "Agree" or "Strongly agree" to the question "WARD-monitoring was beneficial for monitoring of vital signs in this patientparticipant (response options: Strongly Disagree - Disagree - Neutral - Agree - Strongly Agree)., 30 days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University Hospital Bispebjerg and Frederiksberg
Collaborators: Rigshospitalet, Denmark
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 3095
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2203648
Start Date: 2021-02-01
Primary Completion Date: 2023-06-27
Completion Date: 2023-12-22
First Posted: 2022-05-18
Results First Posted:
Last Update Posted: 2023-06-26
Locations: Rigshospitalet, Copenhagen, 2100, Denmark
Study Documents:

NCT Number: NCT05775939
Study Title: PET/CT Imaging to Evaluate Cardiac Radiation Damage in Patients With Lung Cancer, EUCLID Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT05775939
Acronym:
Study Status: RECRUITING
Brief Summary: This clinical trial examines positron emission

tomography (PET)/computed tomography (CT) in evaluating cardiac radiation damage in patients with lung cancer. As part of the treatment for lung cancer, patients will undergo radiation therapy. Sometimes, during this treatment, the heart is also subjected to some radiation which could affect its function, either increasing or decreasing the function. It is not known the consequences of this change nor is it known if doctors can detect the changes associated with the radiation. Sarcoidosis FDG positron emission tomography (PET)-computed tomography (CT) scans are a common way to image cardiac inflammation and myocardial viability. This study may help doctors image the heart before, during and after radiotherapy to monitor any changes.
Study Results: NO
Conditions: Lung Carcinoma
Interventions: OTHER: Fludeoxyglucose F-18|PROCEDURE: Positron Emission Tomography|PROCEDURE: Computed Tomography|OTHER: Questionnaire Administration
Primary Outcome Measures: Change in mean standardized uptake value (SUV) changes in the heart, Measured by sarcoidosis fludeoxyglucose F-18 (FDG) positron emission tomography (PET)-computed tomography (CT) scans., Up to 30 months after radiotherapy
Secondary Outcome Measures: Ability of pre- to post-radiotherapy SUV changes in the heart, Measured by sarcoidosis FDG PET-CT scans., Up to 30 months after radiotherapy|Overall survival, Survival, Up to 30 months after radiotherapy|Cardiac toxicity, Assessed using \>= grade 2 and \>= grade cardiac events using Common Terminology Criteria for Adverse Events (CTCAE) version 5.0., Up to 30 months after radiotherapy|Cardiac toxicity judged to be secondary to radiotherapy by cardiologist and radiation oncologist, Judged to be secondary to radiotherapy by cardiologist and radiation oncologist, Up to 30 months after radiotherapy|Cardiac related death, Death, Up to 30 months after radiotherapy
Other Outcome Measures:
Sponsor: Thomas Jefferson University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 22D.705
Start Date: 2023-01-20
Primary Completion Date: 2026-01
Completion Date: 2029-02
First Posted: 2023-03-20
Results First Posted:
Last Update Posted: 2023-03-20

Locations: Thomas Jefferson University Hospital, Philadelphia, Pennsylvania, 19107, United States
Study Documents:

NCT Number: NCT02006979
Study Title: Acute Exercise Cardioprotection From Doxorubicin
Study URL: https://beta.clinicaltrials.gov/study/NCT02006979
Acronym:
Study Status: COMPLETED
Brief Summary: In rodents, a single bout of exercise prior to injection of a chemotherapy agent used to treat breast cancer prevents or attenuates a number of markers of cardiac injury. This study will investigate whether this finding translates to human breast cancer patients. Participants scheduled to receive chemotherapy for breast cancer will be randomized to exercise or no exercise 24 hours prior to every chemotherapy treatment. The effect on cardiac function will be compared between groups noninvasively by echocardiography and electrocardiography and a venous blood draw at baseline before chemotherapy, after the first treatment and at the end of chemotherapy.
Study Results: YES
Conditions: Breast Cancer
Interventions: OTHER: exercise
Primary Outcome Measures: Global Longitudinal Strain, Assessed with 2D speckle tracking echocardiography, 24-48 hours after first doxorubicin and 7-14 days after completion of last doxorubicin cycle
Secondary Outcome Measures: NT-proBNP, biomarker of cardiac injury, 24-48 hours after first doxorubicin and 7-14 days after completion of last doxorubicin cycle|Cardiac Troponin T, biomarker of cardiac injury, 24-48 hours after first doxorubicin and 7-14 days after completion of last doxorubicin cycle|LV Twist, Assessed with 2D speckle tracking echocardiography, 24-48 hours after first doxorubicin and 7-14 days after completion of last doxorubicin cycle
Other Outcome Measures: Patient-reported Symptoms, As assessed by standardized scores of physical and psychological distress by the Rotterdam Symptom Checklist, <1 week before the first doxorubicin, <3 days before the 2nd, 3rd, and 4th doxorubicin, 7-14 days after completion of the last doxorubicin cycle
Sponsor: University of British Columbia
Collaborators: British Columbia Cancer Agency
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 27
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: H13-03090
Start Date: 2016-01-15

Primary Completion Date: 2016-05-25
Completion Date: 2016-05-25
First Posted: 2013-12-10
Results First Posted: 2017-11-08
Last Update Posted: 2019-10-25
Locations: University of British Columbia Breast Cancer Research Exercise Gym, Vancouver, British Columbia, V5Z 4C2, Canada
Study Documents:

NCT Number: NCT02065908
Study Title: Circulating MicroRNA as Biomarker of Cardiotoxicity in Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02065908
Acronym:
Study Status: COMPLETED
Brief Summary: In the proposed project the investigators will asses whether changes in expression of selected circulating microRNAs in serum could comprise a sensitive and specific biomarker of cardiotoxicity in cancer patients treated with anthracyclines based chemotherapy.
Study Results: NO
Conditions: Breast Cancer
Interventions:
Primary Outcome Measures: Cardiotoxicity events according to CREC (Cardiac Review and evaluation Committee) criteria, either a cardiomyopathy with decreased left ventricular ejection fraction (LVEF), a reduction of LVEF ≥5% to \<55% with symptoms of heart failure (e.g. orthopnoea and paroxysmal nocturnal dyspnoea, elevated jugular venous pressure, S3 gallop, Hepatojugular reflux, tachycardia), or an asymptomatic reduction of LVEF ≥10% to \<55%, up to 76 weeks after chemotherapy conclusion
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: West Pomeranian Cancer Center
Collaborators: Pomeranian Medical University Szczecin
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 128
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ZCO-2014-BD
Start Date: 2014-01
Primary Completion Date: 2016-06
Completion Date: 2016-12
First Posted: 2014-02-19
Results First Posted:
Last Update Posted: 2016-12-08
Locations: Clinical Oncology Department, West Pomeranian Cancer

Center, Szczecin, West Pomeranian, 71-730, Poland|Collegium Medicum of Jagiellonian University, Cracow, 31-513, Poland|Pomeranian Medical University, Department of Cardiology, Szczecin, 70-111, Poland
Study Documents:

NCT Number: NCT05756608
Study Title: Fibrosis in Chronic and Delayed Myocardial Infarction
Study URL: https://beta.clinicaltrials.gov/study/NCT05756608
Acronym: FCDMI
Study Status: RECRUITING
Brief Summary: In this study the investigators aim to examine the role that fibrosis plays in heart conditions such as aortic stenosis , chemotherapy-induced cardiotoxicity and carcinoid syndrome . Fibrosis is a common final result following any injury to the heart muscle and the investigators aim to identify this process early and in its active state. This will be examined by using a radiotracer 68Ga-FAPI or 18F-AlF-FAPI and PET-MRI or PET-CT.
Study Results: NO
Conditions: Aortic Stenosis|Chemotherapy Induced Systolic Dysfunction|Carcinoid Syndrome
Interventions: DIAGNOSTIC_TEST: 68Ga-FAPI and 18F-AlF-FAPI PET-MR
Primary Outcome Measures: Fibrosis activity: Standardised uptake values (SUV, SUV, 1-2 years|Fibrosis activity:Tissue-to-Background Ratio, TBR, 1-2 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Edinburgh
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 180
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 300754
Start Date: 2022-11-10
Primary Completion Date: 2025-11-10
Completion Date: 2025-11-10
First Posted: 2023-03-06
Results First Posted:
Last Update Posted: 2023-03-06
Locations: University of Edinburgh, Edinburgh, Scotland, NE7 7EY, United Kingdom
Study Documents:

NCT Number: NCT02429479
Study Title: Preparing Family Caregivers to Make Medical Decisions for Their Loved Ones
Study URL: https://beta.clinicaltrials.gov/study/NCT02429479

Acronym:
Study Status: COMPLETED
Brief Summary: The overarching goal of the project is to improve the process and experience of surrogate decision-making by family caregivers. Since feeling unprepared to make surrogate decisions is a major contributor to caregiver stress, the primary outcome is caregiver self-efficacy --i.e., caregivers' assessment of how well prepared they feel to serve effectively as a surrogate decision-maker. Through follow-on Renewal funding, we are now also qualitatively examining family caregivers' experience with surrogate decision-making.
Study Results: NO
Conditions: Neoplasms|Heart Failure|Kidney Diseases|Lung Diseases
Interventions: BEHAVIORAL: Making Your Wishes Known|BEHAVIORAL: Standard advance care planning
Primary Outcome Measures: Self-efficacy, Family caregiver self-efficacy is measured using a validated questionnaire to determine if they feel better prepared to serve as surrogates for their loved one., 6 weeks
Secondary Outcome Measures: Accuracy of medical decisions, Family caregiver responses to treatment decisions hypothetical clinical vignettes will be compared to the decisions for the same vignettes made by their loved one. Each vignette has 6-8 associated treatment decisions; the family caregiver's response for each item will be compared with the loved one's (i.e., patient's) response, and a total concordance (i.e., number of items for which there is agreement) will be calculated., 6 weeks|Family caregivers' stress associated with actual (i.e., real-life) surrogate decision-making, Using validated instruments and semi-structured interviews, family caregivers who have made a major medical decision on behalf of their loved one will report their level of distress, decisional conflict, satisfaction with decision, and experience with surrogate decision-making., 1-2 years|Family caregiver knowledge, Family caregivers will complete a questionnaire that assess their knowledge of surrogate responsibilities and end-of-life medical conditions and treatments, 6 weeks - 2 years|Depth of communication, Family Caregivers are interviewed about the depth of communication with their loved one (frequency, content, helpfulness of discussions) regarding advance care planning issues., 2 years|Satisfaction with advance care planning, Participants who complete the advance care planning interventions fill out an evaluation of the intervention using a 16-item questionnaire. This instrument comprises:

Twelve 5-point Likert-style questions on how the program presented various kinds of information; helped the user clarify values, choose a spokesperson, etc.; and helped the user document or be prepared communicate their wishes to others.

Three 10-point Likert-style questions on user overall satisfaction, with the advance directive created by the intervention, and the amount

of information provided.

One open-ended item asking how the intervention was helpful., 1st study visit
Other Outcome Measures:
Sponsor: Milton S. Hershey Medical Center
Collaborators: National Institute of Nursing Research (NINR)|Brigham and Women's Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 570
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: FACTORIAL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 37476|1R01NR012757-01A1
Start Date: 2013-06-01
Primary Completion Date: 2017-06-30
Completion Date: 2021-06-30
First Posted: 2015-04-29
Results First Posted:
Last Update Posted: 2021-08-16
Locations: Brigham & Women's Hospital, Boston, Massachusetts, 02120, United States|Penn State Milton S. Hershey Medical Center / Penn State College of Medicine, Hershey, Pennsylvania, 17033, United States
Study Documents:

NCT Number: NCT00385879
Study Title: The Effects of Case Management in a Medicaid Managed Care Plan
Study URL: https://beta.clinicaltrials.gov/study/NCT00385879
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to evaluate whether or not case management by a social worker and nurse can decrease the number of emergency room visits, increase the number of primary care doctor visits, and increase quality of life of people in a Medicaid managed care plan.
Study Results: NO
Conditions: Neoplasms|Heart Diseases|Adrenal Cortex Diseases
Interventions: BEHAVIORAL: Case management
Primary Outcome Measures: The outcome measure for the number of emergency room visits will be calculated from the medical record counting the number of hospital emergency room visits; for access to primary physicians, the medical record will be reviewed as well.
Secondary Outcome Measures: The outcomes for quality of life will be evaluated from the McGill Quality of Life Questionnaire.
Other Outcome Measures:
Sponsor: Metropolitan Jewish Health System

Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 500
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: CROSSOVER|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: Health Plus at Home
Start Date: 2006-05
Primary Completion Date:
Completion Date: 2008-01
First Posted: 2006-10-11
Results First Posted:
Last Update Posted: 2006-10-11
Locations: Metropolitan Jewish Health System, Brooklyn, New York, 11220, United States
Study Documents:

NCT Number: NCT02604979
Study Title: The Influences of Long Periods of Pneumoperitoneum and Head up Position on the Variation of Heart-rate Corrected QT Interval During Robotic-assisted Laparoscopic Gastrectomy - Observational Study
Study URL: https://beta.clinicaltrials.gov/study/NCT02604979
Acronym:
Study Status: COMPLETED
Brief Summary: Sympathetic activity could be increased during robot-assisted laparoscopic gastrectomy, which is performed in a head up position under CO2 pneumoperitoneum.

Stimulation of the sympathetic nervous system prolongs the QT interval and can increases the susceptibility to life threatening cardiac arrhythmias.

Thus the investigators decided to evaluate the heart-rate corrected QT interval (QTc interval) during robotic-assisted laparoscopic gastrectomy.
Study Results: NO
Conditions: Stomach Cancer
Interventions:
Primary Outcome Measures: Evaluate the heart-rate corrected QT (QTc) interval (msec) during robotic-assisted laparoscopic gastrectomy, (T0: Pre-induction T1: 10min after anesthetic induction T2: 1min after CO2 pneumoperitoneum T3: 5min after CO2 pneumoperitoneum T4: 30min after steep trendelenburg position T5:60min after steep trendelenburg T6: 90min after steep trendelenburg T7: Supine positon following end of pneumoperitoneum T8: 5 min after end of pneumoperitoneum T9: End of surgery T10: 10min after extubation), through study completion, an average of 5 hours

Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Yonsei University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 30
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 4-2015-0607
Start Date: 2015-09-23
Primary Completion Date: 2016-02-06
Completion Date: 2016-02-06
First Posted: 2015-11-16
Results First Posted:
Last Update Posted: 2017-01-25
Locations: Department of Anesthesiology and Pain Medicine, Yonsei University College of Medicine, Seoul, 03722, Korea, Republic of
Study Documents:

NCT Number: NCT02333279
Study Title: Cancer Development In Organ Transplant Recipients
Study URL: https://beta.clinicaltrials.gov/study/NCT02333279
Acronym:
Study Status: COMPLETED
Brief Summary: The investigators will determine the cancer risk in organ transplant recipients compared to the general population with the help of statistical analysis. Secondly the investigators will try to characterize the different cancer types.
Study Results: NO
Conditions: Heart Cancer|Kidney Cancer|Lung Cancer|Pancreas Cancer|Liver Cancer
Interventions:
Primary Outcome Measures: Number of solid cancers, Number of solid cancers, Ten Year followup
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Zurich
Collaborators: University Hospital, Basel, Switzerland|Insel Gruppe AG, University Hospital Bern|Cantonal Hospital of St. Gallen|University Hospital, Geneva|University of Lausanne Hospitals
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 1800
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p

Other IDs: FUP062|snctp000000587
Start Date: 2008-05
Primary Completion Date: 2018-05
Completion Date: 2019-07
First Posted: 2015-01-07
Results First Posted:
Last Update Posted: 2019-07-29
Locations: University Hospital Zurich, Division of Dermatology, Zurich, 8091, Switzerland
Study Documents:

NCT Number: NCT04024917
Study Title: Impact of Cardiac Coherence on Anxiety in Patients Operated on for a Peritoneal Carcinosis
Study URL: https://beta.clinicaltrials.gov/study/NCT04024917
Acronym: COCOON
Study Status: RECRUITING
Brief Summary: The investigator proposes to use the cardiac coherence technique to diminish anxiety before the surgery of a peritoneal carcinosis of colon or stomach or ovary and pseudomyxoma or peritoneal mesothelioma.
Study Results: NO
Conditions: Peritoneal Carcinomatosis|Pseudomyxoma Peritonei|Mesothelioma Peritoneum
Interventions: OTHER: Cardiac coherence|OTHER: Standard care
Primary Outcome Measures: Cardiac Coherence Program Adherence Rate, Cardiac Coherence Program Adherence Rate. Patients are considered in "success" adhere to the program) if they will perform at least 20 of the 30 sessions scheduled until surgery (minimum 1 practice per day)., Around 10 days
Secondary Outcome Measures: Anxiety by using the visual analogue scale (VAS), This scale measures the anxiety of patient. It's a visual analogue scale which is also known as linear analogue scale. These scales require respondents to place a mark on a line on which opposing statements or descriptions are placed at either end of a (usually) 10 cm line. The points at which respondents make their mark represent where they perceive their answer to lie in this continuum. The distance between their mark and one end (or the mid-point) of the scale is recorded. The position on the left being the absence of anxiety and the position on the right an unbearable anxiety., 90 days|Anxiety and depression by using the hospital anxiety and depression scale (HADS), One subscale for evaluation of anxiety from 0 (lower anxiety) to 21 (higher anxiety) and the other subscale for depression from 0 (lower anxiety) to 21 (higher depression), 90 days|Psychological distress scale, This scale measures the psychological distress of the patient . Psychological distress is characterized by the presence of symptoms, most often depressive or anxious.It's a visual analogue scale which is also known as linear analogue scale. These scales require respondents to place a mark on a line on which opposing statements or descriptions are placed at either end of a

line. The position of the mark on the top is the higher psychological distress and at the bottom the lower psychological distress., 90 days|Generalized anxiety by using Freeston's uncertainty tolerance scale, The scale is used to identify people with generalized anxiety disorder compared to people with other anxiety disorders or people without pathologies. Range is from 27 (lower uncertainty) to 135 (higher uncertainty), 90 days|Heart rate variability, The heart rate variability is determined by using the software EmWave Pro which measures the ratio low frequencies/high frequencies., 90 days|Quality of life by using the quality of life questionnaire score (QLQ-C30), The EORTC QLQ-C30 uses for the questions 1 to 28 a 4-point scale. The scale scores from 1 to 4: 1 ("Not at all"), 2 ("A little"), 3 ("Quite a bit") and 4 ("Very much"). Half points are not allowed. The range is 3. For the raw score, less points are considered to have a better outcome.

The EORTC QLQ-C30 uses for the questions 29 and 30 a 7-points scale. The scale scores from 1 to 7: 1 ("very poor") to 7 ("excellent"). Half points are not allowed. The range is 6. First of all, raw score has to be calculated with mean values. Afterwards linear transformation is performed to be comparable. More points are considered to have a better outcome., 90 days|Number of days of hospitalization after surgery, 1 month|Pain by using the visual analogue scale (VAS), This scale measures the pain of patient. It's a visual analogue scale which is also known as linear analogue scale. These scales require respondents to place a mark on a line on which opposing statements or descriptions are placed at either end of a (usually) 10 cm line. The points at which respondents make their mark represent where they perceive their answer to lie in this continuum. The distance between their mark and one end (or the mid-point) of the scale is recorded. The position on the left being the absence of pain and the position on the right an unbearable pain., 90 days|Concentration of salivary immunoglobulin A, 90 days|Number of cardiac coherence sessions per day and by patient, Through the study, an average of 1 year|Reasons of non-participation reported by patients and registered in the form of inclusion, Through study completion, an average of 1 year|Number of patients satisfied with the cardiac coherence program, 90 days|Subjective anxiety score by using the state-trait anxiety inventory form A (STAI-Y form A) questionnaire, State anxiety reflects the current emotional state, which allows the patient's nervousness and worry to be assessed during the session. The range is from 20 (lower anxiety) to 80 (higher anxiety). The patient must answer 20 questions for each part, each answer being on a 4 point Likert scale., 90 days|Subjective anxiety score by using the state-trait anxiety inventory form B (STAI-Y form B) questionnaire, Trait anxiety reflects the usual emotional state. The range is from 20 (lower anxiety) to 80 (higher anxiety).The patient must answer 20 questions for each part, each answer being on a 4 point Likert scale, 90 days|Composite anxiety symptomatology score, Score including psychological, physiological and biological variables, 90 days|Feedback from the instructor and

investigator, 90 days|Recruitment and retention rates, 1 year|Duration of cardiac coherence sessions in minutes, Through study completion, an average of 1 year
Other Outcome Measures:
Sponsor: Institut du Cancer de Montpellier - Val d'Aurelle
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: PROICM 2019-12 COC
Start Date: 2021-09-21
Primary Completion Date: 2024-06
Completion Date: 2024-06
First Posted: 2019-07-18
Results First Posted:
Last Update Posted: 2023-01-18
Locations: ICM, Montpellier, Hérault, 34298, France
Study Documents:

NCT Number: NCT03356171
Study Title: Cardiac Coherence Combined With Personal Physical Activity in Patients With Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03356171
Acronym: APACCHE
Study Status: UNKNOWN
Brief Summary: APACCHE (Adapted Physical Activity and Cardiac Coherence in HEmatologic patients) study investigates effects of heart rate variability biofeedback training, combined with classical adapted physical activity, on health-related quality of life in patients previously treated for hematologic malignancies. It is a prospective, randomized clinical trial from University Hospital of Reunion Island. The main objective is evaluated with QLQ-C30 survey score differences.
Study Results: NO
Conditions: Physical Activity|Cancer|Hematologic Diseases
Interventions: PROCEDURE: Cardiac Coherence|PROCEDURE: Adapted Physical Activity
Primary Outcome Measures: Health-related quality of life, Health-related quality is assessed by the Quality of Life Questionnaire dedicated to cancer patients and including 30 items (QLQ-C30) developed by the European Organization for Research and Treatment of Cancer (EORTC). This questionnaire is a multimodal construct, typically including physical, emotional and psychological health issues; evaluated with the QLQ-C30 survey of the European Organization for Research and Treatment of Cancer.

QLQ-C30 items are coded with the same response categories as items 6 to 28, namely "Not at all", "A little", "Quite a bit" and "Very much." Score ranges from 0 to 100, with higher score indicating higher levels of quality of life., on week 12
Secondary Outcome Measures: Fatigue improvement, Fatigue improvement is assessed by multidimensional fatigue inventory (MFI-20 survey).

MFI-20 consists of five subscales used to express: general fatigue, physical, reduced activities, reduced motivation, mental fatigue.

Each scale contains four items for which the person had to indicate the extent the items describe their situations in the recent few days on a 5-point Likert scale, ranging from "yes, that is true" to "no, that is not true" Scores on each subscale range from 4 to 20, with higher scores indicating higher levels of fatigue., through study completion: initially (T1), at 6 weeks (T2), 12 weeks (T3) and after at 24 weeks (T4) follow-up|Anxiety and depression improvement with Hospital Anxiety and Depression Scale (HADS) survey, Anxiety and depression improvement is assessed by HADS survey. The HADS is a fourteen item scale that generates ordinal data. Seven of the items relate to anxiety and seven relate to depression. Each item on the questionnaire is scored from 0-3: a person can score between 0 and 21 for either anxiety or depression.

Higher scores indicate higher levels of depression or anxiety, through study completion: initially (T1), at 6 weeks (T2), 12 weeks (T3) and after at 24 weeks (T4) follow-up|Cardiac coherence improvement, Increased percentage of cardiac coherence is measured with SYMBIOLINE software, through study completion: initially (T1), at 6 weeks (T2), 12 weeks (T3) and after at 24 weeks (T4) follow-up
Other Outcome Measures:
Sponsor: Centre Hospitalier Universitaire de la Réunion
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 70
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 2017/CHU/06
Start Date: 2018-01
Primary Completion Date: 2019-03
Completion Date: 2019-06
First Posted: 2017-11-29
Results First Posted:
Last Update Posted: 2017-12-19
Locations:
Study Documents:

NCT Number: NCT03850171
Study Title: Cancer Adverse Effects PReventIon With Care & Exercise: the CAPRICE Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03850171
Acronym:
Study Status: TERMINATED
Brief Summary: Breast cancer is the most common cancer among women worldwide. Similarly, Hodgkin and non- Hodgkin lymphomas make up two of the most prevalent cancers in men and women. Even though remarkable improvements in cancer-free survival have been achieved in the last decades, the development of cardiac toxicity, associated with anthracycline-based chemotherapy (Anth-bC) counteracts the improvements in survival in these patient groups. One of the first clinical manifestation of Anth-bC cardiotoxicity is diastolic dysfunction, with further symptoms being left ventricular dysfunction and heart failure as well as a decline in exercise tolerance. Besides the direct cardiotoxic effects of anticancer treatment, many drugs also have adverse effects on the vascular endothelium.

The concept of 'Exercise is Medicine' has become well established in exercise-oncology research. Exercise therapy is now considered a safe and well-tolerated adjunct therapy inducing beneficial effects on body composition, aerobic fitness and muscular strength, pain and fatigue, quality of life (QoL), depressive symptoms, and all cause survival. However, there is insufficient data on the superiority of performing exercise training therapy before and during chemotherapy with regard to cardiotoxic and cardiovascular side effects. Further, there is no data on patient preference for and barriers toward different timings of exercise training therapy.

Therefore, the aim of the study is to compare left ventricular (LV) function measured by LV global longitudinal strain (GLS) in breast cancer and lymphoma patients undergoing Anth-bC randomised to completing an exercise-based rehabilitation programme during chemotherapy to those randomised to complete the programme after chemotherapy. Further, blood samples will be drawn to analyse biomarkers of myocardial injury (brain natriuretic peptide and high-sensitive cardiac troponin).

Additional measurements include aortic distensibility as part of the echocardiographic examination and exercise capacity through cardiopulmonary exercise testing. QoL and fatigue will be assessed in a questionnaire, compliance with exercise training through monitoring and patient preference at 3 and 6 months will be evaluated through an interview. Cardiovascular risk factors will be assessed through body composition, 24h ambulatory blood pressure monitoring, 24h electrocardiogram and the analysis of established blood markers.

Women and men aged 18 years and older with histologically confirmed

breast cancer or lymphoma (ECOG grade 0-2) who are Anth-bC naïve and with reasonable life expectancy will be included in the study.

The exercise programme is part of onco-rehabilitation programmes at the Inselspital Bern, the Spital AG Thun and the Bürgerspital Solothurn. Programmes last for 12 weeks and offer two supervised sessions per week (@ 60-90 min). They usually contain an endurance component (e.g. 40 min of cycling) and a strength, agility or relaxation component. Patients are encouraged to complete a third exercise session per week at home or elsewhere. Home-based training and general physical activity will be assessed by a questionnaire and an activity monitor.

A total of 120 patients will be recruited. Measurements will be performed at baseline, after 3 months (week 13) and after 6 months (week 26).
Study Results: NO
Conditions: Breast Neoplasm Female|Lymphoma|Cardiotoxicity|Anthracyclines|Physical Activity
Interventions: OTHER: Exercise Training
Primary Outcome Measures: Changes from baseline in left ventricular (LV) global longitudinal strain (GLS), GLS assessed by speckle tracking echocardiography is an established marker for LV systolic function with a good reproducibility, which has also been found in the investigators' laboratory. In breast cancer and lymphoma patients LV global longitudinal strain is an established measure to assess cardiotoxicity of Anth-bC., week 13
Secondary Outcome Measures: Change in Blood biomarkers, Blood samples will be collected to determine concentration of Brain Natriuretic Peptide (NT- proBNP) and high- sensitive cardiac Troponin (hsTnT). Cardiac troponin release after high-dose chemotherapy is a marker for chemotherapy-induced cardiotoxicity in cancer patients and identifies patients at different risks of cardiac events in the years thereafter. The increment of hs-TnT has been found to be predictive for cardiotoxicity in breast cancer patients at 3 months after initiation of Anth-bC. Both, NT-proBNP and hs-TnT have been recommended as early biomarkers of cardiotoxicity by the European Society of Cardiology in the guidelines on cancer treatments and cardiovascular toxicity., week 0, 13, and 26|Identification of barriers towards exercise training, Barriers toward exercise training therapy will be identified by a self-designed questionnaire., week 13 and 26|Compliance with exercise training, Number of attended center-based sessions will be monitored by the attending physiotherapists. Additional home-based training and general physical activity will be assessed by the GPAQ- questionnaire. It collects information on physical activity participation in three domains (work, transport and recreational activities) as well as sedentary behaviour, comprising 16 questions (P1-P16). Within the work and discretionary domains, questions assess the frequency and duration of activity defined by the energy requirement or intensity (vigorous- or moderate-intensity). In the transport domain, the frequency and

duration of all walking and cycling for transport is captured. The main outcome variables from GPAQ analysis include a categorical variable of total physical activity (high, moderate and low) and a continuous variable of total physical activity within each domain (reported as Median METmin/week), which will be used to quantify the volume of weekly physical activity., week 0, 13 and 26|Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), The FACIT-F (version 4.0) is a 41-item compilation of general questions divided into four domains of cancer-specific quality of life (physical well-being ranging from 0-28, social/family well-being ranging from 0-28, emotional well-being ranging from 0-24 and functional well-being ranging from 0-28) and a module for fatigue (13 items, ranging from 0-52).FACIT-F total score ranges from 0- 160. It is considered appropriate to use in patients with any form of cancer. This questionnaire has been validated and used extensively, including reference data for clinically meaningful changes. Change in fatigue will be tested as primary quality of life endpoint., week 0, 13, and 26|Vascular function, Vascular function will be assessed by distensibility of the ascending aorta measured on the echocardiography. This is an established measure of arterial stiffness and has recently been shown to decrease from before to after Anth-bC in women with breast cancer. Increased arterial stiffness has been proposed to increase LV afterload, which may lead to LV hypertrophy and in its worst case LV failure., week 0, 13, and 26| Cardiorespiratory fitness, Cardiopulmonary exercise testing (CPET) will be performed on a cycle ergometer according to the recommendations of the American Heart Association. VO2peak has been found to be reduced after chemotherapy. It is an established marker for physical function and survival., week 0, 13, and 26|Cardiovascular risk profile, It has been suggested that the presence of cardiovascular risk factors increase the risk of developing Anth-bC associated cardiac dysfunction. Twenty-four-hour ambulatory blood pressure monitoring will be performed using validated recorders (Spacelabs model 90217, USA) during usual daily activities. Lipid profile and HbA1C will be determined from blood samples. Body composition will be measured by bio-impedance measurement (InBody 720, Biospace Co., Seoul, Korea) and smoking status will be assessed. Also, a 24-hour Holter electrocardiogram will be performed. Both 24-hour monitors will be worn after each visit on two separate days., week 0, 13, and 26|Changes in LV global longitudinal strain, GLS assessed by speckle tracking echocardiography is an established marker for LV systolic function with a good reproducibility, which has also been found in the investigators' laboratory. In breast cancer and lymphoma patients LV global longitudinal strain is an established measure to assess cardiotoxicity of Anth-bC., Week 0 and 26
Other Outcome Measures:
Sponsor: Insel Gruppe AG, University Hospital Bern
Collaborators: Spital STS AG|Bürgerspital Solothurn|Lindenhofspital|University of Bern
Sex: ALL

Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 57
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: CAPRICE
Start Date: 2019-05-01
Primary Completion Date: 2022-12-31
Completion Date: 2023-01-31
First Posted: 2019-02-21
Results First Posted:
Last Update Posted: 2023-02-27
Locations: Lindenhofgruppe, Bern, 3001, Switzerland|University Clinic for Cardiology, Bern, 3010, Switzerland|Bürgerspital Solothurn, Solothurn, 4500, Switzerland|Spital STS AG, Thun, 3600, Switzerland
Study Documents:

NCT Number: NCT01714271
Study Title: Promotora-based Latino Family CVD Risk Reduction
Study URL: https://beta.clinicaltrials.gov/study/NCT01714271
Acronym:
Study Status: UNKNOWN
Brief Summary: This family environment-focused health behavior change intervention is being carried out by extensively trained community health workers (promotores) familiar with the community in East Los Angeles. The hypothesis being tested is that home environment-focused health behavior change will reduce risk of arterial stiffness, an early-in-life predictor of heart disease. The community health workers will provide most of the health promotion counseling. The promotores will provide up to 16 counseling sessions to a designated adult family member without diabetes. The sessions will focus on improving the home environment in order to reduce television viewing, increase fruit and vegetable intake, decrease intake of refined carbohydrates, prompt more frequent monitoring of body weight and increase daily physical activity. The lifestyle change goals will be tailored to the families' capacity for change and will be consistent with the Dietary Guidelines for Americans, especially the MyPlate.gov messages, the Dietary Approaches to Stop Hypertension (DASH) diet and at least 30 minutes of daily moderate physical activity.
Study Results: NO
Conditions: Heart Disease|Cancer
Interventions: BEHAVIORAL: Home environs-based lifestyle counseling|
BEHAVIORAL: Cancer early detection
Primary Outcome Measures: Change in arterial stiffness as measured by pulse wave velocity, Pulse wave velocity is a measure of arterial stiffness that is sensitive to changes in health-related lifestyle changes., baseline, 6, 12, 24 months follow-up|Change in arterial stiffness as measured by the Augmentation index, Augmentation index is

another measure of arterial stiffness, also sensitive to changes in health-related lifestyle behaviors., baseline, 6, 12 and 24 months follow-up
Secondary Outcome Measures: Change in fasting glucose, Fasting blood glucose, baseline, 6, 12, 24 months|Changes in glycosylated hemoglobin A1c (HbA1c), Glycosylated hemoglobin A1c. Measure of glucose control over several months., baseline, 6, 12, 24 months follow-up|Changes in answers to MyPlate evaluation questions, Self-report questions about adherence to MyPlate.gov recommendations. These include questions about daily fruit intake, vegetable intake, replacement of sugary beverages with water, effort to make at least 1/2 of grain intake whole grain, effort to seek out lower sodium options, and daily intake of non-fat or low-fat milk., baseline, 6, 12, 24 months follow-up|Changes in food frequency measure of fruit and vegetable intake, Block Food Frequency assessment conducted in Spanish by interview. Information will include estimate of total fruit and vegetable intake over the last 6 months., Baseline, 6, 12, 24 months follow-up|Changes in waist circumference, Measure of waist circumference, a common predictor of cardiovascular risk, baseline, 6, 12 and 24 months|Change in aerobic capacity, Bruce protocol treadmill test. Estimate the VO2max (maximum aerobic capacity) using Foster's equation., Baseline, 6, 12, 24 months|Change in metabolic syndrome score, Metabolic syndrome marker levels. The ATP III criteria for metabolic syndrome markers include:

* sex-specific excess waist circumference (men \> 102 cm, women \>88 cm),
* fasting plasma triglycerides \>= 120 mg/dl,
* fasting plasma HDL(men)\<40 or (women)\<50 mg/dl,
* blood pressure \>=135/85,
* fasting glucose \>=110 mg/dl). Each subject's metabolic syndrome marker level can range between zero and five, with zero representing no metabolic syndrome risk and five representing maximum risk. The a priori expectation is that each marker will be treated as equally important but this study will provide the opportunity to examine this assumption critically., Baseline, 6, 12, 24 months|Change in plasma lipids, Plasma lipids to be measured include LDL-cholesterol, HDL-cholesterol and triglycerides. Blood samples will be obtained by venipuncture., Baseline, 6, 12, 24 months|Change in blood pressure, Blood pressure will be assessed in study participants sitting quietly by trained personnel using regularly calibrated sphygmomanometry., Baseline, 6, 12, 24 months|Change in physical activity assessment, International Physical Activity Questionnaire - short form (IPAQ-short). Questions ask about the number of days in the last 7 days that the participant exercised vigorously or moderately vigorously. Follow-up questions query the participant about the time (minutes \& hours) spent per day in doing vigorous or moderately vigorous physical activity on those days when they exercised., Baseline, 6, 12, 24 months|Change in body mass index (BMI), Body mass index (BMI) obtained by taking the ratio of measured weight (kg) to measured height (m).

Weight is obtained using a regularly calibrated balance beam scale. Height is obtained using a stationary stadiometer., Baseline, 6, 12, 24 months|Change in quality of life, The SF-12 is a well-accepted short form of the well-known SF-36 quality of life instrument., Baseline, 6, 12, 24|Change in weight loss strategies, Questionnaire includes 11 items that query the participant about weight control strategies used in the last year, including: exercise, restricting calories, fasting, diet pills, vomiting / laxative use, joining a gym, joining a commercial weight loss program such as WeightWatchers, meal replacement products, herbal medicines, diet bars, restriction on TV watching., Baseline, 6, 12, 24|Change in endothelial function, Flow-mediated dilation is the most widely used non-invasive test for assessing endothelial function, that is, the functional status of the inner lining of the major blood vessels. This technique measures endothelial function by inducing reactive hyperemia (blood volume expansion) via temporary arterial occlusion (blocking blood flow with inflated blood pressure cuff) and measuring the resultant relative increase in blood vessel diameter via ultrasound., Baseline, 6, 12, 24 months|Change in self-efficacy to adhere to DASH-style dietary pattern, List of 10 self-efficacy items that assess the study participant's confidence that she/he can adhere to various features of the Dietary Approaches to Stop Hypertension (DASH) diet., Baseline, 6, 12, 24 months|Change in mental health status, Mental health index-5 (MHI-5) consists of 5 questionnaire items designed to assess emotional well-being., Baseline, 6, 12, 24
Other Outcome Measures:
Sponsor: University of California, Los Angeles
Collaborators: University of Southern California|National Heart, Lung, and Blood Institute (NHLBI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 240
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 1P50HL105188-6094|1P50HL105188
Start Date: 2010-10
Primary Completion Date: 2014-10
Completion Date: 2014-10
First Posted: 2012-10-25
Results First Posted:
Last Update Posted: 2012-10-25
Locations: Roybal Comprehensive Health Center, Los Angeles, California, 90022, United States
Study Documents:

NCT Number: NCT01733706
Study Title: Early Smoking Reduction or Cessation by Means of no

Nicotine Electronic Cigarette Added to Standard Counselling.
Study URL: https://beta.clinicaltrials.gov/study/NCT01733706
Acronym:
Study Status: COMPLETED
Brief Summary: The aim of this study is the evaluation of early smoking reduction or cessation by means of no nicotine electronic cigarette added to standard counselling.
Study Results: NO
Conditions: Cancer|Myocardial Infarction
Interventions: DEVICE: No nicotine electronic cigarette|OTHER: Standard counseling
Primary Outcome Measures: Number of cigarettes smoked, two months after event (cancer or myocardial infarction)|psychological conditions, psychological conditions will be assessed by questionnaire, two months after event (cancer or myocardial infarction)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: European Institute of Oncology
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 75
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: IEO S617/211
Start Date: 2011-06
Primary Completion Date: 2015-12
Completion Date: 2015-12
First Posted: 2012-11-27
Results First Posted:
Last Update Posted: 2017-02-09
Locations: European Institute of Oncology, Milan, Italy|Istituto Scientifico San Raffaele del Monte Tabor IRCCS, Milan, Italy
Study Documents:

NCT Number: NCT00002827
Study Title: Chemotherapy Followed by Radiation Therapy in Treating Young Patients With Newly Diagnosed Hodgkin's Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT00002827
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Drugs used in chemotherapy use different ways to stop cancer cells from dividing so they stop growing or die. Radiation therapy uses high-energy x-rays to damage cancer cells. Combining chemotherapy with radiation therapy may kill more cancer cells. It is not yet known if chemotherapy is more effective with or

without dexrazoxane for Hodgkin's disease.

PURPOSE: Randomized phase III trial to compare the effectiveness of combination chemotherapy, with or without dexrazoxane, followed by radiation therapy in treating young patients with newly diagnosed stage I, stage II, or stage III Hodgkin's disease.
Study Results: NO
Conditions: Cardiac Toxicity|Lymphoma
Interventions: BIOLOGICAL: bleomycin sulfate|BIOLOGICAL: filgrastim|DRUG: dexrazoxane hydrochloride|DRUG: doxorubicin hydrochloride|DRUG: etoposide|DRUG: vincristine sulfate|RADIATION: low-LET cobalt-60 gamma ray therapy|RADIATION: low-LET electron therapy|RADIATION: low-LET photon therapy
Primary Outcome Measures: DLCO, The Wilcoxon test will be used to evaluate whether DLCO values differ between the two arms., 1 year post therapy
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Children's Oncology Group
Collaborators: National Cancer Institute (NCI)|Children's Cancer Group
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE3
Enrollment: 294
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: SINGLE (PARTICIPANT)|Primary Purpose: TREATMENT
Other IDs: 9426|POG-9426|CCG-P9426|CDR0000065013|COG-9426
Start Date: 1996-10
Primary Completion Date: 2004-10
Completion Date: 2008-06
First Posted: 2004-05-26
Results First Posted:
Last Update Posted: 2013-08-26
Locations: Long Beach Memorial Medical Center, Long Beach, California, 90806, United States|Children's Hospital Los Angeles, Los Angeles, California, 90027-0700, United States|Jonsson Comprehensive Cancer Center, UCLA, Los Angeles, California, 90095-1781, United States|Children's Hospital of Orange County, Orange, California, 92668, United States|UCSF Cancer Center and Cancer Research Institute, San Francisco, California, 94115-0128, United States|David Grant Medical Center, Travis Air Force Base, California, 94535, United States|Children's Hospital of Denver, Denver, Colorado, 80218, United States|Children's National Medical Center, Washington, District of Columbia, 20010-2970, United States|University of Chicago Cancer Research Center, Chicago, Illinois, 60637, United States|Indiana University Cancer Center, Indianapolis, Indiana, 46202-5265, United States|University of Iowa Hospitals and Clinics, Iowa City, Iowa, 52242, United States|University of Michigan Comprehensive Cancer Center, Ann

Arbor, Michigan, 48109-0752, United States|CCOP - Kalamazoo, Kalamazoo, Michigan, 49007-3731, United States|University of Minnesota Cancer Center, Minneapolis, Minnesota, 55455, United States|Mayo Clinic Cancer Center, Rochester, Minnesota, 55905, United States|Children's Mercy Hospital - Kansas City, Kansas City, Missouri, 64108, United States|University of Nebraska Medical Center, Omaha, Nebraska, 68198-3330, United States|Cancer Institute of New Jersey, New Brunswick, New Jersey, 08901, United States|Kaplan Cancer Center, New York, New York, 10016, United States|Memorial Sloan-Kettering Cancer Center, New York, New York, 10021, United States|Herbert Irving Comprehensive Cancer Center, New York, New York, 10032, United States|Lineberger Comprehensive Cancer Center, UNC, Chapel Hill, North Carolina, 27599-7295, United States|Veterans Affairs Medical Center - Fargo, Fargo, North Dakota, 58102, United States|CCOP - Merit Care Hospital, Fargo, North Dakota, 58122, United States|Children's Hospital Medical Center - Cincinnati, Cincinnati, Ohio, 45229-3039, United States|Ireland Cancer Center, Cleveland, Ohio, 44106-5065, United States|Children's Hospital of Columbus, Columbus, Ohio, 43205-2696, United States|Doernbecher Children's Hospital, Portland, Oregon, 97201-3098, United States|Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, 19104, United States|Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania, 15213, United States|Vanderbilt Cancer Center, Nashville, Tennessee, 37232-6838, United States|University of Texas - MD Anderson Cancer Center, Houston, Texas, 77030, United States|Huntsman Cancer Institute, Salt Lake City, Utah, 84132, United States|Children's Hospital and Regional Medical Center - Seattle, Seattle, Washington, 98105, United States|Fred Hutchinson Cancer Research Center, Seattle, Washington, 98109, United States|University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin, 53792, United States|Princess Margaret Hospital for Children, Perth, Western Australia, 6001, Australia|British Columbia Children's Hospital, Vancouver, British Columbia, V6H 3V4, Canada|IWK Grace Health Centre, Halifax, Nova Scotia, B3J 3G9, Canada
Study Documents:

NCT Number: NCT03235427
Study Title: The CAROLE (CArdiac Related Oncologic Late Effects) Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03235427
Acronym: CAROLE
Study Status: COMPLETED
Brief Summary: CAROLE seeks to evaluate the relationship between chest Radiation Therapy and coronary artery disease.

The purpose of CAROLE is to check the heart health of women who received breast cancer treatments in the past and protect them from future heart disease.
Study Results: NO
Conditions: Coronary Artery Disease|Cardiac Disease|Cardiac Toxicity|Radiation|Radiation Therapy|Atherosclerotic Heart Disease|Cardiotoxicity|Breast Cancer|Lung Cancer|Lymphoma|Cancer|Carcinoma,

Intraductal, Noninfiltrating
Interventions:
Primary Outcome Measures: Multimodality Cardiology Assessment- EKG, Assess whether radiation to the heart is associated with increased pre-clinical and clinical cardiac disease (as determined by a composite of multimodality cardiology assessments including EKG.

Studies will be read using a standard, evidence based, set of criterion and documented using study templates) and compared to patients who did not receive radiation to the heart.

All cardiac tests will be reviewed and reported as a composite with one the following; No evidence of disease/unrelated, preclinical disease, or clinical disease (non-numerically) based on the Cardiologists read of the study based on standard Pre-Specified criteria., 1 Year|Multimodality Cardiology Assessment- Echocardiogram with Strain, Assess whether radiation to the heart is associated with increased pre-clinical and clinical cardiac disease (as determined by a composite of multimodality cardiology assessments including Echocardiogram with Strain.

All cardiac tests will be reviewed and reported as a composite with one the following; No evidence of disease/unrelated, preclinical disease, or clinical disease (non-numerically) based on the Cardiologists read of the study based on standard Pre-Specified criteria., 1 Year|Multimodality Cardiology Assessment- Coronary Artery Calcium (CAC) CT, Assess whether radiation to the heart is associated with increased pre-clinical and clinical cardiac disease (as determined by a composite of multimodality cardiology assessments including Coronary Artery Calcium (CAC) CT.

All cardiac tests will be reviewed and reported as a composite with one the following; No evidence of disease/unrelated, preclinical disease, or clinical disease (non-numerically) based on the Cardiologists read of the study based on standard Pre-Specified criteria., 1 Year
Secondary Outcome Measures: Agatston Score, Individual cardiac structures will be accessed using Agatston score. Agatston score is calculated using a CAC CT scan to measure for the presence of coronary artery disease based on the extent of coronary artery calcification. Specifically the left main, left anterior descending, left circumflex, and right coronary arteries are all read individually and the sum of these cardiac vessels scores is read as the overall Agatston score.

Grading of coronary artery disease (based on total calcium score) measure is without units. Score categories are as follows: No evidence of disease/unrelated, preclinical disease, or clinical disease (non-numerically). Higher Agatston score correlates with more coronary artery disease.

The assessment of calcium (Agatston score) on CAC CT will be compared to the dose received by the specified vessel as determined using deformable registration with prior radiation imaging (simulation CT scan)., 1 Year
Other Outcome Measures: Composite Assessment of Cardiac Disease, Sub-analysis for association of specific oncologic treatment(s) with cardiac disease (as per previously described study templates) will also be performed on patients who received multimodality treatment (RT+ chemotherapy, RT + hormonal treatment, RT+ chemo and hormonal treatment, RT + individual cardio toxic chemotherapies \ [anthracycline, trastuzumab, etc.\]) and on different surgical approaches (lumpectomy and mastectomy). Results will be reported as a single value for each arm/group., 1 Year
Sponsor: Northwell Health
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 201
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IIS-0046
Start Date: 2017-06-27
Primary Completion Date: 2018-06-26
Completion Date: 2018-06-26
First Posted: 2017-08-01
Results First Posted:
Last Update Posted: 2019-05-21
Locations: Northwell Health, Lake Success, New York, 11042, United States
Study Documents:

NCT Number: NCT03620071
Study Title: GoalKeeper: Intelligent Information Sharing for Children With Medical Complexity
Study URL: https://beta.clinicaltrials.gov/study/NCT03620071
Acronym: GoalKeeper
Study Status: UNKNOWN
Brief Summary: This proposal addresses the major challenge of improving health outcomes for children with cancer and other complex conditions, for whom the effectiveness of outpatient care depends on care coordination across a diverse group of caregivers that includes parents, community support organizations and pediatric care providers. The investigators have developed GoalKeeper, a prototype system for supporting care coordination across multiple care providers. The primary aim of the clinical trial is to assess the potential for this new system, GoalKeeper, to improve meaningful use of goal-centered care plans in the care of children with cancer and other complex chronic conditions.

Study Results: NO
Conditions: Childhood Cancer|Cerebral Palsy|Chronic Lung Disease|Congenital Heart Disease|Congenital Metabolic Disorder|Gastrostomy
Interventions: OTHER: GoalKeeper|OTHER: Standard Care
Primary Outcome Measures: Change in Parent Perception of Goal-Centered Care questionnaire from Baseline to 1-Month Follow-up, Parent perception of goal-centered care will be measured using a modified version of the "Patient Assessment of Chronic Illness Care, Goal-Setting Domain" questionnaire, using a scale of 1(Almost Never) to 5 (Almost Always) with higher values representing better goal-centered care., Baseline and 1-Month Follow-up
Secondary Outcome Measures: Count of parent participants with change in perception of goal-centered care from baseline to 3-Month Follow-up based on Investigator assessment., Change in perception in quality of goal-centered care will be assessed by Investigators based on parent baseline interviews and parent exit interviews., Baseline and 3 month follow-up
Other Outcome Measures: Change in parent perception of quality of shared decision making from baseline to 1 month, Parent perception will be measured using the "National Survey of Children with Special Health Care Needs Shared Decision Making Domain," which includes 4 domain items each with a scale of 1 (never), 2 (sometimes), 3 (usually) or 4 (always). Positive SDM is defined as parent report of "usually" or "always" on all 4 items. Shared decision making refers to a communication process where parents and providers participate in decision making to reach treatment plan agreement., Baseline and 1-Month Follow-up
Sponsor: Lee Sanders
Collaborators: National Cancer Institute (NCI)|Harvard University
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 67
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 1R01CA204585-01|1R01CA204585-01
Start Date: 2019-04-19
Primary Completion Date: 2021-06-30
Completion Date: 2021-12-31
First Posted: 2018-08-08
Results First Posted:
Last Update Posted: 2021-06-07
Locations: Stanford Children's Health, Palo Alto, California, 94304, United States
Study Documents:

NCT Number: NCT00459771
Study Title: Evaluating the Effect of Candesartan vs Placebo in

Prevention of Trastuzumab-associated Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT00459771
Acronym:
Study Status: COMPLETED
Brief Summary: Evaluating the effect of the angiotensin II-receptor (AT1) blocker candesartan vs placebo in prevention of trastuzumab-associated cardiotoxicity in patients with primary breast cancer treated with trastuzumab.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: AT1 blocker candesartan|DRUG: Placebo
Primary Outcome Measures: The occurrence of cardiotoxicity, defined as a decline in LVEF (MUGA) of more than 15% or a decrease of less than 15% to an absolute value below 45%., during 1 year trastuzumab therapy and during 26 weeks after discontinuation of trastuzumab
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: The Netherlands Cancer Institute
Collaborators: AstraZeneca|Roche Pharma AG
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 210
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: M06HER|2006-001707-11
Start Date: 2007-06
Primary Completion Date: 2013-12
Completion Date: 2014-12
First Posted: 2007-04-12
Results First Posted:
Last Update Posted: 2014-12-02
Locations: Medisch Centrum Alkmaar, Alkmaar, Netherlands|Flevoziekenhuis, Almere, Netherlands|The Netherlands Cancer Institute, Amsterdam, 1066 CX, Netherlands|Onze Lieve Vrouwe Gasthuis, Amsterdam, Netherlands|Slotervaart Hospital, Amsterdam, Netherlands|Wilhelmina Ziekenhuis, Assen, Netherlands|Jeroen Bosch Hospital, Den Bosch, Netherlands|Deventer Ziekenhuis, Deventer, Netherlands|Medisch Spectrum Twente, Enschede, Netherlands|Martini Ziekenhuis, Groningen, Netherlands|University Medical Center Groningen, Groningen, Netherlands|Ziekenhuis de Tjongerschans, Heerenveen, Netherlands|Medisch Centrum Leeuwarden, Leeuwarden, Netherlands|Antonius Ziekenhuis, Nieuwegein, Netherlands|Canisius-Wilhelmina Hospital, Nijmegen, Netherlands|UMC St. Radboud, Nijmegen, Netherlands|VieCuri Medisch Centrum voor Noord-Limburg, Venlo, Netherlands|Streekziekenhuis Koningin Beatrix, Winterswijk, Netherlands|Isala Klinieken, Zwolle, Netherlands

Study Documents:

NCT Number: NCT05921279
Study Title: Understanding CARdiac Events in Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05921279
Acronym: UCARE
Study Status: RECRUITING
Brief Summary: In Ireland, over 3,000 patients are diagnosed with breast cancer annually, and 1 in 9 Irish women will be diagnosed with breast cancer in their lifetime. There is evidence that female breast cancer survivors are more likely to die of cardiovascular disease than their age-matched counterparts.

This research is focused on evaluating pathways for identifying, managing, and overcoming side effects of cancer therapies that can negatively impact quality-of-life and overall outcomes for women during and after cancer treatment. The Cardio-oncology research team at GUH plan to capitalize on their expertise in both cancer care and cardiology to develop a care pathway for cancer patients who are at increased risk of developing heart disease.
Study Results: NO
Conditions: Breast Cancer|Cardiotoxicity|Cardiomyopathies|Chemotherapeutic Toxicity|Heart Failure|Oncology
Interventions:
Primary Outcome Measures: The number of participants with successful application of guideline-directed Cardio-Oncology assessments and surveillance., To calculate the percentage of patients who successfully completed all guideline required investigations for baseline assessments, during and post chemotherapy surveillance i.e. Echocardiography, ECG, and Cardiac biomarkers (troponin and BNP)., 2 years
Secondary Outcome Measures: The number of participants with cardiovascular disease (CVD) among patients with breast cancer prior to commencement of systemic chemotherapy., To assess the incidence of CVD at baseline, Baseline|The number of participants with common risk factors for CTRCD among patients with breast cancer prior to commencement of systemic chemotherapy., Using the HFA-ICOS risk assessment tool, Baseline|Incidence of CTRCD in Irish breast cancer patients receiving chemotherapy., To assess the incidence of CTRCD at all post-therapy timepoints./, 3M, 6M, 9M, 12M, 24M|The number of participants with successful collection and biobanking specimens among patients with breast cancer undergoing systemic chemotherapy., To collect and biobank relavant samples, Baseline, 3M, 6M, 9M, 12M, 24M|The number of participants with successful collection of guideline-required imaging data among patients with breast cancer undergoing systemic chemotherapy., Feasibility of collection of guideline-required imaging data, defined as the number of participants with successful collection of guidelines-required clinical data among patients with breast cancer undergoing systemic chemotherapy., Baseline, 3M, 6M, 9M, 12M, 24M|The number of participants with

successful collection of guideline-required clinical data among patients with breast cancer undergoing systemic chemotherapy., Feasibility of collection of guideline-required clinical data, defined as the number of participants with successful collection of guidelines-required clinical data among patients with breast cancer undergoing systemic chemotherapy., Baseline, 3M, 6M, 9M, 12M, 24M
Other Outcome Measures:
Sponsor: National University of Ireland, Galway, Ireland
Collaborators: Clinical Research Facility Galway|CORRIB Research Centre for Advanced Imaging and Core Lab, Galway, Ireland
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: C.A. 2890
Start Date: 2023-01-14
Primary Completion Date: 2026-01
Completion Date: 2026-07
First Posted: 2023-06-27
Results First Posted:
Last Update Posted: 2023-07-06
Locations: Galway University Hospital, Galway, H91 T861, Ireland|Galway Clinic, Galway, Ireland|Mayo University Hospital, Mayo, Ireland|Sligo General Hospital, Sligo, Ireland
Study Documents:

NCT Number: NCT02798679
Study Title: Cardiac Fibrosis and Risk Prediction in Cancer Treatment-Related Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT02798679
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine whether pre-existing cardiac fibrosis is a predictor of cancer treatment-related cardiotoxicity.
Study Results: NO
Conditions: Cardiotoxicity
Interventions:
Primary Outcome Measures: Cardiotoxicity assessed clinically or by cardiac MRI, 24 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Minnesota
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:

Enrollment: 40
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CV-2016-24434
Start Date: 2016-08
Primary Completion Date: 2022-09-01
Completion Date: 2022-09-01
First Posted: 2016-06-14
Results First Posted:
Last Update Posted: 2022-10-18
Locations: University of Minnesota, Minneapolis, Minnesota, 55455, United States
Study Documents:

NCT Number: NCT00229879
Study Title: Rare Tumor Case Review
Study URL: https://beta.clinicaltrials.gov/study/NCT00229879
Acronym:
Study Status: TERMINATED
Brief Summary: The purpose of this study is to do a literature review and combine all of the cases of the intrapericardial teratoma tumor and see if some conclusions can be made about this rare tumor in children.
Study Results: NO
Conditions: Intrapericardial Teratoma Tumor|Tumors
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Children's Healthcare of Atlanta
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment:
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 04-119
Start Date: 2004-12
Primary Completion Date:
Completion Date: 2006-09
First Posted: 2005-09-30
Results First Posted:
Last Update Posted: 2012-03-16
Locations: Children's Healthcare of Atlanta at Egleston, Atlanta, Georgia, 30322, United States
Study Documents:

NCT Number: NCT00037245
Study Title: Androgens and Subclinical Atherosclerosis in Young Women - Ancillary to CARDIA
Study URL: https://beta.clinicaltrials.gov/study/NCT00037245
Acronym:
Study Status: COMPLETED
Brief Summary: To examine whether serum androgens, measured earlier in life, and variation in genes related to androgen synthesis, metabolism, and signaling are associated with early-onset subclinical coronary atherosclerosis in young adult women from the community.
Study Results: NO
Conditions: Cardiovascular Diseases|Coronary Arteriosclerosis|Heart Diseases|Polycystic Ovary Syndrome
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Washington
Collaborators: National Heart, Lung, and Blood Institute (NHLBI)
Sex: FEMALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment:
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 1144|R01HL065622
Start Date: 2001-09
Primary Completion Date:
Completion Date: 2005-07
First Posted: 2002-05-17
Results First Posted:
Last Update Posted: 2016-02-10
Locations:
Study Documents:

NCT Number: NCT04407845
Study Title: Atrial Fibrillation in Patients Receiving Ibrutinib
Study URL: https://beta.clinicaltrials.gov/study/NCT04407845
Acronym: FABRIC
Study Status: UNKNOWN
Brief Summary: Ibrutinib (a tyrosine kinase inhibitor targeting Bruton) is a standard of treatment in haematology. According to retrospective data, atrial fibrillation and systemic hypertension are common ibrutinib-related advserse events. The investigators aim at prospectively establishing the incidence of thesedrug related advsere events through clinical monitoring and attempt at identifying populations at risk.
Study Results: NO
Conditions: Leukemia, Chronic Lymphatic|Mantle Cell Lymphoma

Interventions:
Primary Outcome Measures: Incidence of cardiovascular events on ibrutinib, Evaluate the incidence of cardiotoxicity (composite endpoint) in a cohort of patients referred to a cardio-oncology before initiation of ibrutinib., 6 months
Secondary Outcome Measures: Incidence of supra-ventricular arrythmias, Number of patients with supra-ventricular arrythmias, 6 months|Incidence of systemic hypertension, Number of patients with systemic hypertension, 6 months|Incidence of arterial embolism, Number of patients with systemic hypertension, 6 months|Incidence of hemorraghe, Number of patients with hemorraghe, 6 months|Safety mesures, Compare advsere events in patients with supr-ventricular arrhythmias according to the continuation or discontinuation of ibrutinib, 1 year|Anticoagulants, Correlation between anti thrombotic strategies and cardiovascular outcomes, 1 year
Other Outcome Measures:
Sponsor: European Georges Pompidou Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 60
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 00011928 FABRIC
Start Date: 2020-05-21
Primary Completion Date: 2022-05-21
Completion Date: 2022-11-30
First Posted: 2020-05-29
Results First Posted:
Last Update Posted: 2020-06-09
Locations: Assistance Publique Hôpitaux de Paris - Centre Université de Paris, Paris, 75015, France
Study Documents:

NCT Number: NCT03530215
Study Title: Evaluation of Reporting of Cardio-vascular Adverse Events With Antineoplastic and Immunomodulating Agents (EROCA)
Study URL: https://beta.clinicaltrials.gov/study/NCT03530215
Acronym: EROCA
Study Status: COMPLETED
Brief Summary: Antineoplastic and immunomodulating agents may lead to various cardio-vascular adverse reactions. This study investigates reports of cardio-vascular toxicities for treatment including Anatomical Therapeutic Chemical (ATC) classification L (antineoplastic agents, endocrine therapy, immunostimulants, and immunosuppressants drugs) in the World Health Organization's (WHO) global database of individual safety case reports (VigiBase).
Study Results: NO

Conditions: Cardiac Disease|Cancer
Interventions: DRUG: Antineoplastic and Immunomodulating Agents
Primary Outcome Measures: Cardio-vascular toxicity of antineoplastic and immunomodulating agents, Identification and report of cardio-vascular toxicities of antineoplastic and immunomodulating agents. The research includes the report with MedDRA terms: SOC Cardiac Disorders, SOC Vascular Disorders, Sudden death (PT), Cardiac and vascular investigations (excl enzyme tests) (HLGT), Skeletal and cardiac muscle analyses (HLT), Case reported in the World Health Organization (WHO) of individual safety case reports to September 2018
Secondary Outcome Measures: Causality assessment of reported cardiovascular events according to the WHO system, Case reported in the World Health Organization (WHO) of individual safety case reports to September 2018|Description of the type of cardiotoxicity depending on the category of antineoplastic and immunomodulating agents, Case reported in the World Health Organization (WHO) of individual safety case reports to September 2018|Description of the duration of treatment when the toxicity happens, Case reported in the World Health Organization (WHO) of individual safety case reports to September 2018|Description of the drug-drug interactions associated with adverse events, Case reported in the World Health Organization (WHO) of individual safety case reports to September 2018|Description of the pathologies (cancer) for which the incriminated drugs have been prescribed, Case reported in the World Health Organization (WHO) of individual safety case reports to September 2018|Description of the population of patients having a cardio-vascular adverse event, Case reported in the World Health Organization (WHO) of individual safety case reports to September 2018
Other Outcome Measures:
Sponsor: Groupe Hospitalier Pitie-Salpetriere
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 500000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CIC1421-18-12
Start Date: 2018-05-02
Primary Completion Date: 2022-05-01
Completion Date: 2023-04-08
First Posted: 2018-05-21
Results First Posted:
Last Update Posted: 2023-04-13
Locations: AP-HP, Pitié-Salpêtrière Hospital,Department of Pharmacology, CIC-1421, Pharmacovigilance Unit, INSERM., Paris, 75013, France
Study Documents:

NCT Number: NCT02942615
Study Title: The Safety Management of Cardiac Toxicity in Breast Cancer Patients Under Multidiscipline Therapy.
Study URL: https://beta.clinicaltrials.gov/study/NCT02942615
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This trial is to explore the optimal strategies for guaranteeing the cardiac safety of breast cancer patients following adjuvant radiotherapy in the modern era of multidisciplinary treatment.
Study Results: NO
Conditions: Breast Neoplasms|Cardiotoxicity
Interventions: OTHER: limit heart dose
Primary Outcome Measures: cardiac toxicity event free survival, The time from the date of randomization to any recurrence of clinical or subclinical cardiac toxicity, 1 year
Secondary Outcome Measures: cardiac toxicity event free survival, The time from the date of randomization to any recurrence of clinical or subclinical cardiac toxicity, 5 years|cardiac toxicity event free survival, The time from the date of randomization to any recurrence of clinical or subclinical cardiac toxicity, 10 years|overall survival, The time from the date of randomization to the date of death from any cause, 5 years|overall survival, The time from the date of randomization to the date of death from any cause, 10 years|relative change of value of serum cardiac biomarkers of creatine kinase (CK)-MB, The change of value of serum cardiac biomarkers during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 1 year|relative change of value of serum cardiac biomarkers of Cardiac troponin (cTn)-I, The change of value of serum cardiac biomarkers during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 1 year|relative change of value of serum cardiac biomarkers of N-terminal pro brain natriuretic peptide (NT-proBNP), The change of value of serum cardiac biomarkers during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 1 year|relative change of value of serum cardiac biomarkers of CK-MB, The change of value of serum cardiac biomarkers during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 5 years|relative change of value of serum cardiac biomarkers of cTn-I, The change of value of serum cardiac biomarkers during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 5 years|relative change of value of serum cardiac biomarkers of NT-proBNP, The change of value of serum cardiac biomarkers during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 5 years|relative change of left ventricular ejection fraction (LVEF), The change of value of LVEF during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 1 year|relative change of LVEF, The change of value of LVEF during and after adjuvant radiotherapy compared with baseline

before initiation of adjuvant radiotherapyThe change of value of LVEF during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 5 year|relative change of LVEF, The change of value of LVEF during and after adjuvant radiotherapy compared with baseline before initiation of adjuvant radiotherapy, 10 year|Quality of Life-EORTC QLQ-C30, Quality of life will be assessed using self-administered questionnaire EORTC QLQ-C30, 1 year|Quality of Life-EORTC QLQ-BR23, Quality of life will be assessed using self-administered questionnaire EORTC QLQ-BR23, 1 year|Quality of Life-EORTC QLQ-C30, Quality of life will be assessed using self-administered questionnaire EORTC QLQ-C30, 5 years|Quality of Life-EORTC QLQ-BR23, Quality of life will be assessed using self-administered questionnaire EORTC QLQ-BR23, 5 years
Other Outcome Measures:
Sponsor: Ruijin Hospital
Collaborators: RenJi Hospital|Xinhua Hospital, Shanghai Jiao Tong University School of Medicine|Shanghai 6th People's Hospital|Shanghai 10th People's Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 220
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SCREENING
Other IDs: Cardio-RT
Start Date: 2017-06-27
Primary Completion Date: 2020-10-08
Completion Date: 2025-10
First Posted: 2016-10-24
Results First Posted:
Last Update Posted: 2022-12-29
Locations: Ruijin Hospital, Shanghai Jiaotong University School of Medicine, Shanghai, Shanghai, 200025, China
Study Documents:

NCT Number: NCT04036045
Study Title: Approaches to Identify Early Biomarkers and Pathogenesis of Anthracycline Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT04036045
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: Early microRNAs (miRs) and Cardiac Magnetic Resonance (CMR)-derived strain analysis and detection of genes contributing to Anthracycline-Induced Cardiotoxicity (AIC) sensitivity and resistance will identify pediatric cancer patients most and least likely to develop AIC.
Study Results: NO
Conditions: Childhood Cancer

Interventions: OTHER: Cardiac MRI|OTHER: Echocardiogram|OTHER: Blood Draw
Primary Outcome Measures: CMR, 1. Increased myocardial T2 relaxation time in the myocardium compared to baseline as measured by T2 mapping technique, From Baseline to one year after anthracycline therapy
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Connecticut Children's Medical Center
Collaborators: Nationwide Children's Hospital
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 110
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 18-137
Start Date: 2024-01
Primary Completion Date: 2028-08
Completion Date: 2030-08
First Posted: 2019-07-29
Results First Posted:
Last Update Posted: 2023-02-06
Locations: Olga Salazar, Hartford, Connecticut, 06106, United States
Study Documents:

NCT Number: NCT03258515
Study Title: A Study to Investigate the Effect of Single Dose of AZD6094 (600 mg) on Cardiac Repolarization in Healthy Volunteers
Study URL: https://beta.clinicaltrials.gov/study/NCT03258515
Acronym:
Study Status: COMPLETED
Brief Summary: This is a randomized, placebo-controlled, double-blind, 3-way crossover phase I study being conducted on healthy volunteers to investigate the effect of single dose of AZD6094 (600 mg) on cardiac repolarization under well-controlled conditions in accordance with the International Council for Harmonization (ICH) E14 guidelines. An open-label Moxifloxacin (400 mg), a fluoroquinolone broad spectrum antibiotic will be used as a appositive control for the time between the start of the Q wave and the end of the T wave (QT) prolongation in accordance with ICH E14 guidelines, to establish assay sensitivity. The core study consists of screening period, 3 treatment period (AZD6094, placebo and moxifloxacin; with a minimum washout period of 14 days between each treatment period) and follow-up. The study drugs will be administered orally. The study is planned to determine effect of AZD6094 at therapeutic dose, safety and tolerability. This study provides adequate and well-controlled mechanisms to deal with potential bias, facilitate identification of effects related to investigational product (IMP) administration and tolerability issues.
Study Results: NO

Conditions: Solid Tumors
Interventions: DRUG: AZD6094 200 mg|OTHER: Placebo|DRUG: Moxifloxacin
Primary Outcome Measures: Effect of AZD6094 at single therapeutic dose (600 mg) on ventricular repolarization by analysis of change from baseline-corrected QT, To assess the effect of AZD6094 at single therapeutic dose (600mg) on ventricular repolarization by assessing the time matched baseline-adjusted, placebo subtracted QTc interval corrected for RR (R waves on electrocardiogram \[ECG\]) by the Fridericia formula (QTcF). The ECGs -digital (dECG) and page (pECG) would be recorded during the study for the assessment of safety. Paper ECG for safety review will be performed following the dECG recordings and at additional intervals if required., At screening (28 days prior to Day 1 of treatment period 1), treatment period (At pre-dose on Day -1 to Day 3, 48 hours post-dose) and follow-up (14 days after discharge from the treatment period 3)
Secondary Outcome Measures: Effect of AZD6094 at therapeutic dose (600 mg) on additional time-matched ECG variables, To assess the effect of AZD6094 at therapeutic dose (600 mg) on additional time matched ECG variables using the dECG and pECG records. The ECG variables includes Bazett corrected QT interval \[QTcB\], onset of the P wave to the onset of the QRS complex (PR), onset of the QRS complex to the J point (QRS), QT and time interval between corresponding points on 2 consecutive R waves on ECG (RR). Paper ECG for safety review will be performed following the dECG recordings and at additional intervals if required., At screening (28 days prior to Day 1 of treatment period 1), treatment period (At pre-dose on Day -1 to Day 3, 48 hours post-dose) and follow-up (14 days after discharge from the treatment period 3)|Effect of moxifloxacin 400 mg on Fridericia-corrected QT interval (QTcF) compared to placebo., To assess the effect of moxifloxacin 400 mg on the QTcF interval compared to placebo. Paper ECG for safety review will be performed following the dECG recordings and at additional intervals if required., At screening (28 days prior to Day 1 of treatment period 1), treatment period (At pre-dose on Day -1 to Day 3, 48 hours post-dose) and follow-up (14 days after discharge from the treatment period 3)|Area under the plasma concentration-curve from time zero to the time of last quantifiable analyte concentration (AUC(0-∞)) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess AUC(0-∞) after administration of single oral dose of AZD6094, placebo and moxifloxacin. The pharmacokinetic (PK) sampling done post dose must precede with 10 minutes of rest followed by 5 minutes dECG., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)|Area under the plasma concentration-time curve from time zero to t hours after dosing (AUC(0-t)) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess AUC(0-t) after administration of single oral dose of AZD6094, placebo and moxifloxacin. The PK sampling done post dose must precede with 10 minutes of rest followed by 5 minutes dECG., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)|

Observed maximum concentration (Cmax) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess Cmax after administration of single oral dose of AZD6094, placebo and moxifloxacin; Cmax will be taken directly from the individual concentration-time curve. The PK sampling done post-dose must precede with 10 minutes of rest followed by 5 minutes dECG., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)|Time to reach maximum concentration (tmax) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess tmax after administration of single oral dose of AZD6094, placebo and moxifloxacin; tmax will be taken directly from the individual concentration-time curve. The PK sampling done post-dose must precede with 10 minutes of rest followed by 5 minutes dECG., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)|Lag-time (tlag - from the individual concentration-time curve) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess lag-time (tlag) after administration of single oral dose of AZD6094, placebo and moxifloxacin; tlag will be taken directly from the individual concentration-time curve. The PK sampling done post-dose must precede with 10 minutes of rest followed by 5 minutes dECG., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)|Terminal rate constant (λz) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess λz after administration of single oral dose of AZD6094, placebo and moxifloxacin; λz will be estimated by log-linear least squares regression of the terminal part of the concentration-time curve. The PK sampling done post-dose must precede with 10 minutes of rest followed by 5 minutes dECG., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)|Terminal half-life ($t_{\frac{1}{2}}$) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess $t_{\frac{1}{2}}$ after administration of single oral dose of AZD6094, placebo and moxifloxacin. The PK sampling done post-dose must precede with 10 minutes of rest followed by 5 minutes dECG., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)|Apparent clearance for parent drug estimated as dose divided by AUC (CL/F) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess CL/F after administration of single oral dose of AZD6094, placebo and moxifloxacin. The PK sampling done post-dose must precede with 10 minutes of rest followed by 5 minutes dECG., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)|Apparent volume of distribution for parent drug at terminal phase (Vz/F, extravascular administration) assessment for AZD6094, its metabolites (M2 and M3) and moxifloxacin, To assess apparent volume of distribution for parent drug at terminal phase (Vz/F, extravascular

administration) after administration of single oral dose of AZD6094, placebo and moxifloxacin; Vz/F will be estimated by dividing the apparent clearance (CL/F) by λz. 10 min rest + 5 min dECG will always precede the PK sampling when coinciding post-dose., Treatment periods (At pre-dose (Day -1) and post-dose (30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours, 24 hours, 36 hours and 48 hours)| Assessment of relationship between the plasma concentration of AZD6094 and moxifloxacin and ECG variables, including baseline-adjusted and placebo-subtracted QTc interval., To assess the effect of AZD6094 and moxifloxacin on ventricular repolarization by assessing the plasma concentration and ECG variables including baseline-adjusted and placebo subtracted QTc interval, At screening (28 days prior to Day 1 of treatment period 1), treatment period (At pre-dose on Day -1 to Day 3, 48 hours post-dose) and follow-up (14 days after discharge from the treatment period 3)|Number of participants with adverse events (AEs) of AZD6094, To assess AEs as a criteria of safety and tolerability. AEs will be collected from the start of Screening throughout the treatment period up to and including the Follow-up Visit (Visit 5). Serious AEs will be recorded from the time of informed consent., At screening (28 days prior to Day 1 of treatment period 1), treatment period (At pre-dose (Day -1) and post-dose (24 hours and 48 hours) and follow-up (14 days after discharge from the treatment period 3)| Systolic blood pressure [SBP], To assess SBP as criteria of safety and tolerability variables. Blood pressure will be taken after the ECG., At screening (28 days prior to Day 1 of treatment period 1), treatment periods (At pre-dose on Day -1 to Day 3 (48 hours post-dose) and follow-up (14 days after discharge from the treatment Period 3)| Diastolic blood pressure [DBP], To assess DBP as criteria of safety and tolerability variables. Blood pressure will be taken after the ECG., At screening (28 days prior to Day 1 of treatment period 1), treatment periods (At pre-dose on Day -1 to Day 3 (48 hours post-dose) and follow-up (14 days after discharge from the treatment Period 3)| Pulse rate, To assess pulse rate as criteria of safety and tolerability variables., At screening (28 days prior to Day 1 of treatment period 1), treatment periods (At pre-dose on Day -1 to Day 3 (48 hours post-dose) and follow-up (14 days after discharge from the treatment Period 3)|Twelve-lead (12-Lead) electrocardiograms (ECGs), To assess the cardiovascular system functioning using 12-Lead dECG and pECG as a criteria of safety and tolerability variables., At screening, treatment periods (pre-dose and post-dose - 30 min, 60 min, 90 min, 2 hours to 6 hours, 8 hours, 12 hours and 24 hours) and follow-up visits|Physical examination, To assess the physical examination as a criteria of safety and tolerability variables. Brief physical examination will be performed at pre-dose on Day -1 at each treatment period; includes assessment of general appearance, skin, cardiovascular system, respiratory and abdomen. Full physical examination includes assessment of the general appearance, skin, cardiovascular, respiratory, abdomen, head, and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal and neurological systems., At screening (28 days prior to Day 1 of

treatment period 1), treatment periods (At pre-dose on Day -1 to Day 3 (48 hours post-dose) and follow-up (14 days after discharge from the treatment Period 3)|Laboratory assessments of Hematology, To assess the hematology (blood cells count, differential count and hemoglobin count) as a criteria of safety and tolerability variables. A reduced safety laboratory screen will be done at Day -1 or pre-dose at Day 1 and at 48 hours post-dose for all treatment periods., At screening (28 days prior to Day 1 of treatment period 1), treatment periods (At pre-dose on Day -1 to Day 3 (48 hours post-dose) and follow-up (14 days after discharge from the treatment Period 3)|Laboratory assessments of Clinical chemistry, To assess the clinical chemistry (electrolytes, glucose (fasting), C-reactive protein (CRP), liver enzymes, total and unconjugated bilirubin; at screening alone - free thyroxine and thyroid-stimulating hormone) as a criteria of safety and tolerability variables. A reduced safety laboratory screen will be done at Day -1 or pre-dose at Day 1 and at 48 hours post-dose for all treatment periods., At screening (28 days prior to Day 1 of treatment period 1), treatment periods (At pre-dose on Day -1 to Day 3 (48 hours post-dose) and follow-up (14 days after discharge from the treatment Period 3)|Laboratory assessments of urinalysis, To assess the urinalysis (glucose, protein and blood) as a criteria of safety and tolerability variables. If urinalysis is positive for protein or blood, a microscopy test will be performed to assess red blood cells (RBC), white blood cells (WBC), casts (cellular, granular, hyaline)). A reduced safety laboratory screen will be done at Day -1 or pre-dose at Day 1 and at 48 hours post-dose for all treatment periods., At screening (28 days prior to Day 1 of treatment period 1), treatment periods (At pre-dose on Day -1 to Day 3 (48 hours post-dose) and follow-up (14 days after discharge from the treatment Period 3)|Effect of AZD6094 at therapeutic dose (600 mg) on time-matched ECG variable - heart rate (HR), To assess the effect of AZD6094 at therapeutic dose (600 mg) on additional time matched ECG variable - HR using the dECG and pECG records. Paper ECG for safety review will be performed following the dECG recordings and at additional intervals if required., At screening (28 days prior to Day 1 of treatment period 1), treatment period (At pre-dose on Day -1 to Day 3, 48 hours post-dose) and follow-up (14 days after discharge from the treatment period 3)
Other Outcome Measures:
Sponsor: AstraZeneca
Collaborators: Parexel
Sex: MALE
Age: ADULT
Phases: PHASE1
Enrollment: 45
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: TREATMENT
Other IDs: D5084C00001

Start Date: 2017-09-06
Primary Completion Date: 2018-03-24
Completion Date: 2018-03-24
First Posted: 2017-08-23
Results First Posted:
Last Update Posted: 2020-02-20
Locations: Research Site, Baltimore, Maryland, 21225, United States
Study Documents:

NCT Number: NCT03394859
Study Title: Electronic Medical Records and Genomics (eMERGE) Phase III
Study URL: https://beta.clinicaltrials.gov/study/NCT03394859
Acronym: eMERGE
Study Status: COMPLETED
Brief Summary: The Electronic Medical Records and Genomics (eMERGE) Network is in its third phase and during this time is enrolling and sequencing 25,000 individuals on a custom sequencing panel of clinically relevant, actionable genes. The genetic results will be returned to participants and outcomes tracked through the electronic health records.
Study Results: NO
Conditions: Cardiac Disease|Cancer|Hypercholesterolemia|Diabetes|Kidney Diseases|Neuromuscular Diseases
Interventions:
Primary Outcome Measures: Impact of return of clinically actionable results on patient treatment, The network will abstract data from patient electronic health records (EHR) six months after clinically actionable results have been returned to the patients and providers. The Network will determine changes in medication or treatments after return of the sequencing results. Outcome measures on patients receiving both positive and negative results will be analyzed., Six months post return of results
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Vanderbilt University Medical Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 25380
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: eMERGEIII
Start Date: 2015-09-01
Primary Completion Date: 2020-04-01
Completion Date: 2020-04-01
First Posted: 2018-01-09
Results First Posted:

Last Update Posted: 2020-05-28
Locations:
Study Documents:

NCT Number: NCT04758650
Study Title: Study of 68GaNOTA-Anti-MMR-VHH2 in Oncological Lesions, Cardiovascular Atherosclerosis, Syndrome With Abnormal Immune Activation and Cardiac sarcoïdosis.
Study URL: https://beta.clinicaltrials.gov/study/NCT04758650
Acronym: MITRAS
Study Status: RECRUITING
Brief Summary: Phase II study to evaluate the clinical potential of 68GaNOTA-anti-MMR-VHH2 for in vivo imaging of Macrophage Mannose Receptor (MMR)-expressing Macrophages by means of Positron Emission Tomography (PET) in patients with oncological lesions in need of non-surgical therapy, patients with cardiovascular atherosclerosis, syndrome with abnormal immune activation and cardiac sarcoïdosis.
Study Results: NO
Conditions: Squamous Cell Carcinoma of Head and Neck|Cancer|Carotid Stenosis|Atherosclerosis of Artery|Hodgkin Lymphoma, Adult|Non Hodgkin Lymphoma|HLH|Cardiac Sarcoidosis
Interventions: DRUG: 68GaNOTA-Anti-MMR-VHH2
Primary Outcome Measures: Correlation of uptake of 68GaNOTA-Anti-MMR-VHH2 before start of treatment in HNSCC lesions with time to treatment failure after radiotherapy or systemic treatment including immune checkpoint inhibition. (cohort 1), Uptake will be measured in cancer lesions on PET/CT 1. Treatment response will be evaluated by assessing time to treatment failure and by assessment of status of patients for treatment failure (Y/N) at 6 months and 12 months after start of treatment, up to 5 years|Correlation of uptake of 68GaNOTA-Anti-MMR-VHH2 before start of treatment in solid cancer lesions with time to treatment failure after systemic treatment with immune checkpoint inhibition, either or not combined with other systemic therapies. (cohort 2), Uptake will be measured in cancer lesions on PET/CT 1. Treatment response will be evaluated by assessing time to treatment failure and by assessment of status of patients for treatment failure (Y/N) at 6 months and 12 months after start of treatment, up to 5 years|Correlation of uptake of 68GaNOTA-Anti-MMR-VHH2 in atherosclerotic carotid plaques before surgery with the immunohistological MMR-staining of the excised atherosclerotic carotid plaque. (cohort 3), PET/CT and immunohistochemistry will be assessed using a semi-quantitative scale., Resection of lesion up to 21 days after PET/CT|Correlation of uptake of 68GaNOTA-Anti-MMR-VHH2 before start of treatment in Hodgkin and non-Hodgkin lymphoma patients (cohort 4)., Uptake will be measured in lymphoma-related lesions on PET/CT 1, up to 5 years|Correlation of uptake of 68GaNOTA-Anti-MMR-VHH2 in central bone on PET/CT with the presence of hemophagocytosis in bone marrow samples, and the presence of clinical risk factors (cohort 5)., PET/CT, results of additional blood sample analysis and bone marrow aspirate or trephine biopsy will be assessed using a semi-

quantitative scale., up to 5 years|To investigate the uptake of 68GaNOTA-Anti-MMR-VHH2 in cardiac sarcoidosis on PET/CT in patients with endomyocardial biopsy proven cardiac sarcoidosis or suspected CS according to HRS consensus recommendation (2014) (cohort 6), Uptake in lesions involved with cardiac sarcoidosis on MMR-PET/CT, up to 5 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Universitair Ziekenhuis Brussel
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 140
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: UZBRU_VHH2_2|2020-002483-31
Start Date: 2021-01-26
Primary Completion Date: 2025-01-26
Completion Date: 2025-01-26
First Posted: 2021-02-17
Results First Posted:
Last Update Posted: 2022-09-08
Locations: Uz Brussel, Brussels, Brussel, 1090, Belgium
Study Documents:

NCT Number: NCT04567875
Study Title: Evaluation of Cardiotoxicity and Hypertension in Patients With Non Metastatic Castration Resistant Prostatic Carcinoma
Study URL: https://beta.clinicaltrials.gov/study/NCT04567875
Acronym: Apa-CARDIO1
Study Status: UNKNOWN
Brief Summary: This is a prospective observational study on a cohort of patients with castration-resistant prostate cancer M0, treated with Apalutamide, at the Oncology Unit of the "Andrea Tortora" Hospital of Pagani. Data will be collected on the patient's clinical history and the treatments carried out until the start of therapy with Apalutamide. At that time the study will be described to the patient and informed consent will be given.

In case of a favorable opinion from the patient, the CRF will be filled in. Patients with CRPC M0 treated with Apalutamide, belonging to the Oncology Unit of the Pagani Hospital "Andrea Tortora" and of the other Oncology Units of the ASL of Salerno (Hospital of Vallo della Lucania) will be studied with the possibility of enrollment also from other Centers outside the Salerno ASL.
Study Results: NO
Conditions: Castration-resistant Prostate Cancer
Interventions: OTHER: No Intervention on patients

Primary Outcome Measures: Evaluation of arterial hypertension, by creation of a weekly blood pressure diary, 24-hour blood pressure holter every six months, Evaluation of arterial hypertension, by creation of a weekly blood pressure diary, 24-hour blood pressure holter every six months, Almost 1 year
Secondary Outcome Measures: Assessment of biochemical response, such as 50% change in total PSA from baseline in patients receiving apalutamide, Assessment of biochemical response, such as 50% change in total PSA from baseline in patients receiving apalutamide, Almost 1 year|Relationship between changes in blood chemistry parameters and time to onset of metastases, assessed by PET PSMA or bone scan or CT scan, Relationship between changes in blood chemistry parameters and time to onset of metastases, assessed by PET PSMA or bone scan or CT scan, Almost 1 year|Relationship between changes in blood chemistry parameters and overall survival, Relationship between changes in blood chemistry parameters and overall survival, Almost 1 year|Relationship between changes in blood chemistry parameters and occurrence of serious adverse events, Relationship between changes in blood chemistry parameters and occurrence of serious adverse events, Almost 1 year|Association between basophil count and appearance of skin rash, Association between basophil count and appearance of skin rash, Almost 1 year|Evaluation of drug interactions with Apalutamide, Evaluation of drug interactions with Apalutamide, Almost 1 year
Other Outcome Measures:
Sponsor: Ospedale Andrea Tortora di Pagani
Collaborators:
Sex: MALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 54
Funder Type: NETWORK
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: APA-CARDIO_PAG_01
Start Date: 2020-07-16
Primary Completion Date: 2022-03
Completion Date: 2022-09
First Posted: 2020-09-29
Results First Posted:
Last Update Posted: 2020-09-29
Locations: Oncology Unit, Hospital Andrea Tortora, Pagani, Salerno, 84016, Italy|Oncology Unit, Ospedale Andrea Tortora, Pagani, Salerno, 84016, Italy
Study Documents:

NCT Number: NCT02547168
Study Title: Determining the True Incidence of Atrial Fibrillation Before and After Lung Resection
Study URL: https://beta.clinicaltrials.gov/study/NCT02547168
Acronym: Lung-AF

Study Status: TERMINATED
Brief Summary: Lung resections for pulmonary malignancies offer the best chance of survival for patients, but these procedures carry a significant burden of post-operative morbidity and mortality. Patients are particularly at high risk for post-operative atrial fibrillation (a condition involving irregular heart rhythm). Atrial fibrillation with symptoms can increase the risk of stroke - a blockage in a major blood vessel in the brain, which can potentially result in a disability or even death. The objective of this study is to establish the feasibility of using ambulatory heart rate monitoring to determine the total incidence of atrial fibrillation in the peri-operative period before and after anatomic lung resection for malignancies. The study will also investigate the correlation between atrial fibrillation and rates of stroke and other adverse events, as well as serve to identify the patients that are at a higher risk of developing atrial fibrillation.
Study Results: NO
Conditions: Lung Cancer|Atrial Fibrillation|Stroke
Interventions: DEVICE: iRhythm ZIO XT patch
Primary Outcome Measures: Monthly rate of patient accrual, Proportion of patients who are determined to be eligible for study relative to the number of patients actually enrolled and consented for participation in the study. This will help to inform the willingness of patients to participate in this study, Ongoing from date of study initiation through to sample size completion, estimated to be 12 months|Patient adherence to monitoring device use-Wear time, Patient adherence to the device attachment requirements as stated in the study protocol, defined as the device remaining in place for at least 90% of the expected 28 day patch period (14 days before surgery and 14 days after) to determine feasibility of the study protocol in clinical context and patient tolerability. This will be measured by the iRhythm ZIO XT patch output., 28 day time period around lung resection|Patient adherence to monitoring device use-Logging of symptomatic events, Patient adherence to the symptomatic atrial fibrillation event logging task as stated in the study protocol, defined as the successful manual triggering of the device by the patient to note at least 80% of symptomatic events over the expected 28 day patch period (14 days before surgery and 14 days after) to determine feasibility of the study protocol in clinical context and patient tolerability. This will be measured by the iRhythm ZIO XT patch output., 28 day time period around lung resection|Number of patients who withdraw from study protocol, Number of patients who choose to withdraw from the study, defined as those who fail to complete the 14-day baseline monitoring period before surgery, decline to wear the device post-operatively, or drop out partway through the 14-day post-operative monitoring period. This will be measured by ongoing discussion with the patient and will help to determine the feasibility of the study protocol in clinical context and patient tolerability., 28 day time period around lung resection
Secondary Outcome Measures: Baseline incidence of asymptomatic atrial

fibrillation before lung resection, Number of unknown/asymptomatic/ occult atrial fibrillation in the high-risk malignant lung resection population before surgery so that we know whether any differences in the event rate after surgery are likely to be as a result of the surgery itself. This will be measured by having patients wear the iRhythm ZIO XT patch for the 2 weeks before surgery, Measured from 2 weeks preceding lung resection up to the day of procedure|The number of post-operative atrial fibrillation events, Number of symptomatic and asymptomatic atrial fibrillation cases that occurred within 14 days of lung resection surgery, automatically measured by the iRhythm ZIO patch device for 2 weeks from the day after surgery, Measured from post-operative day 1 to 14 days following lung resection|The number of any post-operative recurrent atrial fibrillation events within 14 days of lung resection, To compare the difference in post-operative atrial fibrillation rates between those who experienced any atrial fibrillation pre- and intra-operatively (recurrent atrial fibrillation) with those who did not as measured by a comparison of the two 14 day readings assessed by the iRhythm ZIO XT patch device., Difference in event rates between the 14 day baseline period before surgery and the 14 day period after surgery|Total event rate for asymptomatic atrial fibrillation, Number of asymptomatic atrial fibrillation events during the 28 day monitoring period, adjudicated by cardiology consultation of the ZIO XT patch output, Comparison of the two intervals of 14 days preceding and 14 days following lung resection|Rate of other non- atrial fibrillation arrhythmia, Number of non- atrial fibrillation arrhythmias during the 14-day post-discharge time interval following lung resection, adjudicated by cardiology consultation of the ZIO XT patch output, Measured from post-operative day 1 to 14 days following lung resection|Impact of resection intensity (larger versus smaller resection size) on the development of any atrial fibrillation events, Measure whether there is a difference in the number of recurrent, asymptomatic and/or symptomatic atrial fibrillation events depending on the amount of lung tissue removed as part of the resection, measured as per review of surgical characteristics noted in patient records, Measured from post-operative day 1 to 14 days following lung resection|Impact of use of minimally invasive surgery on the development of any atrial fibrillation events, Measure whether there is a difference in the number of recurrent, asymptomatic and/or symptomatic atrial fibrillation events depending on whether an open or a minimally invasive technique was used to complete resection, measured as per review of surgical characteristics noted in patient records, Measured from post-operative day 1 to 14 days following lung resection|Measurement of the difference of 90 day mortality in event-free patients and those with atrial fibrillation, Number of deaths within 90 days of surgery, comparing between event-free and peri-operative atrial fibrillation sub-cohorts as determined by patient chart review, Interval from the date of surgery to up to 90 days after surgery|Measurement of the difference of rates of stroke in event-free patients and those with atrial fibrillation, Number of strokes in untreated patients in the 30 and 90 day follow up periods,

comparing between event-free and peri-operative atrial fibrillation cohorts as measured by the validated Questionnaire for Verifying Stroke-Free Status (QVSFS), Interval from the date of surgery to up to 90 days after surgery
Other Outcome Measures:
Sponsor: McMaster University
Collaborators: McMaster Surgical Associates
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 27
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING
Other IDs: SJHH_Lung_AF
Start Date: 2017-06-02
Primary Completion Date: 2020-08-28
Completion Date: 2020-08-28
First Posted: 2015-09-11
Results First Posted:
Last Update Posted: 2021-02-25
Locations: St. Joseph's Healthcare Hamilton, Hamilton, Ontario, L8N 4A6, Canada
Study Documents:

NCT Number: NCT04865159
Study Title: Cardiovascular Safety Study of Tipifarnib in Patients With Advanced Solid Malignancies
Study URL: https://beta.clinicaltrials.gov/study/NCT04865159
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: A Phase I, open-label clinical pharmacology study designed to evaluate the effect of tipifarnib on cardiac repolarization (corrected QT interval \[QTc\] duration) following a single dose of 900 mg and after repeated twice daily administration of 600 mg in subjects with advanced solid malignancies. Subjects will receive a 900 mg single dose at cycle 1 day 1 follow by 600 mg twice a day orally with a meal (Days 2-7 and 15-21) in 28-day cycles. Beginning on Day 2 of Cycle 1, subjects will self-administer 600 mg tipifarnib, orally with a meal, bid for 7 days in alternating weeks (Days 2-7 and 15-21) in 28-day cycles. The secondary objectives are to evaluate the safety and PK of tipifarnib. Series of PK will be collected on day -1 of Cycle 1, Cycle 1 day 1 and Cycle 1 day 7.
Study Results: NO
Conditions: Advanced Solid Tumor
Interventions: DRUG: Tipifarnib
Primary Outcome Measures: The change from baseline in time-matched difference in QTc interval to post-baseline time points after a single 900 mg dose and multiple 600 mg BID doses of tipifarnib in subjects

with Advanced Solid Malignancies, The analysis will be performed using the concentration-QTc modeling approach (Garnett 2018) and the by-time point modeling approach defined in the International Council on Harmonisation (ICH) E14 guidance. The analysis will be performed using triplicate, time-matched ECG measurements of the QTc interval will be taken at baseline, Day 1 (900 mg tipifarnib) and Day 7 (600 mg tipifarnib BID) at predose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12 and 24 hours post dose (24 hour on day 1 only)., 7 days
Secondary Outcome Measures: Investigate safety and tolerability of tipifarnib according to NCI CTCAE v5.0, Incidence of adverse events, incidence of abnormal laboratory test results, abnormal vital signs, and abnormal ECG results, 30 days after treatment discontinuation
Other Outcome Measures:
Sponsor: Kura Oncology, Inc.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 20
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: BASIC_SCIENCE
Other IDs: KO-TIP-011
Start Date: 2021-05-06
Primary Completion Date: 2023-05-15
Completion Date: 2023-05-15
First Posted: 2021-04-29
Results First Posted:
Last Update Posted: 2023-04-05
Locations: Gabrail Cancer Center Research, Canton, Ohio, 44718, United States|NEXT Oncology, Austin, Texas, 78758, United States|NEXT Oncology, San Antonio, Texas, 78229, United States
Study Documents:

NCT Number: NCT00005459
Study Title: Risk of Coronary Heart Disease in Women With Polycystic Ovary Syndrome
Study URL: https://beta.clinicaltrials.gov/study/NCT00005459
Acronym:
Study Status: COMPLETED
Brief Summary: To investigate whether women with Polycystic Ovary syndrome (PCOS) have evidence of an increased prevalence rate of subclinical atherosclerosis as measured by the presence of plaque, increased intima-medial carotid artery wall thickness and lower brachial artery flow mediated vasodilation.
Study Results: NO
Conditions: Atherosclerosis|Cardiovascular Diseases|Heart Diseases|Carotid Artery Diseases|Coronary Disease|Polycystic Ovary Syndrome
Interventions:

Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
Collaborators:
Sex: MALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment:
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 4903|R01HL044664
Start Date: 2000-09
Primary Completion Date: 2006-08
Completion Date: 2006-08
First Posted: 2000-05-26
Results First Posted:
Last Update Posted: 2016-07-29
Locations:
Study Documents:

NCT Number: NCT05522959
Study Title: Cardio-Oncology Rehabilitation Exercise
Study URL: https://beta.clinicaltrials.gov/study/NCT05522959
Acronym: CORE
Study Status: RECRUITING
Brief Summary: Women with breast cancer who are referred to the cardiac rehabilitation program at the Toronto Rehabilitation Institute will be invited to enrol in this observational study. Participants will take part in an established 16-week multimodal cardiac rehabilitation program (HEALTh program) at Toronto Rehabilitation Institute and outcome measures will be assessed before and after program participation to determine the effectiveness of the program in improving cardio metabolic health. Change in VO_2peak will be assessed using Cardiopulmonary Exercise Test (CPET). Traditional cardiac risk factors, lifestyle behaviours, exercise adherence, health-related quality of life, and fatigue will also be assessed.
Study Results: NO
Conditions: Breast Cancer
Interventions:
Primary Outcome Measures: Cardiopulmonary Fitness, VO2peak assessed using cardiopulmonary exercise test, post-intervention (16 weeks)
Secondary Outcome Measures: Visceral adipose tissue, Measured only in a subset (n=30) of participants via 1.5T MRI., post-intervention (16 weeks)|Left ventricular ejection fraction, Measured only in a subset (n=30) of participants via 1.5T MRI., post-intervention (16 weeks)|Native myocardial T1 time, Measured only in a subset (n=30) of participants via 1.5T MRI., post-intervention (16 weeks)|Left ventricular mass, Measured only in a subset (n=30) of participants via

1.5T MRI., post-intervention (16 weeks)|lipid profile, Assessed via fasting blood draw, post-intervention (16 weeks)|Fasting glucose, Assessed via fasting blood draw, post-intervention (16 weeks)|hemoglobin A1c, Assessed via fasting blood draw, post-intervention (16 weeks)|Cancer-specific, health-related quality of life, Functional Assessment of Cancer Therapy (FACT) questionnaire. Minimum score = 0, maximum score = 108, with higher score representing better quality of life., post-intervention (16 weeks)|Depressive symptoms, Patient Health Questionnaire 9 scale. Minimum value = 0, maximum value = 27, where higher score represents more depressive symptoms., post-intervention (16 weeks)|Psychosocial Stress, Perceived Stress Scale (PSS). Minimum value = 0, maximum value = 56, where higher score represents more perceived stress., post-intervention (16 weeks)|Cancer-related fatigue, Fatigue sub-scale of the Functional Assessment of Cancer Therapy (FACT) questionnaire. Minimum score = 0, maximum score = 52, with higher score representing less fatigue., post-intervention (16 weeks)
Other Outcome Measures: Smoking Status, Smoking assessment history questionnaire, post-intervention (16 weeks)|Moderate-Intensity Physical Activity Time, PiezoRx® will be worn by participants for 7 days with data used to assess moderate activity time (\>100 steps per minute), averaged over 7 days post-intervention|Vigorous-intensity Physical Activity, PiezoRx® will be worn by participants for 7 days with data used to assess vigorous activity time (\>120 steps per minute), averaged over 7 days post-intervention|Physical Activity Bouts per Day, PiezoRx® will be worn by participants for 7 days with data used to assess bouts of physical activity per day (greater than 10 minutes of moderate/vigorous activity), averaged over 7 days post-intervention|Total daily steps, PiezoRx® will be worn by participants for 7 days with data used to assess total daily steps, averaged over 7 days post-intervention|Self-Reported Physical Activity, Godin Leisure Time Physical Activity Questionnaire, post-intervention (16 weeks)|Diet quality, Rapid Eating and Activity Assessment for Participants (REAP) questionnaire. Minimum score = 13, maximum score = 39, with a higher score indicating a higher diet quality., post-intervention (16 weeks)
Sponsor: University of Toronto
Collaborators: Toronto Rehabilitation Institute
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 19-5080
Start Date: 2022-03-14
Primary Completion Date: 2023-12
Completion Date: 2023-12
First Posted: 2022-08-31

Results First Posted:
Last Update Posted: 2022-08-31
Locations: Toronto Rehabilitation Institute, Toronto, Ontario, Canada
Study Documents:

NCT Number: NCT00733759
Study Title: Contrast Echocardiography in Patients With Pulmonary Arteriovenous Malformations (PAVMs)
Study URL: https://beta.clinicaltrials.gov/study/NCT00733759
Acronym:
Study Status: WITHDRAWN
Brief Summary: Pulmonary arteriovenous malformations (PAVMs) are thin-walled abnormal vessels which provide direct capillary-free communications between the pulmonary and systemic circulations. Patients with PAVMs have usually have low blood oxygen levels and are at risk of other complications including strokes, brain abscesses, pregnancy-related complications and haemorrhage. We hypothesise that the complications of PAVM patients arise from their PAVMs and not the more recognised intracardiac forms of shunting. We propose to perform echocardiograms to enable assessment of the presence of other causes of capillary-free communications between the pulmonary and systemic circulations.
Study Results: NO
Conditions: Pulmonary Arteriovenous Malformations
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Imperial College London
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 0
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IC/CLS10
Start Date: 2004-02
Primary Completion Date: 2008-03
Completion Date: 2008-03
First Posted: 2008-08-13
Results First Posted:
Last Update Posted: 2019-10-09
Locations: Imperial College Hammersmith Campus, London, W12 0NN, United Kingdom
Study Documents:

NCT Number: NCT03211520
Study Title: Magnetic Resonance Imaging:A Window to Anthracycline

Toxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT03211520
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The study is being conducted to see which cardiac tests that monitor how the heart functions during and after treatment with anthracyclines are most effective. This study will assess a new way to check the heart function of children during and after cancer treatment. Currently, doctors use echocardiograms (heart ultrasound) to see how the heart is working. Echocardiograms are currently being done as part of standard of care prior to giving anthracycline chemotherapy doses and if any cardiac problems are suspected. The new method involves Cardiac Magnetic Resonance Imagining (CMRI) and a blood tests for certain biomarkers for heart health: High sensitivity troponin, Caspase, C-reactive Protein (CRP), ventricular derived B-type natriuretic peptide (BNP), Matrix Metalloproteinases (MMPs), Tissue inhibitors of metalloproteinases (TIMPs), C terminal propeptide of type I procollagen (PICP), C terminal telopeptide of collagen type I (CITP), Troponin I, and Bone Alkaline Phosphatase. The purpose of this study is to find out if CMRI and blood tests help us to find heart problems earlier, before they are detected by echocardiograms.
Study Results: NO
Conditions: Cardiac Complications
Interventions:
Primary Outcome Measures: Myocardial edema, Myocardial edema in the acute phase measured by a composite of multiple measures that include T1 and T2 mapping, signal enhancement in T2 weighted images., Time points will be measured over a 1 year time frame|Regional wall motion abnormalities, Decrease in myocardial strain and strain rate compared to baseline calculations, Time points will be measured over a 1 year time frame|Biomarkers of adverse cardiac remodeling, Elevation of serologic biomarkers CRP, Troponin, Caspases, BNP, and extracellular matrix remodeling (PCIP, CITP, PICP/CITP ratio, MMPs and MMPs/TIMP ratio, Time points will be measured over a 1 year time frame
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Connecticut Children's Medical Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 13
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 10-066
Start Date: 2013-02
Primary Completion Date: 2016-06-24
Completion Date: 2023-06-24
First Posted: 2017-07-07

Results First Posted:
Last Update Posted: 2023-02-06
Locations: Olga H Toro-Salazar, Hartford, Connecticut, 06106, United States
Study Documents:

NCT Number: NCT05358093
Study Title: Cardiac Toxicity of Hypo Fractionated Radiotherapy in Left Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05358093
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: Worldwide, Breast cancer is the most common cancer in women,where 1.7 million new cases diagnosed in 2012 . In 2020 number doubled as 2.3 million women diagnosed with breast cancer. According to ACS 1 in 8 women in United states will develop breast cancer in her life .

Similarly again, In Egypt breast cancer is the most common malignancy in women about 22,700 new cases recorded in 2020. Accounting for 38.8% of cancers in this population and forecasted to be approximately 46,000 in 2050 .

Post-operative radiotherapy is fundamental part of treatment after either conservative surgery or mastectomy . Conventionally fractionated radiation therapy (CFRT) ,Delivering 45-50 GY in 1.8-2 GY daily fractions for 5 days per week over 5-7 weeks was the standard schedule to eradicate sub clinical disease ,sparing normal tissues .After the publication of long term results of randomized controlled trials (RCTs) comparing safety and effectiveness of hypo fractionated RT (HFRT)delivered in3 weeks ,vs. CFRT in node negative BC has been implemented . in 2008 numerous international guidelines recommended HFRT as the new standard being Cost effectiveness ,limited resources ,excessively long RT waiting lists ,Another important argument for HFRT utilization ,even assuming alpha/beta of 1.5GY ,is biologically milder or isoeffective for healthy tissues compered to CFRT .

Cardiac toxicity is potentially long or short term complication of various anticancer therapies systemic therapy as anthracyclines or biological agent implicated in causing irreversible cardiac dysfunction.

Radiotherapy also have cardio toxic effect through different mechanisms
Study Results: NO
Conditions: Breast Cancer Female
Interventions:
Primary Outcome Measures: retrospective study of cardiac toxicity in left breast cancer received hypofractionated radiotherapy, detection

of toxicity on cardiac ejection fraction in 45 patients received hypofractionated radiotherapy over left breast, baseline
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Assiut University
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 45
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: left breast cancer
Start Date: 2022-04-27
Primary Completion Date: 2023-10-30
Completion Date: 2023-11-30
First Posted: 2022-05-03
Results First Posted:
Last Update Posted: 2022-05-03
Locations:
Study Documents:

NCT Number: NCT05786482
Study Title: Evidence Based Mental Wellness Programming Online for Adults Across Chronic Physical Conditions
Study URL: https://beta.clinicaltrials.gov/study/NCT05786482
Acronym: EMPOwer
Study Status: RECRUITING
Brief Summary: Chronic physical conditions are defined as conditions that require ongoing management and treatment over extended periods of time. Chronic physical conditions are not only leading causes of death and disability in North America but they are commonly associated with mental distress and reduced quality of life. Online mind-body wellness programming ranging from physical activity to mindfulness interventions has been shown to be effective in improving mental wellness in a variety of chronic disease populations, but there is a need to evaluate scalable ways to deliver these programs. Building upon a previously developed online wellness program for inflammatory bowel disease (IBD) and primary biliary cholangitis (PBC), the research team has developed a mind-body wellness program for adults ≥18 years of age living with different chronic conditions (e.g., cirrhosis, PBC, heart failure). The 12-week program will be delivered online, and include follow- along mindful movement, breathwork and meditation routines, and a psychology based coping skills program. In a three-armed randomized controlled trial, the study will assess the impact on the primary outcome of anxiety and depression as measured through the hospital anxiety and depression scale (HADS). At the beginning and the end of the 12-week research study, participants will complete surveys to assess secondary/exploratory outcome measures

including quality of life, fatigue, frailty, demoralization, and healthcare usage.

After the program, the research team will conduct interviews with participants to allow them to share their other feedback about the program. The researchers will also send surveys to the participants eight weeks after the program ends to assess longer- term impacts on primary and secondary outcomes.
Study Results: NO
Conditions: Primary Biliary Cholangitis|Heart Failure|Obesity|Digestive Diseases|Women Who Have Experienced a Cardiac Event|Cirrhosis, Liver|Post-Transplant|Cancer|Chronic Kidney Diseases|Other Chronic Physical Condition
Interventions: BEHAVIORAL: Online mind-body wellness program|BEHAVIORAL: Online mind-body wellness program + Weekly Check-ins
Primary Outcome Measures: Hospital Anxiety and Depression Scale (HADS), Depression and anxiety will be measured on the Hospital Anxiety and Depression Scale. The minimum value is 0, the maximum is 21, and higher scores mean a worse outcome., 12 weeks
Secondary Outcome Measures: Modified Fatigue Impact Scale (MFIS), The Modified Fatigue Impact Scale (MFIS) assesses the effect of fatigue on cognitive functioning, physical functioning, and psychosocial functioning. The minimum value is 0, the maximum value is 84, and higher scores mean a worse outcome., 12 weeks|Health Related Quality of Life, Health related quality of life captured by the quality-of-life Short Form Survey 12 (SF-12). The minimum value is 0, the maximum value is 100, and a higher score means a better outcome., 12 weeks|EQ-5D-5L, Cost utility analysis will be facilitated by the EQ-5D-5L which consists of 5- dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) where patients are asked to indicate their health state. The minimum value is 5, the maximum value is 25, and a higher score means a worse outcome., 12 weeks|Capability, Opportunity, Motivation, Behaviour (COM-B) Survey, Capability, opportunity, and motivation for behaviour change will be measured on the COM-B survey. The lowest score is 0, the highest score is 60, and higher scores indicate better outcomes., 12 weeks|Satisfaction and Adherence, Satisfaction and adherence will be measured using a self-report tool where participants indicate their satisfaction with program elements, and perceived adherence to the program over the study period. The minimum value is 4, the maximum value is 40, and a higher score means a better outcome., 12 weeks
Other Outcome Measures: Demoralization (Exploratory), Demoralization will be captured through self report using the Demoralization Scale-II. The minimum score is 0, the maximum score is 32, and a higher score means a worse outcome., 12 weeks|Edmonton Frail Scale (Exploratory), Frailty will be captured using the Edmonton Frail Scale. The minimum score is 0, the maximum score is 17, and a higher score means a worse outcome., 12 weeks|Fried Frailty (Exploratory), Frailty will be captured using the Fried Frailty Score. The minimum score is 0, the maximum score is 5, and a higher score means a worse

outcome., 12 weeks|Healthcare Usage (Exploratory), Healthcare usage will be measured using a self-report tool where participants indicate healthcare service usage during the study period., 12 weeks|Sleep (Exploratory), Impacts on sleep will be captured through self-report using the Patient Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance Short Form 8a. The minimum score is 8, the maximum score is 56, and a lower score means a worse outcome., 12 weeks
Sponsor: University of Alberta
Collaborators: Canadian Institutes of Health Research (CIHR)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 500
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: Pro00122568
Start Date: 2023-02-12
Primary Completion Date: 2024-07-31
Completion Date: 2024-12-31
First Posted: 2023-03-27
Results First Posted:
Last Update Posted: 2023-06-01
Locations: University of Alberta, Edmonton, Alberta, T6G2X8, Canada
Study Documents:

NCT Number: NCT00499382
Study Title: Quantitation of Left Ventricular Ejection Fraction as Part of F-18 FDG Whole Body PET/CT Scans For Tumor Staging
Study URL: https://beta.clinicaltrials.gov/study/NCT00499382
Acronym:
Study Status: TERMINATED
Brief Summary: Primary Objective:

* Evaluate the agreement between radionuclide ventriculography (RNV) and gated F-18 fluorodeoxyglucose positron emission tomography/computed tomography (FDG PET/CT) in calculating left ventricular ejection fraction (LVEF), end diastolic volume (EDV) and end systolic volume (ESV).
Study Results: NO
Conditions: Advanced Cancers
Interventions: PROCEDURE: Nuclear Medicine Cardiac Scan|PROCEDURE: PET/CT Cardiac Scan
Primary Outcome Measures: To compare the results, called an ejection fraction, of PET/CT and NM cardiac scans of heart., 5 Years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center

Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 5
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2004-0578
Start Date: 2004-09
Primary Completion Date: 2009-03
Completion Date: 2009-03
First Posted: 2007-07-11
Results First Posted:
Last Update Posted: 2012-08-01
Locations: U.T.M.D. Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT03983382
Study Title: A Study of Limited Heart Monitoring During Non-anthracycline Trastuzumab-based Therapy in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT03983382
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The purpose of this study is to test whether patients with breast cancer who are being treated with non-anthracycline trastuzumab therapy can safely be monitored for heart related side effects less often than usual.
Study Results: NO
Conditions: Breast Cancer
Interventions: DIAGNOSTIC_TEST: Left Ventricular Ejection Fraction
Primary Outcome Measures: Number of participants with treatment-related adverse events as assessed by CTCAE v4.0, Participants have HER2-positive breast cancer treated with non-anthracycline trastuzumab-based therapy., 12 months from baseline
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 194
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 19-045
Start Date: 2019-03-22
Primary Completion Date: 2024-03

Completion Date: 2024-03
First Posted: 2019-06-12
Results First Posted:
Last Update Posted: 2023-01-26
Locations: Hartford Healthcare Cancer Institute @ Hartford Hospital (Data collection only), Hartford, Connecticut, 06102, United States| Memorial Sloan Kettering Cancer Center @ BaskingRidge (Consent and follow-up only), Basking Ridge, New Jersey, 07920, United States| Memorial Sloan Kettering Monmouth (Consent and Follow up), Middletown, New Jersey, 07748, United States|Memorial Sloan Kettering Bergen (Consent and follow-up only), Montvale, New Jersey, 07645, United States|Memorial Sloan Kettering Cancer Center @ Commack (Consent and Follow up), Commack, New York, 11725, United States|Memorial Sloan Kettering Westchester (Consent and Follow-up), Harrison, New York, 10604, United States|Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States|Memorial Sloan Kettering Nassau (Consent and Follow-up), Rockville Centre, New York, 11553, United States
Study Documents:

NCT Number: NCT03674450
Study Title: Lung Heart Rate Variability
Study URL: https://beta.clinicaltrials.gov/study/NCT03674450
Acronym: HRV
Study Status: WITHDRAWN
Brief Summary: The purpose of this study is to examine the effects of heart-rate variability biofeedback training on lung cancer patients receiving definitive radiation therapy. The target population consists of non-small cell lung cancer (NSCLC) patients receiving 6 weeks of radiation therapy. The study will utilize the Physiolab GP8 heart rate variability and respiration system to collect data as well as several survey instruments to analyze quality of life measures. The goal is to show the HRV training can improve certain QOL measures like anxiety and sleep quality.
Study Results: NO
Conditions: Non Small Cell Lung Cancer
Interventions: BEHAVIORAL: Heart Rate Variability Biofeedback Training
Primary Outcome Measures: EORTC QLQ-C30 Questionnaire, Questionnaire developed to assess the quality of life of cancer patients. The QLQ-C30 is composed of both multi-item scales and single-item measures. These include five functional scales, three symptom scales, a global health status / QoL scale, and six single items.

Each of the multi-item scales includes a different set of items - no item occurs in more than one scale. All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level.Thus a high score for a functional scale represents a high / healthy level of functioning, a high score for the global health status / QoL represents a high QoL, but a high score for a symptom scale / item represents a high level of symptomatology /

problems., 2 years
Secondary Outcome Measures: Pittsburgh Sleep Quality Index (PSQI), Measure the quality and patterns of sleep in adults. It differentiates from "poor" and "good" sleep quality by measuring seven areas. The order of the PSQI items has been modified from the original order in order to fit the first 9 items (which are the only items that contribute to the total score). Item 10 does not contribute to the PSQI score. In scoring the PSQI, seven component scores are derived, each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce a global score (range 0 to 21). Higher scores indicate worse sleep quality., 2 years
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: UPCC 05518
Start Date: 2019-01-02
Primary Completion Date: 2019-04-11
Completion Date: 2019-04-11
First Posted: 2018-09-17
Results First Posted:
Last Update Posted: 2020-04-07
Locations: Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT04717050
Study Title: Reducing Metabolic Dysregulation in Obese Latina Breast Cancer Survivors Using Physical Activity
Study URL: https://beta.clinicaltrials.gov/study/NCT04717050
Acronym:
Study Status: RECRUITING
Brief Summary: This study is about testing whether exercise will improve fitness and lessen risk factors related to heart disease, diabetes, and obesity in Latina breast cancer survivors.
Study Results: NO
Conditions: Breast Cancer|Coronary Artery Disease|Stroke|Type2 Diabetes
Interventions: BEHAVIORAL: Progressive combine training (PCT)| BEHAVIORAL: Attention Control (AC)
Primary Outcome Measures: Change in Metabolic Dysregulation (MetD) After Completion of Phase 1 Progressive Combine Training (PCT) -Insulin Resistance, Changes from baseline in insulin resistance (IR)

measured by Homeostasis Model Assessment (HOMA), 16 weeks|Change in Metabolic Dysregulation (MetD) After Completion of Phase 1 Progressive Combine Training (PCT) -Visceral adiposity, Changes from baseline in visceral adiposity (VA) measured by dual-energy X-ray absorptiometry (DXA), waist to hip ratio (WHR) and bioelectrical impedance technology (BIA), 16 weeks|Change in Metabolic Dysregulation (MetD) After Completion of Phase 1 Progressive Combine Training (PCT) -metabolic syndrome (MSY), Frequency of metabolic syndrome (MSY) diagnosed by criteria accepted by the American Heart Association (AHA), 16 weeks
Secondary Outcome Measures: Compare Metabolic Dysregulation (MetD) in Progressive Combine Training (PCT) and Attention (AC) groups -Insulin Resistance, Compare changes from baseline in insulin resistance (IR) measured by Homeostasis Model Assessment (HOMA) in Progressive Combine Training (PCT) and Attention (AC) groups, 16 weeks|Compare Metabolic Dysregulation (MetD) in Progressive Combine Training (PCT) and Attention (AC) groups - Visceral adiposity, Compare changes from baseline in Visceral adiposity (VA) measured by dual-energy X-ray absorptiometry (DXA), waist to hip ratio (WHR) and bioelectrical impedance technology (BIA) in Progressive Combine Training (PCT) and Attention (AC) groups, 16 weeks|Compare Metabolic Dysregulation (MetD) in Progressive Combine Training (PCT) and Attention (AC) groups - metabolic syndrome (MSY), Compare frequency of metabolic syndrome (MSY) diagnosed by criteria accepted by the American Heart Association (AHA) in Progressive Combine Training (PCT) and Attention (AC) groups - metabolic syndrome (MSY), 16 weeks|Metabolic Dysregulation (MetD) Status During 4 month follow up period - insulin resistance (IR), Change in insulin resistance (IR) status from end of study PCT to 4 month follow up measured by Homeostasis Model Assessment (HOMA)., 16 weeks|Metabolic Dysregulation (MetD) Status During 4 month follow up period - Visceral adiposity (VA), Change in Visceral adiposity (VA) status from end of study PCT to 4 month follow up measured by dual-energy X-ray absorptiometry (DXA), waist to hip ratio (WHR) and bioelectrical impedance technology (BIA)., 16 weeks|Metabolic Dysregulation (MetD) Status During 4 month follow up period - metabolic syndrome (MSY), Change in metabolic syndrome (MSY) frequency from end of study PCT to 4 month follow up diagnosed by criteria accepted by the American Heart Association (AHA), 16 weeks
Other Outcome Measures:
Sponsor: Dana-Farber Cancer Institute
Collaborators: American Cancer Society, Inc.
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 160
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 20-221
Start Date: 2021-08-12

Primary Completion Date: 2025-06-15
Completion Date: 2026-06-15
First Posted: 2021-01-20
Results First Posted:
Last Update Posted: 2022-09-13
Locations: Dana Farber Cancer Institute, Boston, Massachusetts, 02215, United States
Study Documents:

NCT Number: NCT02668250
Study Title: Influence of a Multi-parametric Optimization Strategy for General Anesthesia on Postoperative Morbidity and Mortality
Study URL: https://beta.clinicaltrials.gov/study/NCT02668250
Acronym: OPTI-AGED
Study Status: COMPLETED
Brief Summary: With the increasing aging population demographics and life expectancies, the number of very elderly patients undergoing surgery is rising. Elderly patients constitute an increasingly large proportion of the high-risk surgical group.

Cardiac complications and postoperative pulmonary complications are equally prevalent and contribute similarly to morbidity, mortality, and length of hospital stay. Specific optimization strategy of general anesthesia has been tested in high-risk patients undergoing major surgery to improve outcomes.

Our hypothesis is that a combined optimization strategy of anesthesia concerning hemodynamic, ventilation, and depth of anesthesia may improve short- and long- term outcome in elderly undergoing high risk surgery.
Study Results: NO
Conditions: Coronary; Ischemic|Arrhythmias, Cardiac|Heart Failure|Peripheral Vascular Diseases|Dementia|Stroke|Pulmonary Disease, Chronic Obstructive|Respiratory Insufficiency|Alcoholism|Cancer|Diabetes|Renal Insufficiency
Interventions: PROCEDURE: OPTI-AGED|PROCEDURE: Usual Care
Primary Outcome Measures: Incidence of a composite of mortality or major postoperative morbidity., One or more of major postoperative complications : acute kidney injury (defined by Kidney disease : improving Global Outcomes (KDIGO) stage 1 or higher), acute myocardial infarction, heart failure, stroke, development of sepsisand septic shock, acute respiratory failure requiring non-invasive ventilation or intubation, delirium) will be reported in the source folder of the patients, and the mortality will be also focused. The goal of this study is to decrease this incidence., Day 30
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Centre Hospitalier Universitaire de Saint Etienne
Collaborators: Ministry of Health, France
Sex: ALL

Age: OLDER_ADULT
Phases: NA
Enrollment: 2495
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 1508190|ANSM
Start Date: 2017-02-03
Primary Completion Date: 2020-02-05
Completion Date: 2021-03-16
First Posted: 2016-01-29
Results First Posted:
Last Update Posted: 2021-08-26
Locations: CHU Amiens - Picardie, Amiens, France|CHU CAEN, Caen, France|Chu Clermont-Ferrand, Clermont-Ferrand, 63003, France|Chu Dijon, Dijon, 21079, France|Médipôle Lyon - Villeurbanne, Décines-Charpieu, France|Chu Grenoble, Grenoble 9, 38043, France|CHRU Lille - Salengro, Lille, 59000, France|CHU LILLE - Huriez, Lille, 59037, France|CHU LYON, Lyon, France|Lyon Sud - CHU, Lyon, France|Chu Marseille La Timone, Marseille, 13385, France|Chu Marseille Nord, Marseille, 13385, France|Chu Montpellier, Montpellier 5, 34295, France|Chu Nancy, Nancy, 54035, France|CHU de Nantes, Nantes, France|CHU NICE, Nice, France|Chu Nimes, Nîmes, France|Ch Paris Beaujon, Paris, France|Ch Paris Bichat, Paris, France|Ch Paris Pitie Salpetriere, Paris, France|Ch Paris Saint Antoine, Paris, France|Ch Saint Louis-Lariboisiere, Paris, France|Chu Poitiers, Poitiers, 86021, France|Chu Rennes, Rennes, France|Chu Rouen, Rouen, 76031, France|Chu Saint Etienne, Saint Etienne, 42100, France|Hopital Central Strasbourg, Strasbourg, 67098, France|Hopital Hautepierre Strasbourg, Strasbourg, 67098, France|Chu Toulouse, Toulouse 9, 31059, France
Study Documents:

NCT Number: NCT05699915
Study Title: Extensive CArdioVAscular Characterization and Follow-up of Patients Receiving Immune Checkpoint Inhibitors
Study URL: https://beta.clinicaltrials.gov/study/NCT05699915
Acronym: CAVACI
Study Status: RECRUITING
Brief Summary: The goal of this prospective, multicentre study is to investigate short- and long-term cardiovascular effects in cancer patients treated with immune checkpoint inhibitors (ICIs).

The main question\[s\] it aims to answer are:

* To investigate troponin and NT-proBNP values in patients receiving ICIs and their association with ICI-induced CV abnormalities and MACEs.
* Study the calcium score, systolic, and diastolic (dys)function.
* Evaluate associations between patient/disease characteristics /

transthoracic echocardiography parameters / electrocardiography parameters and troponin / NT-proBNP levels.

Participants will be closely monitored by performing the following additional visits and testing:

* Chest CT scan prior to treatment start, after 12 and 24 months.
* Consultation with a cardiologist at baseline, 3, 6, 12 and 24 months, who will perform an electrocardiogram and echocardiogram.
* One additional blood sample prior to treatment start, after 3, 6, 12 and 24 months. An extra blood sample could be taken in case of sudden heart problems.
* Non-invasive endothelial function tests prior to treatment start, after 12 and 24 months.

Study Results: NO
Conditions: Cancer|Immune-related Adverse Event|Cardiac Abnormalities, Variable|Immune Checkpoint Inhibitor-Related Myocarditis|Diastolic Dysfunction|Atherosclerosis|Cardiotoxicity
Interventions: PROCEDURE: Cardiology consultation|DIAGNOSTIC_TEST: Chest Computed Tomography (CT) without contrast|PROCEDURE: Non-invasive endothelial function tests|PROCEDURE: Electrocardiogram|DIAGNOSTIC_TEST: Extra serum sample (7.5 mL)
Primary Outcome Measures: The incidence of an elevated hs-TnT above the ULN if the baseline value was normal; or 1.5 ≥ times baseline if the baseline value was above the ULN within the first three months of treatment. The maximum measured value will be taken into account., For the primary endpoint, the cumulative incidence of troponin elevation will be calculated with death as a competing risk. Cumulative incidences and corresponding 95% confidence intervals will be reported and a cumulative incidence plot will be used to visualize the results., Preliminary analysis once 50 patients have reached their 3-month cardiac follow-up visit and 3 months after last patient is included.
Secondary Outcome Measures: The incidence of hs-TnT/NT-proBNP elevations at 6, 12, and 24 months., Cumulative incidences and 95% confidence intervals, considering death as a competing event., Through study completion, an average of 1 year|The incidence of hs-TnT/NT-proBNP elevations at baseline, 3, 6, 12, and 24 months., Cumulative incidences and 95% confidence intervals, considering death as a competing event., Preliminary analysis once 50 patients have reached their 3-month cardiac follow-up visit and through study completion, an average of 1 year|Evolution of hs-TnT/NT-proBNP in 24 months compared to baseline., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual., Through study completion, an average of 1 year|Evolution of transthoracic 3D echocardiography parameters (dimensions, diastolic function, valvular abnormalities, LVEF, strain analysis) at baseline, 3, 6, 12, and 24 months., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual., reliminary analysis

once 50 patients have reached their 3-month cardiac follow-up visit and through study completion, an average of 1 year|Evolution of electrocardiography parameters (rhythm, heart axis, PQ interval, QRS duration, bundle branch block, QT interval, RR interval, pathological Q's, left ventricular hypertrophy and STT segments) at baseline, 3, 6, 12, and 24 months., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual., reliminary analysis once 50 patients have reached their 3-month cardiac follow-up visit and through study completion, an average of 1 year|Association between the evolution of troponin/NT-proBNP and transthoracic echocardiography parameters at baseline, 3, 6, 12, and 24 months., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual., reliminary analysis once 50 patients have reached their 3-month cardiac follow-up visit and through study completion, an average of 1 year|Association between the evolution of troponin/NT-proBNP and electrocardiography (rhythm, heart axis, PQ, QRS, bundle branch block, QT, RR, pathological Q's, left ventricular hypertrophy and STT segments) parameters at baseline, 3, 6, 12, and 24 months., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual., reliminary analysis once 50 patients have reached their 3-month cardiac follow-up visit and through study completion, an average of 1 year|Cumulative incidence of cardiovascular (CV) abnormalities at 3, 6, 12, and 24 months based on the CARDIOTOX classification system of Sendón et al., with the inclusion of pericardial effusion and new arrhythmias., Cumulative incidences and 95% confidence intervals, considering death as a competing event., Through study completion, an average of 1 year|Association between the evolution of troponin/NT-proBNP and CV abnormalities (as classified based on the CARDIOTOX classification for myocardial injury including cardiac biomarkers, symptoms, LVEF, LA area, LVESV, GLS and diastolic function)., Joint model combining a linear mixed model for troponin and a sub-distributional proportional hazards model for the time-to-event taking into account death as a competing event for CV abnormality and MACE., Through study completion, an average of 1 year|Cumulative incidence of MACEs at 3, 6, 12, and 24 months. MACEs were defined as the composite outcome of nonfatal stroke, nonfatal myocardial infarction, hospital admission for heart failure (HF) and cardiac revascularization, and CV death., Cumulative incidences and 95% confidence intervals, considering death as a competing event., Through study completion, an average of 1 year|Overall survival., Cumulative incidences and 95% confidence intervals, reliminary analysis once 50 patients have reached their 3-month cardiac follow-up visit and through study completion, an average of 1 year|Association between the evolution of troponin/NT-proBNP and MACEs over a period of two years. Nonfatal stroke, nonfatal myocardial infarction, hospital admission for heart failure, cardiac revascularization and CV death will be combined to report MACEs., Joint model combining a linear mixed model for troponin and a sub-

distributional proportional hazards model for the time-to-event taking into account death as a competing event for CV abnormality and MACE., Through study completion, an average of 1 year|The difference in the evolution of hs-TnT/NT-proBNP between combination therapy and monotherapy over a period of two years., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual. This model will be extended with patient and treatment characteristics and their interaction with time, to evaluate their impact on the evolution of these parameters., Through study completion, an average of 1 year|The difference in the evolution of transthoracic echocardiography parameters (dimensions, diastolic function, valvular abnormalities, LVEF, strain analysis) between combination therapy and monotherapy over a period of two years., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual. This model will be extended with patient and treatment characteristics and their interaction with time, to evaluate their impact on the evolution of these parameters., Through study completion, an average of 1 year|The difference in the evolution of electrocardiography parameters (rhythm, heart axis, PQ, QRS, bundle branch block, QT, RR, pathological Q's, left ventricular hypertrophy and STT segments) between combination therapy and monotherapy., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual. This model will be extended with patient and treatment characteristics and their interaction with time, to evaluate their impact on the evolution of these parameters., Through study completion, an average of 1 year|Association between patient characteristics (demographics, medical history, current oncological disease, prior cancer history, prior/concomitant medication and other relevant parameters) and troponin., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual. This model will be extended with patient and treatment characteristics and their interaction with time, to evaluate their impact on the evolution of these parameters., Through study completion, an average of 1 year|Association between patient characteristics (demographics, medical history, current oncological disease, prior cancer history, prior/concomitant medication and other relevant parameters) and NT-proBNP., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual. This model will be extended with patient and treatment characteristics and their interaction with time, to evaluate their impact on the evolution of these parameters., Through study completion, an average of 1 year|Agreement between hs-TnT and hs-TnI levels at baseline, 3, 6, 12, and 24 months., Bland-Altman curves and intraclass correlation coefficient (ICC) based on a two-way mixed effects model. The ICC and 95% confidence interval will be reported., reliminary analysis once 50 patients have reached their 3-month cardiac follow-up visit and through study completion, an average of 1

year|The proportion of severe immune-related non-CV toxicities (grades 3-5)., Proportions and 95% confidence interval, Through study completion, an average of 1 year|Association between the evolution of troponin/NT-proBNP and severe immune-related non-CV toxicities (grades 3-5, e.g. pneumonitis, colitis, thyroiditis, etc. according to the CTCAE criteria)., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual. This model will be extended with patient and treatment characteristics and their interaction with time, to evaluate their impact on the evolution of these parameters., Through study completion, an average of 1 year|Association between the evolution of troponin/NT-proBNP and overall survival., Joint model combining a linear mixed model for troponin and a sub-distributional proportional hazards model for the time-to-event taking into account death as a competing event for CV abnormality and MACE., Through study completion, an average of 1 year|Association between the evolution of troponin and diastolic function (based on the recommendations listed in https://doi.org/10.1016/j.echo.2016.01.011, mitral inflow, tissue doppler imaging parameters)., Linear mixed effects model with a random intercept per subject to account for the correlation measurements coming from the same individual. This model will be extended with patient and treatment characteristics and their interaction with time, to evaluate their impact on the evolution of these parameters., Through study completion, an average of 1 year|Calcium score at baseline, 12 months, and 24 months., Proportions and 95% confidence interval, Through study completion, an average of 1 year|Peripheral vascular function at baseline, 3 months, 6 months, 12 months and 24 months., Flow mediated dilatation: dilatation % from baseline to maximal post-occlusion diameter.

Peripheral arterial tonometry ratio: based on the response to reactive hyperemia using post and pre-occlusion values, Through study completion, an average of 1 year|Association between the evolution of troponin and calcium score., Flow mediated dilatation: dilatation % from baseline to maximal post-occlusion diameter.

Peripheral arterial tonometry ratio: based on the response to reactive hyperemia using post and pre-occlusion values, Through study completion, an average of 1 year
Other Outcome Measures:
Sponsor: Algemeen Ziekenhuis Maria Middelares
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 276
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: PREVENTION

Other IDs: MMS.2021.058
Start Date: 2022-01-07
Primary Completion Date: 2024-11-30
Completion Date: 2026-11-30
First Posted: 2023-01-26
Results First Posted:
Last Update Posted: 2023-06-01
Locations: AZ Sint-Vincentius Deinze, Deinze, East-Flanders, 9800, Belgium|Algemeen Ziekenhuis Maria Middelares, Ghent, East-Flanders, 9000, Belgium|AZ Sint-Elisabeth Zottegem, Zottegem, East-Flanders, 9620, Belgium|Antwerp University Hospital, Antwerp, 2650, Belgium
Study Documents:

NCT Number: NCT02487615
Study Title: Genetical, Anthropometrical and Biochemical Factors Influencing High Risk Subclinical Atherosclerosis
Study URL: https://beta.clinicaltrials.gov/study/NCT02487615
Acronym:
Study Status: COMPLETED
Brief Summary: Subclinical atherosclerosis is the atherosclerotic process identified before clinical symptoms and thus it can be a useful marker of future cardiovascular events. It can be evaluated by many methods. This study included the diagnosis of subclincal atherosclerosis by four different methods: coronary calcium score, carotid doppler ultrasound to quantify intima media thickness and carotid plaques, exercise stress test and ankle brachial index. Clinical data, anthropometric measures (body mass index, abdominal circumference), markers of inflammation (high sensitive - C reactive protein, TNF alfa and Lipoprotein Associated Phospholipase A2), fat tissue function (leptin, resistin and adiponectin), glucose metabolism (fasting plasma glucose, glycated hemoglobin and insulin) and genetics markers of atherosclerotic process were evaluated as biomarkers of subclinical atherosclerosis in a uneventful population.
Study Results: NO
Conditions: Primary Prevention
Interventions:
Primary Outcome Measures: Carotid intima-media thickness (cIMT), Subclinical atherosclerosis evaluation by quantifying intima media thickness by Doppler, Four Weeks
Secondary Outcome Measures: Coronary artery calcium score, Subclinical atherosclerosis evaluation by Coronary Artery Calcium by CT, Four weeks|Brachial Ankle Index, Subclinical atherosclerosis evaluation by brachial ankle index (BAI) by blood pressure measurement, Four weeks|Ischemia induced by exercise stress test, Myocardial ischemia investigation by treadmill exercise test, Four weeks|Adiponectin, resistin, leptin, tumor necrosis factor alpha (TNF-α), lipoprotein associated phospholipase A2 (Lp-PLA2), Blood samples for Adiponectin, resistin, leptin, tumor necrosis factor alpha (TNF-α), lipoprotein associated phospholipase A2 (Lp-PLA2) dosing, Four weeks|Genotyping of DNA at the following rs2383206, rs10757274, rs10757278, rs1051931,

rs16874954 and rs1799724 and RNA of PLA2G7 (2−ΔCT), TNF-α (2−ΔCT), LEP (2−ΔCT), LEPR (2−ΔCT), DNA and extraction from leukocytes, Four weeks
Other Outcome Measures:
Sponsor: Instituto Dante Pazzanese de Cardiologia
Collaborators: University of Campinas, Brazil
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 340
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 3852
Start Date: 2010-02
Primary Completion Date: 2013-03
Completion Date: 2013-03
First Posted: 2015-07-01
Results First Posted:
Last Update Posted: 2015-07-07
Locations: State University Of Campinas, Campinas, Sao Paulo, 13083-887, Brazil|Dante Pazzanese Institute of Cardiology, São Paulo, 04012-909, Brazil
Study Documents:

NCT Number: NCT04046315
Study Title: Early Detection of Cardiac Damage With CMR in Women With Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT04046315
Acronym: EARLY-CATCH
Study Status: UNKNOWN
Brief Summary: With this study the investigators will assess early cardiac damage by means of Global Longitudinal Strain (GLS) in newly diagnosed breast cancer (BC) patients treated with anthracycline-based chemotherapy, and to investigate whether myocardial damage as measured with T1 / T2 Cardiovascular Magnetic Resonance (CMR) mapping and plasma hs-Troponin T is related to changes in GLS.
Study Results: NO
Conditions: Cardiotoxicity|Breast Cancer|Chemotherapy Induced Systolic Dysfunction
Interventions: DIAGNOSTIC_TEST: CMR
Primary Outcome Measures: Global Longitudinal Strain (GLS) change after chemotherapy compared to baseline, A relative reduction in Global Longitudinal Strain (GLS) assessed with CMR, Baseline and 2 weeks after the last chemotherapy cycle
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Radboud University Medical Center
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT

Phases:
Enrollment: 55
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 108818
Start Date: 2020-03-01
Primary Completion Date: 2021-03-31
Completion Date: 2021-03-31
First Posted: 2019-08-06
Results First Posted:
Last Update Posted: 2020-03-16
Locations: Radboud University Medical Center, Nijmegen, 6500 HB, Netherlands
Study Documents:

NCT Number: NCT01270750
Study Title: Bosentan for Severe Mitral Valve Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT01270750
Acronym: BOSMIVAR
Study Status: UNKNOWN
Brief Summary: Vasoconstrictive signaling via endothelin receptors is not limited to primary pulmonary arterial hypertension, but has also been documented in secondary pulmonary hypertension due to congestive heart failure, including cardiac valve disease. The investigators aim to examine the clinical and physiologic effects of bosentan therapy in patients with secondary pulmonary hypertension due to severe, inoperable cardiac valve disease, using a single-center, prospective, open-label, non-randomized study of oral bosentan in outpatients with severe mitral stenosis due to childhood rheumatoid fever. Primary end-point will be exercise capacity at six months determined by six-minute walking distance and cardiopulmonary exercise testing. Secondary end-points will be symptomatic relief, echocardiographic left ventricular function and pulmonary pressure, serum pro-brain natriuretic peptide, and adverse events at six months.
Study Results: NO
Conditions: SECONDARY PULMONARY HYPERTENSION|MITRAL STENOSIS|CHILDHOOD RHEUMATOID FEVER|CONGESTIVE HEART FAILURE
Interventions: DRUG: BOSENTAN
Primary Outcome Measures: SIX MINUTE WALKING DISTANCE, CHANGE IN SIX MINUTE WALKING DISTANCE AFTER 6 MONTHS OF THERAPY COMPARED TO PRE-TREATMENT VALUE., SIX MONTHS|MAXIMAL OXYGEN UPTAKE, CHANGE IN MAXIMAL OXYGEN UPTAKE AFTER 6 MONTHS OF THERAPY COMPARED TO PRE-TREATMENT VALUE., 6 MONTHS
Secondary Outcome Measures: ECHOCARDIOGRAPHIC PULMONARY PRESSURE, ECHOCARDIOGRAPHIC ASSESSMENT OF PEAK AND MEAN PULMONARY PRESSURE AT 6 MONTHS AFTER TREATMENT COMPARED WITH PRE-TREATMENT VALUES., 6 MONTHS|ECHOCARDIOGRAPHIC LEFT VENTRICULAR FUNCTION, ECHOCARDIOGRAPHIC ASSESSMENT OF LEFT VENTRICULAR FUNCTION AT 6 MONTHS AFTER TREATMENT COMPARED WITH PRE-TREATMENT VALUES., 6 MONTHS|SERUM PRO-BNP,

ASSESSMENT OF SERUM PRO-BRAIN NATRIURETIC PEPTIDE LEVELS AT 6 MONTHS AFTER TREATMENT COMPARED WITH PRE-TREATMENT VALUES., 6 MONTHS|DYSPNEA, CHANGE IN BORG DYSPNEA INDEX COMPARED WITH PRE-TREATMENT VALUES., 6 MONTHS
Other Outcome Measures:
Sponsor: General Hospital of Chalkida
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1|PHASE2
Enrollment: 10
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: GHC2/29/22-09-2008
Start Date: 2010-12
Primary Completion Date: 2011-06
Completion Date: 2011-06
First Posted: 2011-01-05
Results First Posted:
Last Update Posted: 2011-01-28
Locations: General Hospital of Chalkida, Chalkida, Evoia, 34100, Greece
Study Documents:

NCT Number: NCT03748550
Study Title: Exercise to Prevent AnthraCycline-based Cardio-Toxicity Study 2.0 (EXACT2)
Study URL: https://beta.clinicaltrials.gov/study/NCT03748550
Acronym: EXACT 2
Study Status: RECRUITING
Brief Summary: Although great progress has been made in treating breast cancer, long-term health may be impaired by cancer therapy. For example, some chemotherapy drugs (e.g., anthracyclines) are known to cause declines in heart health. While the impact can vary, some will experience substantial heart damage that may lead to heart failure and death. As these treatments are highly effective, there is a need to find ways to reduce the damaging effects while not interfering with its anticancer potential. As it is well-known that regular exercise can improve heart health, the purpose of this study is to explore the role of exercise as a heart protective therapy for breast cancer patients receiving heart damaging chemotherapy.
Study Results: NO
Conditions: Cancer, Breast|Cardiotoxicity|Cardiovascular Diseases
Interventions: BEHAVIORAL: Aerobic exercise
Primary Outcome Measures: Change in Left Ventricular (LV) Function, LV function will be assessed using serial transthoracic echocardiography (TTE) as well as tissue velocity imaging (TVI) and strain imaging (SI.) For 2-dimensional (2D) LV cavity dimensions and LVEF will be

determined from the acquired 2D images according to established criteria. Tissue Doppler-derived indexes will be recorded at the base of the lateral mitral annuli to determine longitudinal endocardial velocities. The indexes that will be assessed are systolic (S'), early diastolic (e') and late diastolic (a') velocities. Doppler-independent strain will be assessed offline using semi-automated speckle tracking techniques. These will be performed using parasternal and apical views to determine both global longitudinal and radial strain., LV function will be assessed at baseline (week 0), post-intervention (week-13) and 6 months after the completion of the intervention.
Secondary Outcome Measures: Change in Cardiac Electrical Activity, Cardiac electrocardiogram at rest will be assessed using a 12 lead ECG (General Electric Case System). Specifically, the duration (ms) of the PR interval, RR interval, QRS interval and QT interval will be determined., The cardiac ECG will be assessed at baseline (week 0), post-intervention (week-13) and 6 months after the completion of the intervention.|Change in Aerobic Fitness, Cardiac Stress Tests results will be used to predict peak oxygen consumption (ml/kg/min). In brief, participants will perform a graded exercise test until they reach volitional fatigue or the test is terminated due to adverse physiological changes. Predictive equations will then be used to predict the participant's peak oxygen uptake based on the total duration (seconds) of the treadmill test., Outcome will be assessed at baseline (week 0), post-intervention (week-13) and 6 months after the completion of the intervention.|Change in Blood biomarkers, Venipuncture will be performed by a nurse/phlebotomist to collect blood samples which will be used to quantify systemic levels of c-reactive protein (CRP), high sensitivity troponin (hs-TNT) and NTproBNP levels. Upon collection, blood samples will be processed, and the serum will be extracted and stored at -20°C until it is required for analysis. CRP, hs-TNT and N-terminal pro b-type natriuretic peptide (NTproBNP) levels will be assessed using commercially available ELISA kits. All biomarkers will be measured in pg/ml., Outcome will be assessed at baseline (week 0), post-intervention (week-13) and 6 months after the completion of the intervention.|Change in Functional Assessment for Cancer Therapy, The Functional Assessment for Cancer Therapy survey for patients with breast cancer (FACT-B) will be used to assess quality of life. The FACT-B includes sub-scales for assessing physical, social/family, emotional, and functional well-being. FACT-B total score ranges from 0-148., Outcome will be assessed at baseline (week 0), post-intervention (week-13) and 6 months after the completion of the intervention.|Change in Fatigue, The Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) is a 13 item questionnaire (maximum score =160) that will be used to assess cancer-related fatigue. Higher scores are indicative of higher levels of fatigue., Outcome will be assessed at baseline (week 0), post-intervention (week-13) and 6 months after the completion of the intervention.
Other Outcome Measures:
Sponsor: Nova Scotia Health Authority

Collaborators: Canadian Cancer Society (CCS)|Canadian Institutes of Health Research (CIHR)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 1024489|1024489
Start Date: 2019-04-29
Primary Completion Date: 2023-06-30
Completion Date: 2023-12-31
First Posted: 2018-11-21
Results First Posted:
Last Update Posted: 2022-12-06
Locations: St. Boniface Hospital, Winnipeg, Manitoba, R2H 2A6, Canada|QEII Health Sciences Centre, Halifax, Nova Scotia, B3H 1V8, Canada
Study Documents:

NCT Number: NCT01793168
Study Title: Rare Disease Patient Registry & Natural History Study - Coordination of Rare Diseases at Sanford
Study URL: https://beta.clinicaltrials.gov/study/NCT01793168
Acronym: CoRDS
Study Status: RECRUITING
Brief Summary: CoRDS, or the Coordination of Rare Diseases at Sanford, is based at Sanford Research in Sioux Falls, South Dakota. It provides researchers with a centralized, international patient registry for all rare diseases. This program allows patients and researchers to connect as easily as possible to help advance treatments and cures for rare diseases. The CoRDS team works with patient advocacy groups, individuals and researchers to help in the advancement of research in over 7,000 rare diseases. The registry is free for patients to enroll and researchers to access. Visit sanfordresearch.org/CoRDS to enroll.
Study Results: NO
Conditions: Rare Disorders|Undiagnosed Disorders|Disorders of Unknown Prevalence|Cornelia De Lange Syndrome|Prenatal Benign Hypophosphatasia|Perinatal Lethal Hypophosphatasia|Odontohypophosphatasia|Adult Hypophosphatasia|Childhood-onset Hypophosphatasia|Infantile Hypophosphatasia|Hypophosphatasia|Kabuki Syndrome|Bohring-Opitz Syndrome|Narcolepsy Without Cataplexy|Narcolepsy-cataplexy|Hypersomnolence Disorder|Idiopathic Hypersomnia Without Long Sleep Time|Idiopathic Hypersomnia With Long Sleep Time|Idiopathic Hypersomnia|Kleine-Levin Syndrome|Kawasaki Disease|Leiomyosarcoma|Leiomyosarcoma of the Corpus Uteri|Leiomyosarcoma of the Cervix Uteri|Leiomyosarcoma of Small Intestine|Acquired Myasthenia Gravis|Addison Disease|Hyperacusis (Hyperacousis)|Juvenile Myasthenia Gravis|Transient Neonatal Myasthenia Gravis|Williams Syndrome|Lyme

Disease|Myasthenia Gravis|Marinesco Sjogren Syndrome(Marinesco-Sjogren Syndrome)|Isolated Klippel-Feil Syndrome|Frasier Syndrome|Denys-Drash Syndrome|Beckwith-Wiedemann Syndrome|Emanuel Syndrome|Isolated Aniridia|Axenfeld-Rieger Syndrome|Aniridia-intellectual Disability Syndrome|Aniridia - Renal Agenesis - Psychomotor Retardation|Aniridia - Ptosis - Intellectual Disability - Familial Obesity|Aniridia - Cerebellar Ataxia - Intellectual Disability|Aniridia - Absent Patella|Aniridia|Peters Anomaly - Cataract|Peters Anomaly|Potocki-Shaffer Syndrome|Silver-Russell Syndrome Due to Maternal Uniparental Disomy of Chromosome 11|Silver-Russell Syndrome Due to Imprinting Defect of 11p15|Silver-Russell Syndrome Due to 11p15 Microduplication|Syndromic Aniridia|WAGR Syndrome|Wolf-Hirschhorn Syndrome|4p16.3 Microduplication Syndrome|4p Deletion Syndrome, Non-Wolf-Hirschhorn Syndrome|Autosomal Recessive Stickler Syndrome|Stickler Syndrome Type 2|Stickler Syndrome Type 1|Stickler Syndrome|Mucolipidosis Type 4|X-linked Spinocerebellar Ataxia Type 4|X-linked Spinocerebellar Ataxia Type 3|X-linked Intellectual Disability - Ataxia - Apraxia|X-linked Progressive Cerebellar Ataxia|X-linked Non Progressive Cerebellar Ataxia|X-linked Cerebellar Ataxia|Vitamin B12 Deficiency Ataxia|Toxic Exposure Ataxia|Unclassified Autosomal Dominant Spinocerebellar Ataxia|Thyroid Antibody Ataxia|Sporadic Adult-onset Ataxia of Unknown Etiology|Spinocerebellar Ataxia With Oculomotor Anomaly|Spinocerebellar Ataxia With Epilepsy|Spinocerebellar Ataxia With Axonal Neuropathy Type 2|Spinocerebellar Ataxia Type 8|Spinocerebellar Ataxia Type 7|Spinocerebellar Ataxia Type 6|Spinocerebellar Ataxia Type 5|Spinocerebellar Ataxia Type 4|Spinocerebellar Ataxia Type 37|Spinocerebellar Ataxia Type 36|Spinocerebellar Ataxia Type 35|Spinocerebellar Ataxia Type 34|Spinocerebellar Ataxia Type 32|Spinocerebellar Ataxia Type 31|Spinocerebellar Ataxia Type 30|Spinocerebellar Ataxia Type 3|Spinocerebellar Ataxia Type 29|Spinocerebellar Ataxia Type 28|Spinocerebellar Ataxia Type 27|Spinocerebellar Ataxia Type 26|Spinocerebellar Ataxia Type 25|Spinocerebellar Ataxia Type 23|Spinocerebellar Ataxia Type 22|Spinocerebellar Ataxia Type 21|Spinocerebellar Ataxia Type 20|Spinocerebellar Ataxia Type 2|Spinocerebellar Ataxia Type 19/22|Spinocerebellar Ataxia Type 18|Spinocerebellar Ataxia Type 17|Spinocerebellar Ataxia Type 16|Spinocerebellar Ataxia Type 15/16|Spinocerebellar Ataxia Type 14|Spinocerebellar Ataxia Type 13|Spinocerebellar Ataxia Type 12|Spinocerebellar Ataxia Type 11|Spinocerebellar Ataxia Type 10|Spinocerebellar Ataxia Type 1 With Axonal Neuropathy|Spinocerebellar Ataxia Type 1|Spinocerebellar Ataxia - Unknown|Spinocerebellar Ataxia - Dysmorphism|Non Progressive Epilepsy and/or Ataxia With Myoclonus as a Major Feature|Spasticity-ataxia-gait Anomalies Syndrome|Spastic Ataxia With Congenital Miosis|Spastic Ataxia - Corneal Dystrophy|Spastic Ataxia|Rare Hereditary Ataxia|Rare Ataxia|Recessive Mitochondrial Ataxia Syndrome|Progressive Epilepsy and/or Ataxia With Myoclonus as a Major Feature|Posterior Column Ataxia - Retinitis Pigmentosa|Post-Stroke Ataxia|Post-Head Injury Ataxia|Post Vaccination Ataxia|Polyneuropathy - Hearing Loss - Ataxia - Retinitis Pigmentosa - Cataract|Muscular Atrophy - Ataxia -

Retinitis Pigmentosa – Diabetes Mellitus|Non-hereditary Degenerative Ataxia|Paroxysmal Dystonic Choreathetosis With Episodic Ataxia and Spasticity|Olivopontocerebellar Atrophy – Deafness|NARP Syndrome| Myoclonus – Cerebellar Ataxia – Deafness|Multiple System Atrophy, Parkinsonian Type|Multiple System Atrophy, Cerebellar Type|Multiple System Atrophy|Maternally-inherited Leigh Syndrome|Machado-Joseph Disease Type 3|Machado-Joseph Disease Type 2|Machado-Joseph Disease Type 1|Leigh Syndrome|Late-onset Ataxia With Dementia|Infection or Post Infection Ataxia|GAD Ataxia|Hereditary Episodic Ataxia|Gliadin/ Gluten Ataxia|Friedreich Ataxia|Fragile X-associated Tremor/Ataxia Syndrome|Familial Paroxysmal Ataxia|Exposure to Medications Ataxia| Episodic Ataxia With Slurred Speech|Episodic Ataxia Unknown Type| Episodic Ataxia Type 7|Episodic Ataxia Type 6|Episodic Ataxia Type 5| Episodic Ataxia Type 4|Episodic Ataxia Type 3|Episodic Ataxia Type 1| Epilepsy and/or Ataxia With Myoclonus as Major Feature|Early-onset Spastic Ataxia-neuropathy Syndrome|Early-onset Progressive Neurodegeneration – Blindness – Ataxia – Spasticity|Early-onset Cerebellar Ataxia With Retained Tendon Reflexes|Early-onset Ataxia With Dementia|Childhood-onset Autosomal Recessive Slowly Progressive Spinocerebellar Ataxia|Dilated Cardiomyopathy With Ataxia|Cataract – Ataxia – Deafness|Cerebellar Ataxia, Cayman Type|Cerebellar Ataxia With Peripheral Neuropathy|Cerebellar Ataxia – Hypogonadism|Cerebellar Ataxia – Ectodermal Dysplasia|Cerebellar Ataxia – Areflexia – Pes Cavus – Optic Atrophy – Sensorineural Hearing Loss|Brain Tumor Ataxia| Brachydactyly – Nystagmus – Cerebellar Ataxia|Benign Paroxysmal Tonic Upgaze of Childhood With Ataxia|Autosomal Recessive Syndromic Cerebellar Ataxia|Autosomal Recessive Spastic Ataxia With Leukoencephalopathy|Autosomal Recessive Spastic Ataxia of Charlevoix-Saguenay|Autosomal Recessive Spastic Ataxia – Optic Atrophy – Dysarthria|Autosomal Recessive Spastic Ataxia|Autosomal Recessive Metabolic Cerebellar Ataxia|Autosomal Dominant Spinocerebellar Ataxia Due to Repeat Expansions That do Not Encode Polyglutamine|Autosomal Recessive Ataxia, Beauce Type|Autosomal Recessive Ataxia Due to Ubiquinone Deficiency|Autosomal Recessive Ataxia Due to PEX10 Deficiency|Autosomal Recessive Degenerative and Progressive Cerebellar Ataxia|Autosomal Recessive Congenital Cerebellar Ataxia Due to MGLUR1 Deficiency|Autosomal Recessive Congenital Cerebellar Ataxia Due to GRID2 Deficiency|Autosomal Recessive Congenital Cerebellar Ataxia| Autosomal Recessive Cerebellar Ataxia-pyramidal Signs-nystagmus-oculomotor Apraxia Syndrome|Autosomal Recessive Cerebellar Ataxia-epilepsy-intellectual Disability Syndrome Due to WWOX Deficiency| Autosomal Recessive Cerebellar Ataxia-epilepsy-intellectual Disability Syndrome Due to TUD Deficiency|Autosomal Recessive Cerebellar Ataxia-epilepsy-intellectual Disability Syndrome Due to KIAA0226 Deficiency| Autosomal Recessive Cerebellar Ataxia-epilepsy-intellectual Disability Syndrome|Autosomal Recessive Cerebellar Ataxia With Late-onset Spasticity|Autosomal Recessive Cerebellar Ataxia Due to STUB1 Deficiency|Autosomal Recessive Cerebellar Ataxia Due to a DNA Repair Defect|Autosomal Recessive Cerebellar Ataxia – Saccadic Intrusion| Autosomal Recessive Cerebellar Ataxia – Psychomotor Retardation|

Autosomal Recessive Cerebellar Ataxia - Blindness - Deafness|Autosomal Recessive Cerebellar Ataxia|Autosomal Dominant Spinocerebellar Ataxia Due to a Polyglutamine Anomaly|Autosomal Dominant Spinocerebellar Ataxia Due to a Point Mutation|Autosomal Dominant Spinocerebellar Ataxia Due to a Channelopathy|Autosomal Dominant Spastic Ataxia Type 1|Autosomal Dominant Spastic Ataxia|Autosomal Dominant Optic Atrophy|Ataxia-telangiectasia Variant|Ataxia-telangiectasia|Autosomal Dominant Cerebellar Ataxia, Deafness and Narcolepsy|Autosomal Dominant Cerebellar Ataxia Type 4|Autosomal Dominant Cerebellar Ataxia Type 3|Autosomal Dominant Cerebellar Ataxia Type 2|Autosomal Dominant Cerebellar Ataxia Type 1|Autosomal Dominant Cerebellar Ataxia|Ataxia-telangiectasia-like Disorder|Ataxia With Vitamin E Deficiency|Ataxia With Dementia|Ataxia - Oculomotor Apraxia Type 1|Ataxia - Other|Ataxia - Genetic Diagnosis - Unknown|Acquired Ataxia|Adult-onset Autosomal Recessive Cerebellar Ataxia|Alcohol Related Ataxia|Multiple Endocrine Neoplasia|Multiple Endocrine Neoplasia Type II|Multiple Endocrine Neoplasia Type 1|Multiple Endocrine Neoplasia Type 2|Multiple Endocrine Neoplasia, Type IV|Multiple Endocrine Neoplasia, Type 3|Multiple Endocrine Neoplasia (MEN) Syndrome|Multiple Endocrine Neoplasia Type 2B|Multiple Endocrine Neoplasia Type 2A|Atypical Hemolytic Uremic Syndrome|Atypical HUS|Wiedemann-Steiner Syndrome|Breast Implant-Associated Anaplastic Large Cell Lymphoma|Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA)|Hemophagocytic Lymphohistiocytosis|Behcet's Disease|Alagille Syndrome|Inclusion Body Myopathy With Early-onset Paget Disease and Frontotemporal Dementia (IBMPFD)|Lowe Syndrome|Pitt Hopkins Syndrome|1p36 Deletion Syndrome|Jansen Type Metaphyseal Chondrodysplasia|Cockayne Syndrome|Chronic Recurrent Multifocal Osteomyelitis|CRMO|Malan Syndrome|Hereditary Sensory and Autonomic Neuropathy Type Ie|VCP Disease|Hypnic Jerking|Sleep Myoclonus|Mollaret Meningitis|Recurrent Viral Meningitis|CRB1|Leber Congenital Amaurosis|Retinitis Pigmentosa|Rare Retinal Disorder|KCNMA1-Channelopathy|Primary Biliary Cirrhosis|ZMYND11|Transient Global Amnesia|Glycogen Storage Disease|Alstrom Syndrome|White Sutton Syndrome|DNM1|EIEE31|Myhre Syndrome|Recurrent Respiratory Papillomatosis|Laryngeal Papillomatosis|Tracheal Papillomatosis|Refsum Disease|Nicolaides Baraitser Syndrome|Leukodystrophy|Tango2|Cauda Equina Syndrome|Rare Gastrointestinal Disorders|Achalasia-Addisonian Syndrome|Achalasia Cardia|Achalasia Icrocephaly Syndrome|Anal Fistula|Congenital Sucrase-Isomaltase Deficiency|Eosinophilic Gastroenteritis|Idiopathic Gastroparesis|Hirschsprung Disease|Rare Inflammatory Bowel Disease|Intestinal Pseudo-Obstruction|Scleroderma|Short Bowel Syndrome|Sacral Agenesis|Sacral Agenesis Syndrome|Caudal Regression|Scheuermann Disease|SMC1A Truncated Mutations (Causing Loss of Gene Function)|Cystinosis|Juvenile Nephropathic Cystinosis|Nephropathic Cystinosis|Kennedy Disease|Spinal Bulbar Muscular Atrophy|Warburg Micro Syndrome|Mucolipidoses|Mitochondrial Diseases|Mitochondrial Aminoacyl-tRNA Synthetases|Mt-aaRS Disorders|Hypertrophic Olivary Degeneration|Non-Ketotic Hyperglycinemia|Fish Odor Syndrome|Halitosis
Interventions:
Primary Outcome Measures: To accelerate research into rare disorders

by connecting individuals who are interested in research and who have been diagnosed with a rare disorder (or a disorder of unknown prevalence, or who are undiagnosed) with researchers who study rare diseases., 100 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Sanford Health
Collaborators: National Ataxia Foundation|International WAGR Syndrome Association|4p- Support Group|ML4 Foundation|Cornelia de Lange Syndrome Foundation|Stickler Involved People|Kawasaki Disease Foundation|Klippel-Feil Syndrome Alliance|Klippel-Feil Syndrome Freedom|Hyperacusis Research Limited|Hypersomnia Foundation|Kabuki Syndrome Network|Kleine-Levin Syndrome Foundation|Leiomyosarcoma Direct Research Foundation|Marinesco-Sjogren Syndrome Support Group - NORD|Mucolipidosis Type IV (ML4) Foundation|People with Narcolepsy 4 People with Narcolepsy (PWN4PWN)|Soft Bones Incorporated|American Multiple Endocrine Neoplasia Support|Atypical Hemolytic Uremic Syndrome Foundation|All Things Kabuki|Wiedemann-Steiner Syndrome Foundation|Breast Implant Victim Advocates|PROS Foundation|American Behcet's Disease Association|Alstrom United Kingdom|Athymia|Curing Retinal Blindness Foundation|HSAN1E Society|1p36 Deletion Support and Awareness|The Alagille Syndrome Alliance|Autoinflammatory Alliance| Beyond Batten Disease Foundation|Bohring-Opitz Syndrome Foundation, INC|Cockayne Syndrome Network (Share and Care)|CRMO Foundation|Cure VCP Disease,INC|FOD Support|Cystinosis Research Foundation|Global DARE Foundation|Hypnic Jerk-Sleep Myoclonus Support Group|Jansen's Foundation|KCNMA1 Channelopathy International Advocacy Foundation| Kawasaki Disease Foundation Australia|Life with LEMS Foundation|Lowe Syndrome Association|The Malan Syndrome Foundation|Maple Syrup Urine Disease Family Support Group|International Association for Muscle Glycogen Storage Disease (IamGSD)|Myhre Syndrome Foundation|DNM1 Families|Nicolaides Baraitser Syndrome (NCBRS) Worldwide Foundation| The PBCers Organization|Pitt Hopkins Research Foundation|Progressive Familial Intrahepatic Cholestasis Advocacy and Resource Network, Inc| Recurrent Meningitis Association|Recurrent Respiratory Papillomatosis Foundation|Remember the Girls|Smith-Kingsmore Syndrome Foundation|SPG Research Foundation|Team Telomere|Transient Global Amnesia Project|The Charlotte & Gwenyth Gray Foundation|The Cute Syndrome Foundation|The Maddi Foundation|White Sutton Syndrome Foundation|Zmynd11 Gene Disorder|Cauda Equina Foundation, Inc|Tango2 Research Foundation| Noah's Hope - Hope4Bridget Foundation|Project Sebastian|SMC1A Epilepsy Foundation|International Foundation for Gastrointestinal Disorders| Endosalpingiosis Foundation, Inc|International Sacral Agenesis/Caudal Regression Association (ISACRA)|Scheuermann's Disease Fund|Batten Disease Support and Research Association|Kennedy's Disease Association|Cure Mito Foundation|Warburg Micro Research Foundation| Cure Mucolipidosis|Riaan Research Initiative|CureARS A NJ Nonprofit Corporation|CACNA1H Alliance|IMBS Alliance|SHINE-Syndrome Foundaion| Non- Ketotic Hyperglycinemia (NKH) Crusaders|Hypertrophic Olivary Degeneration Association (HODA)|National Organization for Disorders of

the Corpus Callosum (NODCC)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 20000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 03-10-014|Hypersomnia Foundation|National Ataxia Foundation|4p- Support Group|CdLS Foundation|Hyperacusis Research Limited|Kabuki Syndrome Network|Kawasaki Disease Foundation|Klippel-Feil Syndrome Freedom|Leiomyosarcoma Direct Research|MSS Support Group|ML4 Foundation|Stickler Involved People|IWSA|Soft Bones|PWN4PWN|aHUS|Klippel-Feil Syndrome Alliance|American MEN Support|Kleine-Levin Syndrome|All Things Kabuki|WSS Foundation|BIVA|ABDA|PROS Foundation (HLH)|Alagille Syndrome Association|Cure VCP Disease, Inc.|Lowe Syndrome Association|Pitt Hopkins|Cure Batten Disease|Hypnic Jerk/Sleep Myoclonus|1p36 DSA|Jansen Foundation|Share and Care Network|CRMO|The Malan Syndrome Foundation|HSAN1E Society|Alstrom United Kingdomg|Athymia|CRB1 Foundation|DNM1 Families|Global DARE Foundation|KCIAF|MSUD FSG|IamGSD|Myhre Syndrome Foundation|NCBRS|PBCers Organization|DBA - PFIC Network|Remember the Girls|RRPF|SKS Foundation|SPG15 Research Foundation|Team Telomere|TGA Project|The Cute Syndrome Foundation|WSS Foundation|Zmynd11 Gene Disorder|SPG11 and SPG15|Endosalpingiosis Foundation|Cauda Equina Foundation|Tango2 Research Foundation|SMC1A Epilepsy|IFFGD|Noah's Hope - Hope4Bridget|Project Sebastian|ISACRA|Scheuermann's Disease Fund|BDSRA|Kennedy's Disease Assocation|Cystinosis Research Foundation|Cure Mito Foundation|Warburg Micro Research|Riaan Research Initiative|Cure Mucolipidosis|CureARS A NJ Nonprofit|CACNA1H Alliance|IMBS Alliance|Non-Ketotic Hyperglycinemia|Corpus Callosum Disorders|SHINE Syndrome Foundation|HODA
Start Date: 2010-07
Primary Completion Date: 2100-12
Completion Date: 2100-12
First Posted: 2013-02-15
Results First Posted:
Last Update Posted: 2022-06-27
Locations: Sanford Health, Sioux Falls, South Dakota, 57104, United States|Online Patient Enrollment System, Sydney, Australia
Study Documents:

NCT Number: NCT04472468
Study Title: Primary Percutaneous Pericardiotomy for Malignant Pericardial Effusion (PMAP)
Study URL: https://beta.clinicaltrials.gov/study/NCT04472468
Acronym: PMAP
Study Status: RECRUITING
Brief Summary: Pericardial effusion is a common complication in patients with metastatic malignancy. While pericardiocentesis provide

effective relieve from life-threatening situation such as cardiac tamponade, recurrence of pericardial effusion after pericardiocentesis is common. We hypothesize that percutaneous balloon pericardiotomy in addition to standard pericardiocentesis with prolonged drainage can prevent pericardial effusion recurrence in patients with malignant pericardial effusion.
Study Results: NO
Conditions: Pericardial Effusion Malignant
Interventions: DEVICE: Percutaneous Balloon Pericardiotomy
Primary Outcome Measures: Pericardial effusion recurrence, Recurrence of pericardial effusion after index procedure, defined as development of moderate or more pericardial effusion (\>10mm) on follow-up imaging., 3 months|Procedural related complications, Procedural related complications including procedural related death, need for urgent surgical intervention, pleural effusion and pneumothorax, Immediate after intervention
Secondary Outcome Measures: Survival, overall survival, 3 months|Pericardial effusion free survival, survival without recurrence of pericardial effusion, 3 months|cardiac tamponade, Occurrence of cardiac tamponade as defined by echocardiographic finding of any of the following: 1. diastolic collapse of the right atrium, 2. Diastolic collapse of the right ventricle, 3. respiratory variation of the mitral E' velocity \> 25% or tricuspid E' velocity \>40%, 4. dilated IVC \>20mm and \<50% respiratory reduction., 3 months|Quality of life measure (using Functional Assessment of Cancer Therapy - General version (Chinese version))., 27 items self-administered questionnaire examining the impact of a cancer related therapy on 4 domains of life using a 5-points scale., 3 months|Pericardial drain indwelling time, Pericardial drain indwelling time at index procedure, during index procedure|Catheter tract tumor seeding, Evidence of tumour seeding in catheter tract or extra-pericardial cavity, 3 months|Ascites/Pleural effusion, Occurrence of ascites and pleural effusion by either clinical examination or on radiological investigation., 3 months
Other Outcome Measures:
Sponsor: Chinese University of Hong Kong
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 150
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: C18-004
Start Date: 2020-03-01
Primary Completion Date: 2024-03-30
Completion Date: 2024-06-30
First Posted: 2020-07-15
Results First Posted:

Last Update Posted: 2022-03-21
Locations: Prince of Wales Hospital, Hong Kong, Shatin, 0000, Hong Kong
Study Documents:

NCT Number: NCT03050268
Study Title: Familial Investigations of Childhood Cancer Predisposition
Study URL: https://beta.clinicaltrials.gov/study/NCT03050268
Acronym: SJFAMILY
Study Status: RECRUITING
Brief Summary: NOTE: This is a research study and is not meant to be a substitute for clinical genetic testing. Families may never receive results from the study or may receive results many years from the time they enroll. If you are interested in clinical testing please consider seeing a local genetic counselor or other genetics professional. If you have already had clinical genetic testing and meet eligibility criteria for this study as shown in the Eligibility Section, you may enroll regardless of the results of your clinical genetic testing.

While it is well recognized that hereditary factors contribute to the development of a subset of human cancers, the cause for many cancers remains unknown. The application of next generation sequencing (NGS) technologies has expanded knowledge in the field of hereditary cancer predisposition. Currently, more than 100 cancer predisposing genes have been identified, and it is now estimated that approximately 10% of all cancer patients have an underlying genetic predisposition.

The purpose of this protocol is to identify novel cancer predisposing genes and/or genetic variants. For this study, the investigators will establish a Data Registry linked to a Repository of biological samples. Health information, blood samples and occasionally leftover tumor samples will be collected from individuals with familial cancer. The investigators will use NGS approaches to find changes in genes that may be important in the development of familial cancer. The information gained from this study may provide new and better ways to diagnose and care for people with hereditary cancer.

PRIMARY OBJECTIVE:

* Establish a registry of families with clustering of cancer in which clinical data are linked to a repository of cryopreserved blood cells, germline DNA, and tumor tissues from the proband and other family members.

SECONDARY OBJECTIVE:

* Identify novel cancer predisposing genes and/or genetic variants in families with clustering of cancer for which the underlying genetic basis is unknown.

Study Results: NO
Conditions: Acute Leukemia|Adenomatous Polyposis|Adrenocortical Carcinoma|AML|BAP1 Tumor Predisposition Syndrome|Carney Complex|Choroid Plexus Carcinoma|Constitutional Mismatch Repair Deficiency Syndrome|Diamond-Blackfan Anemia|DICER1 Syndrome|Dyskeratosis Congenita|Emberger Syndrome|Familial Acute Myeloid Leukemia|Familial Adenomatous Polyposis|Fanconi Anemia|Familial Cancer|Familial Wilms Tumor|Familial Neuroblastoma|GIST|Hereditary Breast and Ovarian Cancer|Hereditary Paraganglioma-Pheochromocytoma Syndrome|Hodgkin Lymphoma|Juvenile Polyposis|Li-Fraumeni Syndrome|Lynch Syndrome|MDS|Melanoma Syndrome|Multiple Endocrine Neoplasia Type 1|Multiple Endocrine Neoplasia Type 2|Neuroblastoma|Neurofibromatosis Type 1|Neurofibromatosis Type II|Nevoid Basal Cell Carcinoma Syndrome|Non Hodgkin Lymphoma|Noonan Syndrome and Other Rasopathy|Overgrowth Syndromes|Pancreatic Cancer|Peutz-Jeghers Syndrome|Pheochromocytoma/Paraganglioma|PTEN Hamartoma Tumor Syndrome|Retinoblastoma|Rhabdoid Tumor Predisposition Syndrome|Rhabdomyosarcoma|Rothmund-Thomson Syndrome|Tuberous Sclerosis|Von Hippel-Lindau Disease
Interventions:
Primary Outcome Measures: Identification of novel cancer predisposing genes, Probands and cancer affected and unaffected relatives from selected families will be sequenced using Whole Genome Sequencing (WGS) or possibly Whole Exome Sequencing (WES) and analyzed to identify new predisposing genetic variants that co-segregate with the tumor phenotype. Data will be analyzed using annotation and filtering strategies to identify potentially deleterious germline mutations that co-segregate with disease., Up to 20 years following study activation
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: St. Jude Children's Research Hospital
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 3000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SJFAMILY
Start Date: 2017-04-06
Primary Completion Date: 2037-03-31
Completion Date: 2037-03-31
First Posted: 2017-02-10
Results First Posted:
Last Update Posted: 2023-05-17
Locations: St. Jude Children's Research Hospital, Memphis, Tennessee, 38105, United States
Study Documents:

NCT Number: NCT00854568

Study Title: Comparison Study of Doxorubicin Versus Epirubicin-induced Cardiotoxicity in Patients With DLBCL
Study URL: https://beta.clinicaltrials.gov/study/NCT00854568
Acronym:
Study Status: COMPLETED
Brief Summary: The aim of this study is to compare CHOP versus CEOP-induced cardiotoxicity in patients with aggressive B-cell lymphoma. The hypothesis is epirubicin is associated with less cardiotoxicity without compromising the efficacy.
Study Results: NO
Conditions: Lymphoma
Interventions: DRUG: CEOP regimen|DRUG: CHOP regimen
Primary Outcome Measures: Cardiotoxicity (Class III or IV cardiotoxicity according to New York Heart Association (NYHA) Classification or LVEF abnormality [< 50% or a decrease in absolute LVEF ≥ 10%) by post-treatment RNA]), 18 weeks
Secondary Outcome Measures: Objective response rate, Six weeks
Other Outcome Measures:
Sponsor: Fudan University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 398
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: LMTG 09-01
Start Date: 2009-03
Primary Completion Date: 2012-12
Completion Date: 2013-02
First Posted: 2009-03-03
Results First Posted:
Last Update Posted: 2014-08-20
Locations: Fudan University Cancer Hospital, Shanghai, Shanghai, 200032, China
Study Documents:

NCT Number: NCT03391115
Study Title: Personalized Experiences to Inform Improved Communication for Minorities With Life Limiting Illness
Study URL: https://beta.clinicaltrials.gov/study/NCT03391115
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this research is to develop patient-centered palliative care interventions to improve patient-provider communication and Quality of Life (QoL) of ethnic and racial minority patients living with life-limiting illnesses. Eliciting personal experiences is an effective way for patients to communicate their

cultural values and beliefs. This study will assess how to integrate the patients' personal experience narratives into the electronic health record (EHR). The primary hypothesis is that the implementation of a patient-centered intervention to elicit personal experiences that are included in the EHR will improve patient-provider communication and patients' QoL.
Study Results: YES
Conditions: COPD|Heart Failure|Cancer
Interventions: BEHAVIORAL: Storytelling Intervention for Patient Participants|BEHAVIORAL: Storytelling Intervention for Nurse Participants
Primary Outcome Measures: Number of Completed Exit Interviews From Patients on Feasibility of Their Use of Their Narrative Integrated Into EHR, Using an observational design, this measure (exit interviews) were completed with 20 inpatient participants and 18 nurse participants. The qualitative data from the interviews were used to define and refine the storytelling intervention. The data collected from the exit interview is qualitative in nature and therefore does not have a numerical value., 1-2 weeks
Secondary Outcome Measures:
Other Outcome Measures: Usability Assessment Via the System Usability Scale(SUS), Range of 0 to 100, With Higher Number Representing a Better Outcome SUS Scores Have a Range of 0 to 100, the Higher the Number Represents a Better Outcome., This study will utilize an observational design to define and refine the storytelling intervention, seeking input from the key stakeholders: providers (acute care bedside nurses).The SUS scale is a 10 item Likert scale which gives a global view of subjective assessment of usability with five item responses options from strongly agree to strongly disagree. SUS yields a single number representing a composite measure of the overall usability of the system being studied. Note that scores for individual items are not meaningful on their own. To calculate the SUS score, first sum the score contributions from each item. Each item's score contribution will range from 0 to 4. For items 1,3,5,7, and 9, the score contribution is the scale position minus 1. For items 2,4,6,8, and 10, the contribution is 5 minus the scale position. Multiply the sum of the scores by 2.5 to obtain the overall value of the SUS, with the higher the number, the better the outcome., 1-2 weeks
Sponsor: University of Colorado, Denver
Collaborators: National Institute of Nursing Research (NINR)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 38
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 17-1885.cc|1K99NR016686-01A1
Start Date: 2017-11-15

Primary Completion Date: 2018-11-30
Completion Date: 2018-11-30
First Posted: 2018-01-05
Results First Posted: 2019-09-26
Last Update Posted: 2021-02-18
Locations: University of Colorado Hospital, Aurora, Colorado, 80045, United States
Study Documents: Study Protocol|Informed Consent Form

NCT Number: NCT05703126
Study Title: Clinical and Diagnostic Significance of Endothelial Dysfunction and Myocardial Contractility in Patients With AML
Study URL: https://beta.clinicaltrials.gov/study/NCT05703126
Acronym:
Study Status: RECRUITING
Brief Summary: Acute myeloid leukemia (AML) is a clonal neoplastic disease of the hematopoietic tissue associated with a mutation in the precursor cell of hematopoiesis, which results in a differentiation block and uncontrolled proliferation of immature myeloid cells.

Anthracycline antibiotics have been an integral part of the treatment of acute myeloid leukemia since the 1970s. However, the clinical usefulness of anthracyclines is limited primarily by the high incidence of cardiotoxicity. According to the European Society of Cardiology guidelines for cardio-oncology, cardiovascular toxicity is defined as any impairment of cardiac function associated with anticancer treatment, as the term encompasses both a wide range of possible clinical manifestations and an etiological relationship with various treatments, including chemotherapy, radiation therapy, immunotherapy and treatment with targeted drugs. Cardiovascular toxicity can be acute, subacute or delayed, manifesting many years after chemotherapy or radiation therapy, involving a number of cardiac structures, which can lead to the development of heart failure, coronary heart disease, valvular heart disease, arrhythmias, including cardiac conduction disorders and diseases of the pericardium.

Anthracycline-induced cardiotoxicity is the negative effect of anthracyclines on normal cardiac activity due to their toxic effects on the heart muscle and the cardiac conduction system. Anthracycline-induced cardiotoxicity manifests as asymptomatic left ventricular dysfunction in 57% of treated patients and restrictive or dilated cardiomyopathy leading to congestive heart failure (CHF) in 16% to 20% of patients. Anthracycline-induced congestive heart failure is often resistant to therapy and has a mortality rate of up to 79%. Thus, there is a need for early detection of cardiovascular dysfunction associated with chemotherapy treatment of acute myeloid leukemia in order to timely prescribe drug therapy.

Purpose of the study To optimize the early detection of endothelial dysfunction and left ventricular myocardial contractility in patients

with acute myeloid leukemia during chemotherapy treatment based on a comprehensive assessment of instrumental and laboratory research parameters.

Expected results Based on a comprehensive analysis using laser Doppler flowmetry, stress echocardiography with the determination of global longitudinal strain of the myocardium, biochemical markers of endothelial damage and cardiac biomarkers, a correlation between violations of the contractility of the left ventricular myocardium and violations of the vasoregulatory function of the vascular endothelium will be revealed, which will allow developing an algorithm for early detection of cardiomyopathy and vascular complications in patients with acute myeloid leukemia during chemotherapy treatment.
Study Results: NO
Conditions: Acute Myeloid Leukemia, Adult|Cardiotoxicity|Endothelial Dysfunction
Interventions: DIAGNOSTIC_TEST: History taking|DIAGNOSTIC_TEST: Anthropometry|DIAGNOSTIC_TEST: Complete blood count|DIAGNOSTIC_TEST: Biochemical blood test|DIAGNOSTIC_TEST: Coagulogram|DIAGNOSTIC_TEST: Immunoenzymatic analysis of the level of endothelin-1, asymmetric dimethylarginine|DIAGNOSTIC_TEST: Stress echocardiography with the definition of global longitudinal deformation of the myocardium|DIAGNOSTIC_TEST: Triplex scanning of neck vessels|DIAGNOSTIC_TEST: Electrocardiography|DIAGNOSTIC_TEST: Ultrasound of the abdominal cavity (with calculation of the area of the spleen) and lymph nodes|DIAGNOSTIC_TEST: Cytogenetic examination of the bone marrow to determine genetic abnormalities.|DIAGNOSTIC_TEST: Cytological examination of bone marrow cells with cytochemical examination|DIAGNOSTIC_TEST: Immunophenotypic examination of the bone marrow by flow cytometry|DIAGNOSTIC_TEST: Determination of the presence of a FLT3 mutation using the PCR Method|DIAGNOSTIC_TEST: laser Doppler flowmetry
Primary Outcome Measures: Change of global longitudinal strain of 15% or more relative to the initial values, Change of global longitudinal strain of the myocardium according to stress echocardiography by 15% or more relative to the values obtained before the start of chemotherapy treatment., Evaluation is carried out within 1 week after each course of chemotherapy up to 10 months, evaluated after each course of induction of remission and consolidation of remission.
Secondary Outcome Measures: Change of the index of microcirculation according to laser Doppler flowmetry, Change of the microcirculation index according to the results of laser Doppler flowmetry in relation to the values obtained before the start of chemotherapy treatment., Evaluation is carried out within 1 week after each course of chemotherapy up to 10 months, evaluated after each course of induction of remission and consolidation of remission.|Change of the Coefficient of Variation of Microcirculation According to Laser Doppler Fluometry, Change of the coefficient of variation of microcirculation according to the results of laser Doppler flowmetry in relation to the values obtained before the start of chemotherapy treatment., Evaluation is

carried out within 1 week after each course of chemotherapy up to 10 months, evaluated after each course of induction of remission and consolidation of remission.|Change of the level of highly sensitive T-troponin, Change of the level of highly sensitive T-troponin, which goes beyond the reference values, in relation to the values obtained before the start of chemotherapy treatment., Evaluation is carried out within 1 week after each course of chemotherapy up to 10 months, evaluated after each course of induction of remission and consolidation of remission.|Change of brain natriuretic peptide level, Change of the level of brain natriuretic peptide that goes beyond the reference values, in relation to the values obtained before the start of chemotherapy treatment., Evaluation is carried out within 1 week after each course of chemotherapy up to 10 months, evaluated after each course of induction of remission and consolidation of remission.|Change of the level of asymmetric dimethylarginine, Change of the level of asymmetric dimethylarginine that goes beyond the reference values, in relation to the values obtained before the start of chemotherapy treatment., Evaluation is carried out within 1 week after each course of chemotherapy up to 10 months, evaluated after each course of induction of remission and consolidation of remission.|Change of the level of endothelin-1, Change of the level of endothelin-1, which goes beyond the reference values, in relation to the values obtained before the start of chemotherapy treatment., Evaluation is carried out within 1 week after each course of chemotherapy up to 10 months, evaluated after each course of induction of remission and consolidation of remission.
Other Outcome Measures:
Sponsor: Samara State Medical University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: DIAGNOSTIC
Other IDs: 77880421319552
Start Date: 2022-12-01
Primary Completion Date: 2025-01-01
Completion Date: 2025-08-03
First Posted: 2023-01-27
Results First Posted:
Last Update Posted: 2023-01-27
Locations: Clinics of the Samara Medical University, Samara, Samara Region, 443079, Russian Federation
Study Documents:

NCT Number: NCT00159926
Study Title: Cleansing of Suction Blood in Cardiac Surgery for Reduced

Inflammatory Response
Study URL: https://beta.clinicaltrials.gov/study/NCT00159926
Acronym:
Study Status: TERMINATED
Brief Summary: Cardiac surgery using heart and lung machine produces an inflammatory reaction in the body. This leads in few percent of cases to heart, lung, and kidney disturbances that potentially causes death. White blood cells in contact with the heart and lung machine and external surfaces release mediators partly responsible for this. Blood collected by the suction and the blood remaining in the heart and lung machine after its use, can be cleaned by a cell saver before reinfusion, and this might reduce the inflammatory response.
Study Results: NO
Conditions: Systemic Inflammatory Response Syndrome|Coronary Arteriosclerosis
Interventions: PROCEDURE: Cell saver|PROCEDURE: No cell saver
Primary Outcome Measures: Concentrations of IL-1B, IL-6, IL-8, IL-10, IL-12p70, TNFa, TNF-R1, TNF-R2, PCT and LPS in patient blood., 6, 24 and 72 hours after termination of CPB.
Secondary Outcome Measures: Bleeding, Intra- and postoperatively|Need for allogenic blood transfusions and blood products, Within submission|Clinical effect focusing on known complications to cardiac surgery and CPB, Within submission
Other Outcome Measures:
Sponsor: Rigshospitalet, Denmark
Collaborators: Danish Heart Foundation|Copenhagen Hospital Corporation
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 30
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 959583153|961501172|DHF: 03-2-3-35-22109|CHC: 20/fo03
Start Date: 2003-01
Primary Completion Date:
Completion Date: 2004-02
First Posted: 2005-09-12
Results First Posted:
Last Update Posted: 2008-01-14
Locations: Department of Cardiothoracic Surgery, Rigshospitalet, Copenhagen, 2100, Denmark
Study Documents:

NCT Number: NCT01431326
Study Title: Pharmacokinetics of Understudied Drugs Administered to Children Per Standard of Care
Study URL: https://beta.clinicaltrials.gov/study/NCT01431326
Acronym: PTN_POPS

Study Status: COMPLETED
Brief Summary: Understudied drugs will be administered to children per standard of care as prescribed by their treating caregiver and only biological sample collection during the time of drug administration will be involved. A total of approximately 7000 children aged \<21 years who are receiving these drugs for standard of care will be enrolled and will be followed for up a maximum of 90 days. The goal of this study is to characterize the pharmacokinetics of understudied drugs for which specific dosing recommendations and safety data are lacking. The prescribing of drugs to children will not be part of this protocol. Taking advantage of procedures done as part of routine medical care (i.e. blood draws) this study will serve as a tool to better understand drug exposure in children receiving these drugs per standard of care. The data collected through this initiative will also provide valuable pharmacokinetic and dosing information of drugs in different pediatric age groups as well as special pediatric populations (i.e. obese).
Study Results: NO
Conditions: Adenovirus|Anesthesia|Anxiety|Anxiolysis|Autism|Autistic Disorder|Bacterial Meningitis|Bacterial Septicemia|Benzodiazepine|Bipolar Disorder|Bone and Joint Infections|Central Nervous System Infections|Convulsions|Cytomegalovirus Retinitis|Early-onset Schizophrenia Spectrum Disorders|Epilepsy|General Anesthesia|Gynecologic Infections|Herpes Simplex Virus|Infantile Hemangioma|Infection|Inflammation|Inflammatory Conditions|Intra-abdominal Infections|Lower Respiratory Tract Infections|Migraines|Pain|Pneumonia|Schizophrenia|Sedation|Seizures|Skeletal Muscle Spasms|Skin and Skin-structure Infections|Treatment-resistant Schizophrenia|Urinary Tract Infections|Withdrawal|Sepsis|Gram-negative Infection|Bradycardia|Cardiac Arrest|Cardiac Arrhythmia|Staphylococcal Infections|Nosocomial Pneumonia|Neuromuscular Blockade|Methicillin Resistant Staphylococcus Aureus|Endocarditis|Neutropenia|Headache|Fibrinolytic Bleeding|Pulmonary Arterial Hypertension|CMV Retinitis|Hypertension|Chronic Kidney Diseases|Hyperaldosteronism|Hypokalemia|Heart Failure|Hemophilia|Heavy Menstrual Bleeding|Insomnia
Interventions: DRUG: The POPS study is collecting PK data on children prescribed the following drugs of interest per standard of care:
Primary Outcome Measures: Composite of pharmacokinetic outcomes for understudied drugs in children, As appropriate for each study drug, the following additional PK parameters will be estimated:

* maximum concentration (Cmax)
* time to achieve maximum concentration (Tmax)
* absorption rate constant (ka)
* elimination rate constant (kel)
* half-life (t1/2)
* area under the curve (AUC)

Penetration into body fluids will be determined by comparing exposure (i.e. AUC, Cmax) ratios between the body fluid and plasma or

comparison of concentrations in paired samples., Data will be collected throughout the hospital or outpatient stay up to 90 days
Secondary Outcome Measures: Composite pharmacodynamic outcomes of understudied drugs in children, When applicable, Monte Carlo simulations will be performed to evaluate therapeutic target attainment rates (pharmacodynamics) in the population of interest. The final PK model and parameters estimated in the population PK analysis will be used to perform these simulations., Data will be collected throughout the hospital or outpatient stay up to 90 days|Biomarkers associated with understudied drugs in children, The dosing, sampling, and demographic information recorded on the electronic data collection forms will be merged with the bioanalytical information to create a biomarker dataset for each study drug. Biomarkers will be identified using metabolomics/proteomics and pharmacogenomics methodologies. Samples for biomarker analysis will be stored for future use in a PTN designated biorepository. Associations between biomarkers and drug exposure will be explored by visual inspection (i.e. scatter plots) and statistical comparisons as needed., Data will be collected throughout the hospital or outpatient stay up to 90 days
Other Outcome Measures:
Sponsor: Daniel Benjamin
Collaborators: Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)|The Emmes Company, LLC
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 3520
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Pro00029638|IND 113645|IND 114369|IND 114531|IND 118358|HHSN20100006|HHSN27500020|HHSN27500027|HHSN27500043|HHSN27500049
Start Date: 2011-11
Primary Completion Date: 2019-11
Completion Date: 2019-11
First Posted: 2011-09-09
Results First Posted:
Last Update Posted: 2019-12-20
Locations: Alaska Native Medical Center, Anchorage, Alaska, 99508, United States|Arkansas Children's Hospital, Little Rock, Arkansas, 72202, United States|University of California at San Diego Medical Center, La Jolla, California, 92093, United States|Axis Clinical Trials, Los Angeles, California, 90036, United States|University of California, Los Angeles Medical Center, Los Angeles, California, 90095, United States|The Children's Hospital Colorado, Aurora, Colorado, 80045, United States|Yale New Haven Children's Hospital, New Haven, Connecticut, 06504, United States|Alfred I. DuPont Hospital for Children, Wilmington, Delaware, 19803, United States|Children's National Medical Center, Washington, District of Columbia, 20010, United States|University of Florida Jacksonville Shands Medical

Center, Jacksonville, Florida, 32209, United States|Kapiolani Womens and Childrens Medical Center, Honolulu, Hawaii, 96826, United States|Lurie Children's Hospital of Chicago, Chicago, Illinois, 60614, United States|Riley Hospital for Children at Indiana University, Indianapolis, Indiana, 46202, United States|University of Kansas Medical Center, Fairway, Kansas, 66205, United States|Children's Mercy Hospital and Clinics, Kansas City, Kansas, 66160, United States|Wesley Medical Center, Wichita, Kansas, 67214, United States|Norton Children's Hospital, Louisville, Kentucky, 40202, United States|Tulane University Health Science Center, New Orleans, Louisiana, 70112, United States|Ochsner Baptist Clinical Trials Unit, New Orleans, Louisiana, 70115-6969, United States|University of Maryland, Baltimore, Maryland, 21201, United States|Children's Hospital of Michigan, Detroit, Michigan, 48201, United States|University of Mississippi Medical Center, Jackson, Mississippi, 39216, United States|Children's Mercy Hospitals and Clinics, Kansas City, Missouri, 64108, United States|University of Montana, Missoula, Montana, 59804, United States|University of Nebraska Medical Center, Omaha, Nebraska, 68198, United States|Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, 03756, United States|University of New Mexico, Health Sciences Center, Albuquerque, New Mexico, 87131, United States|UNC Hospital Neonatal-Perinatal Medicine, Chapel Hill, North Carolina, 27599, United States|Duke University Medical Center (PICU / NICU), Durham, North Carolina, 27710, United States|Cincinnati Childrens Hospital Medical Center, Cincinnati, Ohio, 45229-3039, United States|Rainbow Babies and Children's Hospital, Cleveland, Ohio, 44106, United States|Akron Children's Hospital, Cleveland, Ohio, 44313, United States|Board of Regents of the University of Oklahoma, Oklahoma City, Oklahoma, 73104, United States|Oregon Health and Science University, Portland, Oregon, 97201-2701, United States|Rhode Island Hospital, Providence, Rhode Island, 02903, United States|Medical University of South Carolina, Charleston, South Carolina, 29425, United States|University of South Carolina, Columbia, South Carolina, 29203, United States|University of Utah Hospitals and Clinics, Salt Lake City, Utah, 84108, United States|University of Vermont Medical Center, Burlington, Vermont, 05405, United States|University of Virginia Children's Hospital, Charlottesville, Virginia, 22908-0386, United States|Seattle Children's Hospital, Seattle, Washington, 98105, United States|West Virginia University Hospital, Morgantown, West Virginia, 26506, United States|Medical College of Wisconsin, Milwaukee, Wisconsin, 53226, United States|Manitoba Institute of Child Health, Winnipeg, Manitoba, R3E 3P4, Canada|Children's Hospital of Eastern Ontario, Ottawa, Ontario, K1H 8L1, Canada|The Hospital for Sick Children, Toronto, Ontario, M5G 1X8, Canada|Hospital Sainte-Justine, Montreal, Quebec, T3T 1C5, Canada|Assaf Harofeh Medical Center, Zerifin, Tel Aviv, 70300, Israel|Schneider Children's Medical Center of Israel, Petah Tikva, 49202, Israel|KK Women's and Children's Hospital Pte Ltd, Singapore, 229899, Singapore|Southampton General Hospital, Southampton, Hampshire, SO16 6YD, United Kingdom|Alder Hey Children's Hospital, Liverpool, Merseyside, L12 2AP, United Kingdom

Study Documents:

NCT Number: NCT01867879
Study Title: Study to Evaluate the Cardiac Safety of TAS-102 in Patients With Advanced Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT01867879
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate the cardiac safety of TAS-102 in patients with advanced solid tumors.
Study Results: NO
Conditions: Advanced Solid Tumors (Excluding Breast Cancer)
Interventions: DRUG: TAS-102|DRUG: Placebo
Primary Outcome Measures: QTc interval, Predose (Day -2) to post-dose changes and absolute values in QTc interval after placebo (Day -1, Cycle 1), after a single dose of TAS-102 (Day 1, Cycle 1), and after multiple doses (Day 12, Cycle 1), Days -2, -1, 1, and 12 of Cycle 1
Secondary Outcome Measures: Quantitative and Qualitative ECG parameters, Predose (Day -2) to postdose changes and absolute values in quantitative Holter ECG parameters (heart rate, RR, PR and QRS intervals) after placebo (Day -1, Cycle 1), after a single dose of TAS-102 (Day 1, Cycle 1), and after multiple doses (Day 12, Cycle 1). In addition, qualitative assessments of Holter ECG recordings will be performed., Days -2, -1, 1, and 12 of Cycle 1|Relationship between TAS-102 pharmacokinetics and its effect on cardiac repolarization, Pharmacokinetic samples are taken on Days 1 and 12 of Cycle 1. The relationship between plasma concentrations of TAS-102 and the change from baseline in QTc adjusted by placebo will be quantified using a linear mixed effect model approach., Days 1 and 12 of Cycle 1|Safety monitoring including adverse events, vital signs, and laboratory assessments, Standard safety monitoring and grading using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) will be used., Through 30 days following last administration of study medication or until initiation of new anticancer treatment|Tumor assessments using Response Evaluation Criteria in Solid Tumors (RECIST), Every 8 weeks through Cycle 6 (ie, through 24 weeks). Thereafter, assessments will be performed at least every 12 weeks according to site standard of care, until at least one of the treatment discontinuation criteria is met.
Other Outcome Measures:
Sponsor: Taiho Oncology, Inc.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 44
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: SINGLE (PARTICIPANT)|Primary Purpose: TREATMENT

Other IDs: TPU-TAS-102-103|2013-000650-21
Start Date: 2013-06
Primary Completion Date: 2014-08
Completion Date: 2015-04
First Posted: 2013-06-04
Results First Posted:
Last Update Posted: 2015-11-09
Locations: Sarah Cannon Research Institute, Nashville, Tennessee, 37203, United States
Study Documents:

NCT Number: NCT05598879
Study Title: Global Cardio Oncology Registry
Study URL: https://beta.clinicaltrials.gov/study/NCT05598879
Acronym: G-COR
Study Status: RECRUITING
Brief Summary: G-COR is the first Global Prospective Cardio-Oncology Registry. It is a multinational, multicenter prospective observational cohort registry, with the goal of collecting clinical, laboratory, imaging, demographic, and socioeconomic data to identify risk factors associated with increased incidence of cancer therapy related cardiovascular toxicity (CTR-CVT) in different settings and to derive and validate risk scores for cardio oncology patients treated in different geographic locations throughout the world.
Study Results: NO
Conditions: Breast Cancer|Hematologic Malignancy|Immune Checkpoint Inhibitor-Related Myocarditis|Cardiotoxicity|Cardiovascular Diseases
Interventions: OTHER: anonymized data collection during programmed surveillance clinical follow up
Primary Outcome Measures: Cardiotoxicity, Any new cardiac event occurring during or after cancer treatment, 18 months of prospective follow up|New cardiovascular events, Heart failure, myocardial infarction, cardiac arrhythmias, syncope, coronary revascularization, heart transplant, cerebrovascular accident, peripheral arterial disease, hypertension, pulmonary hypertension. All events will be adjudicated according to standard clinical definitions., 18 months of prospective follow up|Cardiovascular death., Death during or after cancer treatment, adjudicated to cardiovascular causes by treating physicians., 18 months of prospective follow up
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: The Cleveland Clinic
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 5000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p

Other IDs: IRB 22-211
Start Date: 2022-07-01
Primary Completion Date: 2025-07-01
Completion Date: 2027-07-01
First Posted: 2022-10-28
Results First Posted:
Last Update Posted: 2022-10-28
Locations: Cleveland Clinic Florida, Weston, Florida, 33331, United States
Study Documents:

NCT Number: NCT05652179
Study Title: Effect of Stellate Ganglion Block on Cardiac and Renal Function After Cardiopulmonary Bypass Cardiac Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT05652179
Acronym:
Study Status: RECRUITING
Brief Summary: The incidence of acute kidney injury after cardiopulmonary bypass cardiac surgery is high, which increases postoperative mortality and is not conducive to the prognosis of patients. Stellate ganglion blocks increase renal blood flow, reduce inflammation and stress, and protect the heart muscle. In this study, stellate ganglion block was used to promote rapid recovery of heart and kidney function after cardiopulmonary bypass cardiac surgery.
Study Results: NO
Conditions: Stellate Ganglion Block
Interventions: DRUG: Stellate ganglion block
Primary Outcome Measures: Changes in renal blood flow, Renal blood flow indicators, 30 minutes after the start of the operation , 30 minutes after the start of cardiopulmonary , 30 minutes after the end of cardiopulmonary bypassbypass|Indicators of kidney function, Cystatin C,, 1 day before surgery, 1 hour after the end of the operation, 1 day after the end of the operation, 3 day after the end of the operation, 7 day after the end of the operation|Changes in left ventricular systolic function, EDV, ESV, EF are assessed by TEE, from 30 minutes after intubation to 1 hour after intubation , from 30minutes before the end of the surgery to the end of the surgery| Changes in right ventricular systolic function, Right ventricular systolic function changes, such as TAPSE, are assessed by TEE, from 30 minutes after intubation to 1 hour after intubation , from 30minutes before the end of the surgery to the end of the surgery|Changes in right ventricular diastolic function, Right ventricular diastolic function changes, from 30 minutes after intubation to 1 hour after intubation , from 30minutes before the end of the surgery to the end of the surgery|Changes in blood flow in the coronary sinuse, TEE assessment of coronary sinus flow changes, such as maximum systolic flow,, from 30 minutes after intubation to 1 hour after intubation , from 30minutes before the end of the surgery to the end of the surgery|Changes in myocardial performance index, ET, IVCT, IVRT are measured by TEE to calculate the myocardial performance index, from 30

minutes after intubation to 1 hour after intubation , from 30minutes before the end of the surgery to the end of the surgery|Changes in cerebral blood flow, Cerebral flow tests are performed by TCD, such as systolic peak flow velocity (Vs),, The day before surgery , 30 min after the start of extracorporeal bypass , 30 minutes after the end of extracorporeal bypass
Secondary Outcome Measures: Changes in the level of Cardiac output, The above results should be measured immediately after induction, at the beginning, into ICU 30 minutes|Changes in the level of SVR, The above results should be measured immediately after induction, at the beginning, into ICU 30 minutes|Changes in the level of SVRI, The above results should be measured immediately after induction, at the beginning, into ICU 30 minutes
Other Outcome Measures:
Sponsor: Yangzhou University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 20221107
Start Date: 2022-08-01
Primary Completion Date: 2023-08-01
Completion Date: 2024-07-01
First Posted: 2022-12-15
Results First Posted:
Last Update Posted: 2022-12-15
Locations: the Affiliated Hospital of Yangzhou University, Yangzhou University, Yangzhou, Jiangsu, China
Study Documents:

NCT Number: NCT00000479
Study Title: Women's Health Study (WHS): A Randomized Trial of Low-dose Aspirin and Vitamin E in the Primary Prevention of Cardiovascular Disease and Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00000479
Acronym: WHS
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate the effects of low-dose aspirin and vitamin E in primary prevention of cardiovascular disease and cancer in apparently healthy women.
Study Results: YES
Conditions: Cardiovascular Diseases|Cerebrovascular Disorders|Coronary Disease|Heart Diseases|Myocardial Infarction|Myocardial Ischemia|Vascular Diseases

Interventions: DRUG: Aspirin|DRUG: Vitamin E|BEHAVIORAL: Placebo
Primary Outcome Measures: Number of Participants With Major Cardiovascular Events (a Combined Endpoint of Nonfatal Myocardial Infarction, Nonfatal Stroke, and Total Cardiovascular Death), Average follow-up 10.1 years|Number of Participants With Cancer, Excluding Nonmelanoma Skin Cancer, Average follow-up 10.1 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Brigham and Women's Hospital
Collaborators: National Cancer Institute (NCI)|National Heart, Lung, and Blood Institute (NHLBI)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 39876
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: FACTORIAL|Masking: TRIPLE (PARTICIPANT, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 69|R01HL043851|HL043851|CA047988
Start Date: 1992-09
Primary Completion Date: 2004-03
Completion Date: 2005-02
First Posted: 1999-10-28
Results First Posted: 2011-12-05
Last Update Posted: 2012-06-15
Locations:
Study Documents:

NCT Number: NCT02181049
Study Title: Cardiac and Vascular Late Sequelae in Long-term Survivors of Childhood Cancer (CVSS)
Study URL: https://beta.clinicaltrials.gov/study/NCT02181049
Acronym: CVSS
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Due to remarkable advances in childhood cancer therapy the 10-year survival rate increased to over 80% and late sequelae come to the fore. Childhood cancer survivors (CCS) suffer from significant excess in mortality risk associated with treatment-related complications at least for 25 years after the initial cancer diagnosis. In particular, the prevalence of cardiovascular disease seems to be elevated compared to the general population. The CVSS study is a multi-disciplinary cooperation project between the Institute for Medical Biostatistics, Epidemiology and Informatics (IMBEI) and the German Childhood Cancer Registry (GCCR), the Preventive Cardiology and Preventive Medicine and the Pediatric Hematology and Oncology all at the University Medical Center of the Johannes Gutenberg University Mainz. The central element is a thorough clinical cardiovascular examination of all patients, which permits

detecting subclinical disease. Therapy data will be extracted retrospectively from various sources. The study intends to describe the current situation of a cohort of approximately 1000 CCS in Germany aged 24 to 49 years with respect to cardiovascular health. The role of risk factors (treatment related and classic cardiovascular risk factors), as well as related predisposing genetic factors is investigated. The results will contribute to recommendations to improve follow-up care.
Study Results: NO
Conditions: Childhood and Adolescence Cancer (Survivors and Deceased)
Interventions:
Primary Outcome Measures: Heart failure, up to 35 years after exposure to childhood cancer therapy|Hypertension, up to 35 years after exposure to childhood cancer therapy
Secondary Outcome Measures: Myocardial infarction, up to 35 years after exposure to childhood cancer therapy|Late-occurring stroke, "late" is defined as 5 years or more after diagnosis of cancer, up to 35 years after exposure to childhood cancer therapy|Carotid artery disease, up to 35 years after exposure to childhood cancer therapy
Other Outcome Measures:
Sponsor: CVSS study
Collaborators: Univ. Prof. Dr. med. Joerg Faber, Center for Pediatrics, Hematology, Oncology and Hemostaseology|Univ. Prof. Dr. med. Philipp S. Wild, MSc, Preventive Cardiology and Preventive Medicine, Center for Cardiology, Clinical Epidemiology, CTH|Dr. oec. troph. Hiltrud Merzenich, Insitute for Medical Biometry, Epidemiology and Informatics (IMBEI)
Sex: ALL
Age: ADULT
Phases:
Enrollment: 1000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CVSS-study
Start Date: 2013-10
Primary Completion Date: 2018-10
Completion Date: 2028-10
First Posted: 2014-07-03
Results First Posted:
Last Update Posted: 2020-09-17
Locations: University Medical Center of the Johannes Gutenberg University Mainz, Mainz, Rhineland-Palatinate, 55131, Germany
Study Documents:

NCT Number: NCT03767517
Study Title: A Culturally-Based Palliative Care Tele-consult Program for Rural Southern Elders
Study URL: https://beta.clinicaltrials.gov/study/NCT03767517
Acronym:

Study Status: RECRUITING
Brief Summary: Rural patients with life-limiting illness are at very high risk of not receiving appropriate care due to a lack of health professionals, long distances to treatment centers, and limited palliative care (PC) clinical expertise. Secondly, although culture strongly influences people's response to diagnosis, illness and treatment preferences, culturally-based care models are not currently available for most seriously-ill rural patients and their family caregivers. Lack of sensitivity to cultural differences may compromise PC for minority patients. The purpose of this study is to compare a culturally-based Tele-consult program to usual hospital care to determine whether a culturally-based PC Tele-consult program leads to lower symptom burden in hospitalized African American and White older adults with a life-limiting illness.
Study Results: NO
Conditions: Cancer|Cardiac Disease|Pulmonary Disease|Neuro-Degenerative Disease|Renal Disease|Stroke|Sepsis|Hepatic Disease
Interventions: OTHER: Active Intervention|OTHER: Usual Care
Primary Outcome Measures: Patient symptom burden (Edmonton Symptom Assessment Scale [ESAS]), Change from baseline in patient-reported symptom burden measured using the Edmonton Symptom Assessment Scale (ESAS) at baseline; change from baseline measured using the ESAS at 7 days post-baseline. Each item is scored using: 0-10 (0= no pain; 10= worst possible pain), yielding a total score between 0 and 90., baseline and 7 days post-baseline
Secondary Outcome Measures: Family satisfaction with care (FAMCARE-2), Change from baseline in family-reported satisfaction with care measured using the FAMCARE-2 scale at baseline; change from baseline measured using FAMCARE-2 at 7 days post-baseline. Each item is scored using: vs (very satisfied), s (satisfied), u (undecided), d (dissatisfied), vd (very dissatisfied), or NA (not applicable)., baseline and 7 days post-baseline|Patient quality of life (Patient-Reported Outcomes Measurement Information System Global Health-10 [PROMIS Global Health-10]), Change from baseline in patient-reported quality of life using the Patient-Reported Outcomes Measurement Information System Global Health-10 (PROMIS Global Health-10) at baseline; change from baseline measured using the PROMIS Health-10 at 7 days post-baseline. Items 1-6 are scored using: 1-5 (1=poor; 5=excellent). Item 7 is scored using 1-5 (1= not at all; 5= completely). Item 8 is scored using 1-5 (1= always; 5=never). Item 9 is scored using 1-5 (1=very severe; 5=none). Item 10 is scored using 0-10 (0=no pain; 10=worst pain imaginable)., baseline and 7 days post-baseline|Caregiver quality of life (Patient-Reported Outcomes Measurement Information System Global Health-10 [PROMIS Global Health-10]), Change from baseline in caregiver-reported quality of life using the Patient-Reported Outcomes Measurement Information System Global Health-10 (PROMIS Global Health-10) at baseline; change from baseline measured using the PROMIS Global Health-10 at 7 days post-baseline. Items 1-6 are scored using: 1-5 (1=poor; 5=excellent). Item 7 is scored using 1-5 (1= not at all; 5= completely). Item 8 is

scored using 1-5 (1= always; 5=never). Item 9 is scored using 1-5 (1=very severe; 5=none). Item 10 is scored using 0-10 (0=no pain; 10=worst pain imaginable)., Baseline and 7 days post-Baseline|Caregiver burden scale (Montgomery Borgatta Caregiver Burden Scale [MBCB]), Change from baseline in caregiver-reported burden using the Montgomery Borgatta Caregiver Burden Scale (MBCB) at baseline; change from baseline measured using the MBCB at 7 days post-baseline. This scale contains a total of 14 questions and 5 Likert scale responses (a lot less, a little less, the same, a little more, or a lot more). Caregiver burden will be quantified by three subscales; objective, subjective and demand burdens. Objective burden is measured by 6 questions (total score between 0-30), subjective burden is measured by 4 questions (total score between 4-20), and demand burden is measured by 4 questions (total score between 4-20)., Baseline and 7 days post-Baseline|Resource Use, Patient resource use (e.g., number of hospital readmissions, number of hospital days, number of ICU days, number of Emergency Department \[ED\] visits, and hospice days during the 30 days following discharge) will be collected via electronic health records (eHR) 30 days post-discharge., 30 days post-Baseline|Patient satisfaction with care (Feeling Heard and Understood), Change from baseline in patient-reported satisfaction with care using the Feeling Heard and Understood questionnaire at baseline; change from baseline using the Feeling Heard and Understood questionnaire at 7 days post-baseline. Likert scale using: completely, quite a bit, moderately, slightly, not at all., Baseline and 7 days post-Baseline
Other Outcome Measures: Exploratory Aim 1a. Patient symptom burden (Edmonton Symptom Assessment Scale [ESAS]), Patient symptom burden measured by Edmonton Symptom Assessment Scale \[ESAS\] mediated and/or moderated by hospitalist/clinician implementation of palliative care recommendations. Implementation of palliative care recommendations are measured using Electronic Health Record \[eHR\] documentation of recommendations by hospitalist/clinician at Day 7. Each item in the ESAS is scored using: 0-10 (0= no pain; 10= worst possible pain), yielding a total score between 0 and 90., Day 7|Exploratory Aim 1b. Patient symptom burden (Edmonton Symptom Assessment Scale [ESAS]), Patient symptom burden measured by Edmonton Symptom Assessment Scale \[ESAS\] mediated and/or moderated by patient/caregiver implementation of palliative care recommendations. Patient/caregiver implementation of palliative care recommendations are measured using patient/caregiver report at Day 7. Each item in the Edmonton Symptom Assessment Scale \[ESAS\] is scored using: 0-10 (0= no pain; 10= worst possible pain), yielding a total score between 0 and 90., Day 7|Exploratory Aim 1c. Caregiver burden (Montgomery Borgatta Caregiver Burden Scale [MBCB]), Caregiver burden measured by Montgomery Borgatta Caregiver Burden Scale \[MBCB\] mediated and/or moderated by hospitalist/clinician implementation of palliative care recommendations. Implementation of palliative care recommendations are measured using Electronic Health Record \[eHR\] documentation of recommendations by hospitalist/clinician at Day 7. This scale contains a total of 14 questions and 5 Likert scale responses (a lot less, a

little less, the same, a little more, or a lot more). Caregiver burden will be quantified by three subscales; objective, subjective and demand burdens. Objective burden is measured by 6 questions (total score between 0-30), subjective burden is measured by 4 questions (total score between 4-20), and demand burden is measured by 4 questions (total score between 4-20)., Day 7|Exploratory Aim 1d. Caregiver burden (Montgomery Borgatta Caregiver Burden Scale [MBCB]), Caregiver burden measured by Montgomery Borgatta Caregiver Burden Scale \[MBCB\] mediated and/or moderated by caregiver/patient implementation of palliative care recommendations. Caregiver/patient implementation of palliative care recommendations are measured using caregiver/patient report at Day 7. This scale contains a total of 14 questions and 5 Likert scale responses (a lot less, a little less, the same, a little more, or a lot more). Caregiver burden will be quantified by three subscales; objective, subjective and demand burdens. Objective burden is measured by 6 questions (total score between 0-30), subjective burden is measured by 4 questions (total score between 4-20), and demand burden is measured by 4 questions (total score between 4-20)., Day 7|Exploratory Aim 1e. Caregiver Evaluation of Quality of End-of-Life Care [CEQUEL], Caregiver evaluation of end-of-life care quality measured by Caregiver Evaluation of Quality of End-of-Life Care \[CEQUEL\], 2-3 Months after death of patient, if applicable|Exploratory Aim 1f. Caregiver bereavement (Caregiver Bereavement Items ([CBI]), Caregiver bereavement measured by Caregiver Bereavement Items (\[CBI\], 2-3 Months after death of patient, if applicable
Sponsor: University of Alabama at Birmingham
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 352
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IRB300002420
Start Date: 2020-08-24
Primary Completion Date: 2024-01-20
Completion Date: 2024-06-30
First Posted: 2018-12-06
Results First Posted:
Last Update Posted: 2023-06-15
Locations: Russell Medical Center, Alexander City, Alabama, 35010, United States|Anderson Regional Medical Center, Meridian, Mississippi, 39301, United States|Highland Community Hospital, Picayune, Mississippi, 39466, United States|Aiken Regional Medical Center, Aiken, South Carolina, 29801, United States
Study Documents:

NCT Number: NCT05607017
Study Title: Losartan in Prevention of Radiation-Induced Heart Failure
Study URL: https://beta.clinicaltrials.gov/study/NCT05607017
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: This study is being done to see if losartan affects the chances of developing radiation-induced heart failure in patients who are receiving radiation therapy as part of standard of care treatment for breast cancer.

The interventions involved in this study are:

* Losartan
* Radiation Therapy (standard of care)
Study Results: NO
Conditions: Breast Cancer|Myocardial Fibrosis|Radiation-Induced Fibrosis
Interventions: DRUG: Losartan|RADIATION: Radiation Therapy
Primary Outcome Measures: Extracellular Volume (ECV) of Myocardial Fibrosis, The primary endpoint is detectable decrease in extracellular volume as measured by cardiac MRI, 6 months
Secondary Outcome Measures: Serum cardiac biomarker, The secondary objective of this study is to compare pre- and post-Radiation Therapy changes in serum TGF-β levels, 6 months
Other Outcome Measures:
Sponsor: Massachusetts General Hospital
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: EARLY_PHASE1
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 22-457
Start Date: 2023-01
Primary Completion Date: 2023-06-01
Completion Date: 2023-12-01
First Posted: 2022-11-07
Results First Posted:
Last Update Posted: 2022-11-07
Locations: Massachusetts General Hospital Cancer Center, Boston, Massachusetts, 02114, United States
Study Documents:

NCT Number: NCT02596126
Study Title: Secondary Prevention of Cardiovascular Disease in the Elderly Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT02596126

Acronym: SECURE
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate the efficacy of a polypill strategy containing aspirin (100 mg), ramipril (2.5, 5 or 10 mgs), and atorvastatin (40 mgs) compared with the standard of care (usual care according to the local clinical practices at each participating country) in secondary prevention of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal ischemic stroke, and urgent revascularization) in elderly patients with a recent myocardial infarction.
Study Results: NO
Conditions: Myocardial Infarction|Cardiovascular Disease
Interventions: DRUG: Cardiovascular Polypill|DRUG: Treatment Prevention for Secondary CV
Primary Outcome Measures: Difference in the occurrence of Major Adverse Cardiovascular Events (MACE) between the Cardiovascular Combination Polypill AAR and the Standard of Care Treatment, Cardiovascular death, non-fatal myocardial infarction, non-fatal ischemic stroke, and urgent revascularization, 24 months
Secondary Outcome Measures: Incidence of the first occurrence of any component of the following composite endpoint: CV death, MI, stroke., Cardiovascular death, non-fatal myocardial infarction, non-fatal ischemic stroke, and urgent revascularization, Baseline|Incidence of the first occurrence of any component of the following composite endpoint: CV death, MI, stroke., Cardiovascular death, non-fatal myocardial infarction, non-fatal ischemic stroke, and urgent revascularization, 6 months after treatment initiation|Incidence of the first occurrence of any component of the following composite endpoint: CV death, MI, stroke., Cardiovascular death, non-fatal myocardial infarction, non-fatal ischemic stroke, and urgent revascularization, 12 months after treatment initiation|Evaluate the first occurrence of the individual components of the primary endpoint,
* CV death.
* Nonfatal type 1 myocardial infarction.
* Nonfatal ischemic stroke.
* Urgent coronary revascularization., 18 months after treatment initiation|Evaluate the first occurrence of the individual components of the primary endpoint, * CV death.
* Nonfatal type 1 myocardial infarction.
* Nonfatal ischemic stroke.
* Urgent coronary revascularization., 24 months after treatment initiation|Evaluate the first occurrence of the individual components of the primary endpoint, * CV death.
* Nonfatal type 1 myocardial infarction.
* Nonfatal ischemic stroke.
* Urgent coronary revascularization., 36 months after treatment initiation|Evaluate the first occurrence of the individual components of the primary endpoint, * CV death.
* Nonfatal type 1 myocardial infarction.
* Nonfatal ischemic stroke.

* Urgent coronary revascularization., 48 months after treatment initiation|Change in Treatment Adherence, The Morisky-Medication Adherence Scale (8 item) Questionnaire will be administered, 6 months after patient treatment|Change in Treatment Adherence, The Morisky-Medication Adherence Scale (8 item) Questionnaire will be administered, 24 months after patient treatment|Change in Patient Satisfaction, The treatment Satisfaction Questionnaire for Medication (TSQM) will be administered, 6 months after patient treatment|Change in Patient Satisfaction, The treatment Satisfaction Questionnaire for Medication (TSQM) will be administered, 24 months after patient treatment|Change in Systolic and Diastolic Blood Pressure (SBP and DBP), Systolic and diastolic blood pressure will be collected and summarized at each timepoint., Baseline|Change in Systolic and Diastolic Blood Pressure (SBP and DBP), Systolic and diastolic blood pressure will be collected and summarized at each timepoint., 6 months after patient treatment|Change in Systolic and Diastolic Blood Pressure (SBP and DBP), Systolic and diastolic blood pressure will be collected and summarized at each timepoint., 12 months after patient treatment|Change in Systolic and Diastolic Blood Pressure (SBP and DBP), Systolic and diastolic blood pressure will be collected and summarized at each timepoint., 24 months after patient treatment|Change in LDL cholesterol level, Non-fasting blood analysis will be collected and LDL cholesterol level evaluated at each timepoint., Baseline|Change in LDL cholesterol level, Non-fasting blood analysis will be collected and LDL cholesterol level evaluated at each timepoint., 12 months after patient treatment|Change in LDL cholesterol level, Non-fasting blood analysis will be collected and LDL cholesterol level evaluated at each timepoint., 24 months after patient treatment|Regional differences in performance of the polypill in the previous endpoints, Assessed, 6 months after patient treatment|Regional differences in performance of the polypill in the previous endpoints, Assessed, 12 months after patient treatment|Regional differences in performance of the polypill in the previous endpoints, Assessed, 24 months after patient treatment|Health Economic Evaluation Comparing Intervention and Usual Care Arm, Cost differences and Incremental Cost-Effectiveness Ratio (ICER) will be assessed at each timepoint., 6 months after patient treatment|Health Economic Evaluation Comparing Intervention and Usual Care Arm, Cost differences and Incremental Cost-Effectiveness Ratio (ICER) will be assessed at each timepoint., 12 months after patient treatment|Health Economic Evaluation Comparing Intervention and Usual Care Arm, Cost differences and Incremental Cost-Effectiveness Ratio (ICER) will be assessed at each timepoint., 24 months after patient treatment|Change in Quality of Life, The European Quality of Life- 5 Dimensions (EQ-5D) Questionnaire will be administered at each timepoint to evaluate change in quality of life., Baseline|Change in Quality of Life, The European Quality of Life- 5 Dimensions (EQ-5D) Questionnaire will be administered at each timepoint to evaluate change in quality of life., 24 months after patient treatment|Incidence of Treatment-Emergent Adverse Events (Safety and Tolerability), All-cause mortality and

adverse events (bleeding, renal dysfunction, drug, allergies, and refractory cough leading to drug discontinuation)., Baseline|Incidence of Treatment-Emergent Adverse Events (Safety and Tolerability), All-cause mortality and adverse events (bleeding, renal dysfunction, drug, allergies, and refractory cough leading to drug discontinuation)., 6 months after patient treatment|Incidence of Treatment-Emergent Adverse Events (Safety and Tolerability), All-cause mortality and adverse events (bleeding, renal dysfunction, drug, allergies, and refractory cough leading to drug discontinuation)., 12 months after patient treatment|Incidence of Treatment-Emergent Adverse Events (Safety and Tolerability), All-cause mortality and adverse events (bleeding, renal dysfunction, drug, allergies, and refractory cough leading to drug discontinuation)., 18 months after patient treatment|Incidence of Treatment-Emergent Adverse Events (Safety and Tolerability), All-cause mortality and adverse events (bleeding, renal dysfunction, drug, allergies, and refractory cough leading to drug discontinuation)., 24 months after patient treatment|Incidence of Treatment-Emergent Adverse Events (Safety and Tolerability), All-cause mortality and adverse events (bleeding, renal dysfunction, drug, allergies, and refractory cough leading to drug discontinuation)., 36 months after patient treatment|Incidence of Treatment-Emergent Adverse Events (Safety and Tolerability), All-cause mortality and adverse events (bleeding, renal dysfunction, drug, allergies, and refractory cough leading to drug discontinuation)., 48 months after patient treatment
Other Outcome Measures:
Sponsor: Fundación Centro Nacional de Investigaciones Cardiovasculares Carlos III
Collaborators: Charite University, Berlin, Germany|Centre Hospitalier Universitaire de Besancon|Wroclaw Medical University|Semmelweis University|General University Hospital, Prague|Servicio Madrileño de Salud, Madrid, Spain|London School of Hygiene and Tropical Medicine|Ferrer Internacional S.A.|Istituto Di Ricerche Farmacologiche Mario Negri
Sex: ALL
Age: OLDER_ADULT
Phases: PHASE3
Enrollment: 2499
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 633765|2015-002868-17
Start Date: 2016-07
Primary Completion Date: 2021-10-31
Completion Date: 2022-03-31
First Posted: 2015-11-04
Results First Posted:
Last Update Posted: 2022-10-07
Locations: Fakultní nemocnice Královské Vinohrady, Praha, Praha 10, 10034, Czechia|Nemocnice Na Homolce, Praha, Praha 5, 15030, Czechia|

Všeobecná fakultní nemocnice v Praze, Praha 2, Praha, 12808, Czechia| Nemocnice Rudolfa a Stefanie Benešov, Benešov, 25601, Czechia| Nemocnice Jihlava, Jihlava, 58633, Czechia|Krajská necmonice Liberec, Liberec, 46030, Czechia|Fakultní nemocnice Olomouc, Olomouc, 77900, Czechia|Nemocnice Slaný, Slaný, 27401, Czechia|Nemocnice Podlesí, Třinec, 73961, Czechia|Centre Hospitalier Universitaire d'Angers, Angers, 49933, France|Centre Hospitalier Régional Universitaire de Besançon, Besançon, 25030, France|Centre Hospitalier Universitaire de Lyon, Bron, 69500, France|Centre Hospitalier Universitaire de Caen, Caen, 14000, France|Centre Hospitalier Metropole Savoie, Chambéry, 73000, France|Centre Hospitalier Universitaire Henri Mondor, Créteil, 94000, France|Centre Hospitalier Universitaire de Dijon, Dijon, 21000, France|Centre Hospitalier Universitaire de Grenoble, Grenoble, 38000, France|Centre Hospitalier Régional et Universitaire de Lille, Lille, 59037, France|Centre Hospitalier St Joseph St Luc, Lyon, 69365, France|Centre Hospitalier Universitaire de Nice, Nice, 06002, France| Hôpital Bichât, Paris, 75010, France|Centre hospitalier Universitaire de Bordeaux, Pessac, 33604, France|Centre Hospitalier Universitaire de Toulouse, Toulouse, 31403, France|Medical Park Berlin Humboldtmühle, Berlin – Tegel, Berlin, 13507, Germany|Immanuel Klinikum Bernau Herzzentrum Brandenburg, Bernau, Berlin, 16321, Germany| Brandenburgklinik Berlin–Brandenburg GmbH, Haus Brandenburg/ Kardiologie, Waldsiedlung, Berlin, 16321, Germany|Klinik am See, Rehabilitationszentrum für innere Medizin, Rüdersdorf, Brandenburg, 15562, Germany|GLG Fachklinik Wolletzsee GmbH, Angermünde, 16278, Germany|AVK Vivantes Rehabilitation GmbH, Berlin, 12157, Germany|DRK–Kliniken Berlin/ Köpenick, Berlin, 12559, Germany|Maria Heimsuchung Caritas–Klinik Pankow, Berlin, 13187, Germany|Jüdisches Krankenhaus, Berlin, 13347, Germany|Charité – Universitätsmedizin Berlin, Centrum für Schlaganfallforschung (CSB), Berlin, 13353, Germany|Vivantes Humboldt Klinikum, Berlin, 13509, Germany|Vivantes Klinikum Spandu, Berlin, 13585, Germany|DRK Klinik Berlin Westend, Berlin, 14050, Germany|GK Havelhöhe, Berlin, 14089, Germany|Gesundheitszentrum Bitterfeld /Wolfen GmbH, Bitterfeld–Wolfen, 06749, Germany|Mediclin Reha–Zentrum Spreewald Fachklinik für innere Medizin, Burg, 03096, Germany|MediClin Herzzentrum Coswig, Coswig, 06869, Germany|Semmelweis Egyetem Városmajori Szív– és Érgyógyászati Klinika, Budapest, 1122, Hungary|Fővárosi Szent János Kórház, Budapest, 1125, Hungary|Szent Rókus Kórház és Intézményei, Budapest, H–1085, Hungary|Békés Megyei Pándy Kálmán Kórház, Gyula, 5700, Hungary|Bács– Kiskun Megyei Kórház, Kecskemét, 6000, Hungary|Fejér Megyei Szent György Egyetemi Kórház, Székesfehérvár, 8000, Hungary|Sydó és Tsa Kft., Veszprém, H–8200, Hungary|IRCCS Fondazione S. Maugeri Istit. di Cassano Murge, Cassano Delle Murge, BA, 70020, Italy|IOB–Policlinico San Marco, Osio Sotto, BG, 24040, Italy|Ospedale Bolognini di Seriate – ASST BERGAMO EST, Seriate, BG, 24068, Italy|ASST di Bergamo Ovest–Ospedale di Treviglio, Treviglio, BG, 24047, Italy|ASST Degli Spedali Civili di Brescia, Brescia, BS, 25123, Italy|Ospedale S.Lazzaro, Alba, CN, 12051, Italy| Ospedale Generale di Zona–Ospedale Valduce, Como, CO, 22100, Italy|ASL FG Ospedale "Teresa Masselli Mascia", San Severo, FG, 71016, Italy|

Ospedale Misericordia ASL 9 Grosseto, Grosseto, GR, 58100, Italy| Ospedale Sacro Cuore di Gesù, Gallipoli, LE, 73014, Italy|ASST Di Monza-Presidio Ospedaliero di Desio, Desio, MB, 20832, Italy|ASST Di Monza-Ospedale San Gerardo, Monza, MB, 20900, Italy|IRCCS Ospedale Policlinico di Milano, Milano, MI, 20122, Italy|Centro Cardiologico Monzino SpA, Milano, MI, 20138, Italy|ASST Santi Paolo e Carlo-Ospedale San Paolo-Polo Univ., Milano, MI, 20142, Italy|IRCCS-Fondazione Don Carlo Gnocchi, Milano, MI, 20149, Italy|IRCCS Istituto Clinico Humanitas, Rozzano, MI, 20089, Italy|IRCCS Policlinico San Donato, San Donato Milanese, MI, 20097, Italy|Ospedale di Sassuolo S.P.A., Sassuolo, MO, 41049, Italy|ASST Rhodense Ospedale di Passirana, Passirana, Passirana-rho, 20017, Italy|Presidio Ospedaliero San Filippo Neri-ASL Roma E, Roma, RM, 00135, Italy|A.O. San Camillo Forlanini, Roma, RO, 00149, Italy|Ospedale Ss Giovanni di Dio e Ruggi d'Aragona, Salerno, SA, 84131, Italy|Casa di Cura Villa Bianca, Trento, TN, 38122, Italy|AAS3 "Alto Friuli, Collinare, Medio Friuli" Ospedale di San Daniele del Friuli-Tolmezzo sede di S. D. del Friuli, San Daniele Del Friuli, UD, 33038, Italy|ASST Della Valle Olona-Ospedale di Saronno, Saronno, VA, 21047, Italy|Samodzielny Publiczny Szpital Kliniczny nr 7, Śląskiego Uniwersytetu Medycznego w Katowicach, Górnośląskie Centrum Medyczne im. prof. Leszka Gieca, Katowice, Ochojec, 40-635, Poland|Uniwersyteckie Centrum Kliniczn, Gdańsk, 80-952, Poland|Szpital Wielospecjalistyczny im. Dr. Ludwika Błażka w Inowrocławiu, Inowrocław, 88-100, Poland|Krakowski Szpital Specjalistyczny im. Jana Pawła II, Kraków, 31-202, Poland|Zespół Opieki Zdrowotnej w Kłodzku, Kłodzko, 57-300, Poland|Wojewódzki Szpital Specjalistyczny w Legnicy, Legnica, 59-220, Poland| Specjalistyczny Szpital im. Dra Alfreda Sokołowskiego, Wałbrzych, 58-309, Poland|Centrum Kardiologiczne "Pro Corde" Sp. z o.o., Wrocław, 50-315, Poland|Wojskowy Szpital Kliniczny z Poliklinika SP ZOZ, Wrocław, 50-981, Poland|Samodzielny Publiczny Zespół Opieki Zdrowotnej w Świdnicy, Świdnica, 58-100, Poland|Hospital Universitario de Cabueñes, Gijón, Asturias, 33203, Spain|Hospital Univeristari de Bellvitge, L'Hospitalet De Llobregat, Barcelona, 08997, Spain|H.C.U.de Santiago De Compostela, Santiago De Compostela, Galicia, 15706, Spain| Complejo Asistencial Universitario de Leon, León, Leon, 24008, Spain| Hospital Universitario Principe de Asturias, Alcalá De Henares, Madrid, 28805, Spain|Hospital General de Villalba, Collado-Villalba, Madrid, 28400, Spain|Hospital de Fuenlabrada, Fuenlabrada, Madrid, 28492, Spain|Hospital Universitario Puerta de Hierro, Majadahonda, Madrid, 28222, Spain|Hospital Universitario Rey Juan Carlos, Móstoles, Madrid, 28933, Spain|Hospital Universitario QuironSalud Madrid, Pozuelo De Alarcón, Madrid, 28223, Spain|Hospital Universitario Infanta Elena, Valdemoro, Madrid, 28340, Spain|H.C.U. Virgen De La Arrixaca De Murcia, El Palmar, Murcia, 30120, Spain|Hospital Universitario A Coruña, A Coruña, 15006, Spain|Hospital General Universitario de Alicante, Alicante, 03010, Spain|Hospital Universitari Vall D'hebron, Barcelona, 08035, Spain|Hospital Clinic de Barcelona, Barcelona, 08036, Spain|Hospital Universitario Reina Sofia de Cordoba, Córdoba, 14004, Spain|Hospital La Luz Quiron, Madrid,

28003, Spain|C.H.U. Ruber Juan Bravo, Madrid, 28006, Spain|Hospital Universitario La Princesa, Madrid, 28006, Spain|Hospital General Universitario Gregorio Marañón, Madrid, 28009, Spain|Hospital Universitario Clinico San Carlos, Madrid, 28040, Spain|Hospital Universitario Fundación Jiménez Díaz, Madrid, 28040, Spain|Hospital Universitario 12 de Octubre, Madrid, 28041, Spain|Hospital Virgen de la Victoria, Málaga, 29010, Spain|Complejo Asistencial Universitario de Salamanca, Salamanca, 37007, Spain|Hospital Universitario Virgen Macarena, Sevilla, 41009, Spain|Hospital Universitario Virgen del Rocio, Sevilla, 41013, Spain|Hospital Clinic Universitari de Valencia, Valencia, 46010, Spain|Hospital Universitario y Politécnico de La Fe, Valencia, 46026, Spain
Study Documents:

NCT Number: NCT02020226
Study Title: A Cardiac Safety Study of TH-302 in Patients With Advanced Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT02020226
Acronym:
Study Status: UNKNOWN
Brief Summary: The Primary objective of this study is:

1. To determine the cardiac safety of TH-302 in patients with advanced solid tumors

The Secondary objectives are:

1. To assess the pharmacokinetics (PK) of TH-302
2. To evaluate whether there is an association between plasma exposure to TH-302 and its active metabolite, Br-IPM, and effects on cardiac repolarization
3. To assess the safety and antitumor activity of TH-302 in patients with advanced solid tumors
Study Results: NO
Conditions: Solid Tumors
Interventions: DRUG: TH-302
Primary Outcome Measures: Evaluate the potential for QT/QTc interval prolongation of TH-302 in patients with solid tumors, 2 years
Secondary Outcome Measures: Evaluate association between plasma exposure to TH-302 and its active metabolite, Br-IPM, and effects on cardiac repolarization, 2 years|Safety and antitumor activity of TH-302 in patients with advanced solid tumors, 2 years
Other Outcome Measures:
Sponsor: Threshold Pharmaceuticals
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 40
Funder Type: INDUSTRY

Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: TH-CR-414
Start Date: 2013-11
Primary Completion Date: 2016-07
Completion Date: 2016-12
First Posted: 2013-12-24
Results First Posted:
Last Update Posted: 2016-06-02
Locations: The University of Arizona Cancer Center, Tucson, Arizona, 85719, United States|Yuma Regional Cancer Center, Yuma, Arizona, 85364, United States
Study Documents:

NCT Number: NCT02440906
Study Title: Evaluation of the Texas Wellness Incentives and Navigation (WIN) Project
Study URL: https://beta.clinicaltrials.gov/study/NCT02440906
Acronym: WIN
Study Status: COMPLETED
Brief Summary: The Wellness Incentives and Navigation (WIN) project is designed to help improve health self-management and reduce the incidence and consequences of chronic disease among non-elderly adult Medicaid Supplemental Security Income (SSI) beneficiaries. WIN targets SSI beneficiaries with behavioral health (mental health and substance abuse) diagnoses. Research demonstrates that these individuals are more likely to suffer chronic physical co-morbidities, experience debilitating chronic illnesses earlier in life and have elevated healthcare costs.

WIN uses person-centered wellness planning and navigation facilitated by trained, professional health Navigators, dedicated specifically to the WIN project, who use Motivational Interviewing (MI) techniques, and a personal wellness account. Participants with more serious mental illnesses will be offered additional support in the form of Wellness Recovery Action Planning (WRAP) to enable them to take full advantage of person-centered wellness planning.
Study Results: NO
Conditions: Chronic Mental Illness|Chronic Physical Illness
Interventions: BEHAVIORAL: Patient-Directed Wellness Account|BEHAVIORAL: Health Navigator
Primary Outcome Measures: Self-reported physical health related quality of life (HRQOL) using the Short Form-12 (SF-12), The SF-12 has been validated across a number of chronic diseases and conditions. The survey consists of 12 questions measuring functional health and well-being. Patients answer questions related to daily functioning, difficulties in physical tasks, and disruptions in life due to mental illness (e.g. depression, anxiety). The overall score can be further classified into two summary scores for physical and mental health.,

(Change) baseline, 12 months, 24 months and 36 months|Self-reported mental health related quality of life (HRQOL) using the Short Form-12 (SF-12), The SF-12 has been validated across a number of chronic diseases and conditions. The survey consists of 12 questions measuring functional health and well-being. Patients answer questions related to daily functioning, difficulties in physical tasks, and disruptions in life due to mental illness (e.g. depression, anxiety). The overall score can be further classified into two summary scores for physical and mental health., (Change) baseline, 12 months, 24 months and 36 months
Secondary Outcome Measures: Change in Total Healthcare expenditures as measured through Medicaid claims data, We will use Medicaid claims and enrollment expenditure data to examine changes in total medical expenditures between the three groups of participants across baseline, 12 months, 24 months and 36 months., (Change) baseline, 12 months, 24 months, 36 months, and 1 year after month 36|Changes in Inpatient Hospitalization expenditures as measured through Medicaid claims data, We will use Medicaid claims and enrollment expenditure data to examine changes in inpatient hospitalization expenditures between the three groups of participants across baseline, 12 months, 24 months and 36 months., (Change) baseline, 12 months, 24 months, 36 months, and 1 year after month 36|Changes in Outpatient expenditures as measured through Medicaid claims data, We will use Medicaid claims and enrollment expenditure data to examine changes in outpatient expenditures between the three groups of participants across baseline, 12 months, 24 months and 36 months., (Change) baseline, 12 months, 24 months, 36 months, and 1 year after month 36|Changes in Emergency Department expenditures as measured through Medicaid claims data, We will use Medicaid claims and enrollment expenditure data to examine changes in emergency department expenditures between the three groups of participants across baseline, 12 months, 24 months and 36 months., (Change) baseline, 12 months, 24 months, 36 months, and 1 year after month 36
Other Outcome Measures:
Sponsor: University of Florida
Collaborators: Centers for Medicare and Medicaid Services|RTI International|Econometrica, Inc.
Sex: ALL
Age: ADULT
Phases: NA
Enrollment: 1663
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 168-2012
Start Date: 2012-06
Primary Completion Date: 2015-12
Completion Date: 2016-12
First Posted: 2015-05-12

Results First Posted:
Last Update Posted: 2017-10-03
Locations: University of Florida, Institute for Child Health Policy, Gainesville, Florida, 32608, United States
Study Documents:

NCT Number: NCT02232126
Study Title: Social Work Intervention Focused on Transitions
Study URL: https://beta.clinicaltrials.gov/study/NCT02232126
Acronym: SWIFT
Study Status: COMPLETED
Brief Summary: In response to Program Announcement (PA)-09-164, "NIH Exploratory/Developmental Research Grant Program (R21) a randomized pilot study testing the efficacy of SWIFT: Social Work Intervention Focused on Transitions among at-risk older adults following hospital discharge to home. This study is drawn from several observations. First, transitions between care settings create elevated risk for poor outcomes and for readmission among older adults leaving the hospital for home largely due to fragmented care and poor communication. Next, while few studies exist that test methods to improve transitions, those available are largely medically focused, using a nurse or advanced practice nurse in their approach. Although evidence exists to support the effectiveness of these models, few have been replicated and none have been integrated into standard health care practice. This may be attributed to several factors including the availability of the needed staff, the lack of existing structures to support these roles, and the costs of implementing these interventions. Finally, a social work driven intervention may provide a replicable mechanism for bridging medical care, addressing psychosocial needs as well as medical needs, and improving linkages with community services while reducing care duplication. This study aimed to test a structured social work transition intervention model to reduce rates of hospital readmission and medical service use while improving patient satisfaction with the care transition process. A randomized pilot study was used to test a social work transitions model designed to improve care provided to frail older adults being discharged from the hospital to return to the community. Eligible patients consenting to participate (n=181) were randomly assigned to either the social work transitions model intervention or usual care. This project was conducted at Huntington Hospital, a 525-bed, nonprofit, community hospital located in Pasadena, California. In an average year, Huntington Hospital has approximately 10,000 older adults discharged from their facility, 44% of who are 80 years old or older. Those randomized to the intervention arm received up to six sessions from the social worker, at least one provided in the home. The social work intervention was designed to overcome common problems following hospital discharge including medication review, discussion and planning around discharge instruction, assistance in scheduling follow up appointments, assessments of psychosocial and other support service needs and provision of linkages to address those needs. Outcomes were

measured three and six months following arrival at home, with an interim measure of satisfaction at 10 days following arrival at home, with measures including patient level of depression, pain, physical functioning, self-efficacy with disease management, and medical service use.
Study Results: YES
Conditions: Study Focus: 30-day Rehospitalizations Among At-risk Older Adults Randomized to a Social Work-driven Care Transitions Intervention|Heart Disease|Diabetes|Hypertension|Cancer|Depression|Asthma|Chronic Heart Failure|Chronic Obstructive Pulmonary Disease|Stroke
Interventions: OTHER: SWIFT home intervention
Primary Outcome Measures: 30-day Hospital Readmission, The outcome measure is the number of readmissions experienced by participants in the Usual Care and Intervention groups within 30-days of their index discharge., 30-days post hospitalization
Secondary Outcome Measures: 30-day Readmission Among Intervention Participants, The outcome measure is the rate of 30-day readmissions among Intervention group participants that declined to receive the in-home social work intervention versus those Intervention group participants that received the in-home social work intervention., 30-days
Other Outcome Measures:
Sponsor: University of Southern California
Collaborators: Huntington Hospital|National Institute on Aging (NIA)
Sex: ALL
Age: OLDER_ADULT
Phases: NA
Enrollment: 181
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: UP-10-00372|5R21AG034557-02
Start Date: 2011-02
Primary Completion Date: 2013-10
Completion Date: 2013-10
First Posted: 2014-09-05
Results First Posted: 2014-12-04
Last Update Posted: 2017-02-10
Locations: University of Southern California, Los Angeles, California, 90089, United States|Huntington Hospital, Pasadena, California, 91105, United States
Study Documents:

NCT Number: NCT03969693
Study Title: Lymphoma Patients Undergoing Mediastinal Radiotherapy in the Era of Modern Chemoradiation
Study URL: https://beta.clinicaltrials.gov/study/NCT03969693

Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: Malignant anterior mediastinal tumors essentially include lymphomas and thymomas. The location of mediastinum is anatomically close to several critical organs such as heart, lung, and breasts, which might be affected meaningfully when the mediastinal region is irradiated. There have been quite a few studies investigating long-term toxicities concerning the above critical organs and risks of secondary malignancies related to treatment regimens combining chemotherapy and mediastinal radiotherapy. With the advancement of modern radiotherapy, highly conformal and intensity modulated radiotherapy have become a radiotherapeutic standard in recent years. However, most previous studies analyzed patients treated in the era of 2D techniques rather than conformal 3D plans. Almost inevitably, a large volume of the heart and lung was irradiated via the 2D technique with which substantial dose levels might be given to these organs unavoidably. Certainly long-term radiotherapy related toxicities are significantly associated with the dose and volume irradiating the normal organs at risk. Relying on the techniques of modern conformal radiotherapy and the contemporary strategy of multimodality therapy, the dose and volume irradiating the heart and lung were considerably reduced. Therefore, objective tools including heart echocardiography and lung function test will be utilized in this prospective study to evaluate and monitor mainly the patients diagnosed as malignant lymphoma who are recommended to receive mediastinal radiotherapy in the era of modern treatment strategy and techniques.

The participants potentially included in the current study are mainly lymphoma patients with mediastinal malignant lymphoma or patients whose radiation therapy field essentially encompasses anterior mediastinum. Patients are prospectively enrolled in this study after physicians' clinical judgement. After signing the consent form, the recruited patient will receive comprehensive pre-radiotherapy evaluations, including cardiac echocardiography, laboratory tests (BNP, and NT-pro BNP), and lung function tests. Participants who are particularly female patients under the age of 45 will receive pre-radiotherapy breast echocardiography. Radiotherapy treatment planning of both photon and proton respectively will be simulated on Eclipse® treatment planning system. Subsequently participants will receive mediastinal RT within one month after being enrolled in the study. Eligible patients should receive standard multidisciplinary treatment as the tumor board at our institute has suggested. Modern radiotherapy techniques comprise all available modalities in our hospital, including photon or proton beams, intensity-modulated radiotherapy, volumetric modulated arc therapy, image-guidance, and breathing control system. The prescription of treatment field designing and dose scheme will comply with our institutional protocols and updated cancer treatment guidelines. Participants will receive longitudinal follow-up examinations at 3, 6, 9, 12, 18, 24, 36 months after the start of RT

course. Standardized examinations include the above mentioned cardiac echocardiography and relevant tests.

It is anticipated that long-term mediastinal RT-related late effects are prospectively and longitudinally surveyed through consistent heart examinations and lung function tests. Long-term effects are expected to be lower with using maturely and widely adopted modern RT techniques. Therapeutic and survival outcomes are expected to be satisfactory, achieving the international level in this prospective observational study focusing on mainly lymphoma patients with mediastinal involvement who are suggested and scheduled to receive mediastinal RT as part of the combined modality treatment.

This study aims to standardize the application of clinical examinations including cardiac echocardiography, lung function tests, and relevant laboratory tests as part of objective tools for monitoring patients' cardiac and pulmonary functions after receiving mediastinal RT. Therefore, it is expected that the risk factors of predisposing patients to develop cardiac toxicities after chemoradiation particularly including mediastinal RT will be explored and identified. In addition objectivity of BNP (or NT-pro BNP) will also be verified in combination with the objective measurement and findings obtained from cardiac echocardiography. It is anticipated that our study would be an important and leading one that integrates radiation oncology, hematology, cardiology, and pulmonology into prospective and longitudinal cardiopulmonary surveillance carried out for mainly malignant lymphoma patients undergoing mediastinal RT in this era of modern chemoradiation.
Study Results: NO
Conditions: Mediastinal Lymphoma|Hodgkin Lymphoma|Non Hodgkin Lymphoma
Interventions: RADIATION: Standard treatment protocol with combined chemoradiation
Primary Outcome Measures: Change in heart function., The outcome assessed by cardiac echocardiography. Our study use the standard imaging modality -cardiac echocardiography, 12 month, and 24 month.
Secondary Outcome Measures: Change in cardiac biomarkers., The outcome assessed by plasma concentrations of BNP and NT-proBNP, 1 year, 2 years, 3 years|Change in lung function., The outcome assessed by lung function test. The lung function tests contain following four tests: "Determination of F. R. C" \& "Diffusion capacity rate" \& "Screening sporometry before \& after B. D." and "Simple bronchodilator test"., 1 year, 2 years, 3 years|Change in cardiac systolic and diastolic functions including left ventricular global longitudinal strain., The outcomes assessed by echocardiography, 1 year, 2 years, 3 years|Significant toxicities., The outcome assessed by CTCAE v5.0, 1 year, 2 years, 3 years|Disease failure rate within radiation fields, 3 years|Event-free survival, 3 years|Overall survival, Overall survival time, indicated by the time from the date of recruitment to the date of expiring, 3 years|Progression-Free Survival, 3 years
Other Outcome Measures:

Sponsor: Chang Gung Memorial Hospital
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 50
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 1810020038
Start Date: 2023-05-01
Primary Completion Date: 2028-12-31
Completion Date: 2028-12-31
First Posted: 2019-05-31
Results First Posted:
Last Update Posted: 2023-04-18
Locations: Chang Gung Memorial Hospital, Taoyuan, 333, Taiwan
Study Documents:

NCT Number: NCT01230905
Study Title: Study to Monitor the Effects of Androgen Suppression Treatment on the Heart
Study URL: https://beta.clinicaltrials.gov/study/NCT01230905
Acronym: AST
Study Status: COMPLETED
Brief Summary: Suppression of effects of androgens with male sex hormones, androgen suppression treatment (AST), has been known to reduce deaths and prolong life in advanced prostate cancer. There have, however, been concerns raised in previous studies that androgen suppression may be associated with increased rate of heart attacks, particularly in older men. This study looks at prostate cancer patients in The Ottawa Hospital Cancer Clinic to see if treating these patients with androgen suppression is associated with a decrease in blood flow to the heart muscles by using Positron Emission Tomography (PET) and brachial artery ultrasound.
Study Results: NO
Conditions: Prostate Cancer
Interventions: RADIATION: PET scan and ultrasound
Primary Outcome Measures: myocardial flow reserve, The change in global absolute MFR between baseline and follow up PET studies, at a patient level. MFR is defined as the ratio between regional blood flow with maximum vasodilation and baseline regional blood flow., 6 - 9 months
Secondary Outcome Measures: Regional myocardial perfusion, The change in absolute MFR between baseline and follow up tests for the 3 major coronary territories. Territories with severe reduction in flow or no flow on baseline images will be censored from this analysis. Regional myocardial perfusion will be assessed semi-quantitatively by summed stress scores and summed difference scores in each of the PET scans in the treatment and control groups.

Two-dimensional scans and pulse measures will be taken of the brachial artery with flow-mediated vasodilatation expressed as a percent change in arterial diameter from resting diameter., 6 - 9 months
Other Outcome Measures:
Sponsor: Ottawa Heart Institute Research Corporation
Collaborators:
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 181
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING
Other IDs: 2008341-01H
Start Date: 2008-07
Primary Completion Date: 2011-09
Completion Date: 2011-09
First Posted: 2010-10-29
Results First Posted:
Last Update Posted: 2017-04-24
Locations: University of Ottawa Heart Institute, Ottawa, Ontario, K1Y 4W7, Canada
Study Documents:

NCT Number: NCT04039516
Study Title: Carcinoid Heart Disease and Peptide Receptor Radiotargetted Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04039516
Acronym: CHARRT
Study Status: NOT_YET_RECRUITING
Brief Summary: Randomised trial to assess progression of carcinoid heart disease in patients treated with Lutathera therapy compared to best supportive care.
Study Results: NO
Conditions: Carcinoid Heart Disease|Carcinoid Syndrome|Carcinoid Tumor
Interventions: DRUG: Lutathera
Primary Outcome Measures: The rate of progression of moderate carcinoid heart disease (CHD), The rate of progression of carcinoid heart disease (CHD) in patients with moderate CHD will be compared across the Lutathera Therapy and Best Supportive Care Arms and will be assessed through RECIST CT/MRI imaging and urinary 5-HIAA levels throughout the duration of the study.

The rate of progression will be assessed at each study visit across both arms during the intervention and follow-up phase. If the study treatment is successful in delaying the rate of progression, then the rate of progression in the Lutathera (study intervention) arm is expected to be much slower than in the Best Supportive Care arm., 5

years
Secondary Outcome Measures: Change in NYHA heart failure score, The association between Lutathera Therapy against Best Supportive Care will be assessed by comparing the change in NYHA heart failure score in patients enrolled in both study arms.

The NYHA Heart Failure Score is grade I to IV, with Grade I being No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath) and Grade IV being Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

The change in grade will be assessed with an anticipated reduction in grade if the study treatment is successful in reducing symptoms., 5 years|Progressive disease, Progressive disease will be determined according to RECIST 2.0 criteria, following imaging (CT/MRI) conducted throughout the study, on all enrolled participants across the Lutathera Therapy and Best Supportive Care arm.

Tumour size according to RECIST 2.0 criteria will be examined with an anticipated decrease in tumour size should the study intervention be successful., 5 years|Reduction in urinary 5-HIAA levels, Reduction in urinary 5-HIAA levels throughout the course of the study will be compared across the Lutathera Therapy and Best Supportive Care arms.

Elevated 5-HIAA levels are an indicator of Carcinoid Syndrome, which is the condition under study in this clinical trial. A reduction in urinary 5-HIAA levels is expected should the study intervention prove successful., 5 years|Change in quality of life measurements (European Organization for Research and Treatment of Cancer questionnaires, QLQ-C30 and QLQ-GI.NET2), All enrolled patients will be required to complete the following validated quality of life questionnaires:

- European Organization for Research and Treatment of Cancer questionnaires, QLQ-C30 and QLQ-GI.NET2

The change in quality of life scores will be compared across the Lutathera Therapy arm and Best Supportive Care arm. If the study intervention is successful in moderating disease, a positive increase in the quality of life scores is expected., 5 years
Other Outcome Measures:
Sponsor: King's College Hospital NHS Trust
Collaborators: Advanced Accelerator Applications
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL

Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 263064
Start Date: 2020-10
Primary Completion Date: 2024-11
Completion Date: 2024-12
First Posted: 2019-07-31
Results First Posted:
Last Update Posted: 2020-08-04
Locations:
Study Documents:

NCT Number: NCT00190593
Study Title: Raloxifene Use for The Heart
Study URL: https://beta.clinicaltrials.gov/study/NCT00190593
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine whether raloxifene compared with placebo lowers the risk of coronary events and reduces the risk of invasive breast cancer in postmenopausal women at risk for major coronary events.
Study Results: NO
Conditions: Cardiovascular Diseases|Breast Neoplasms
Interventions: DRUG: raloxifene|DRUG: placebo
Primary Outcome Measures: Time to first occurrence of coronary death, non-fatal myocardial infarction (MI), or hospitalized acute coronary syndrome other than MI combined after an expected 5 to 7.5 years of follow-up.|Time to first occurrence of invasive breast cancer after an expected 5 to 7.5 years of follow-up.
Secondary Outcome Measures: After an expected 5 to 7.5 years of follow-up:|Cardiovascular death, non-fatal MI, hospitalized acute coronary syndrome other than MI, myocardial revascularization, and stroke (individually and combined)|All-cause hospitalization and mortality|Non-coronary artery revascularization|Non-traumatic lower extremity amputation|Fractures|Venous thromboembolism.
Other Outcome Measures:
Sponsor: Eli Lilly and Company
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 10000
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE|Primary Purpose: PREVENTION
Other IDs: 1865|H3S-MC-GGIO
Start Date: 1998-06
Primary Completion Date:
Completion Date: 2005-11

First Posted: 2005-09-19
Results First Posted:
Last Update Posted: 2007-01-26
Locations: For additonal information regarding investigative sites for this trial, please call 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559), Monday-Friday, 9:00 AM to 5:00 PM Eastern Time (UTC/GMT - 5 hours, EST) or speak with your personal physician, Minneapolis, Minnesota, United States
Study Documents:

NCT Number: NCT04072393
Study Title: Cardiac Rehabilitation for Patients Receiving Radiation Therapy for Thoracic Cancers
Study URL: https://beta.clinicaltrials.gov/study/NCT04072393
Acronym:
Study Status: RECRUITING
Brief Summary: Other than optimizing medical management of cardiac risk factors, and reducing radiotherapy (RT) dose to the heart, there currently exist no interventions to mitigate or reverse the adverse cardiac effects of RT. Aerobic exercise has been demonstrated to improve patient quality of life, cardiac outcomes, and cardiorespiratory fitness in patients with cancer receiving cardiotoxic systemic therapies, but the effects of aerobic exercise on patients at high risk for radiation induced heart disease (RIHD) is unknown. In addition, home-based cardiac rehabilitation has not been tested in patients with thoracic cancers.
Study Results: NO
Conditions: Lung Cancer|Esophageal Cancer|Thoracic Cancer|Hodgkin Lymphoma|Hodgkin Disease|Non-hodgkin Lymphoma|Sarcoma|Thymoma|Breast Cancer
Interventions: PROCEDURE: Home-based cardiac rehabilitation
Primary Outcome Measures: Feasibility of cardiac rehabilitation after definitive radiation therapy as measured by number of participants who complete at least 75% of prescribed cardiac rehabilitation sessions, -Cardiac rehabilitation will be considered as feasible if 75% of participants enrolled participate in at least 75% of prescribed cardiac rehabilitation sessions, Through completion of cardiac rehabilitation for all patients enrolled (estimated to be 33 months)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Washington University School of Medicine
Collaborators: The Foundation for Barnes-Jewish Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 25
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE

Other IDs: 201909133
Start Date: 2021-01-15
Primary Completion Date: 2023-09-30
Completion Date: 2023-09-30
First Posted: 2019-08-28
Results First Posted:
Last Update Posted: 2023-04-07
Locations: Washington University School of Medicine, Saint Louis, Missouri, 63110, United States
Study Documents:

NCT Number: NCT01511263
Study Title: Epigallocatechingallate (EGCG) in Cardiac AL Amyloidosis
Study URL: https://beta.clinicaltrials.gov/study/NCT01511263
Acronym: EpiCardiAL
Study Status: TERMINATED
Brief Summary: In a proportion of patients with AL amyloidosis there is no improvement of cardiac function despite hematologic response to treatment. The aim of the study is to assess whether treatment with EGCG increases the rate of cardiac response in patients with AL amyloidosis who completed chemotherapy.
Study Results: NO
Conditions: Primary Amyloidosis of Light Chain Type
Interventions: DRUG: Diuretics (plus antiarrhythmic drugs, i.e. amiodarone, in case of complex ventricular arrhithmias)|DRUG: Diuretics (plus antiarrhythmic drugs, i.e. amiodarone, in case of complex ventricular arrhythmias) plus EGCG
Primary Outcome Measures: Cardiac response, The primary objective is to assess whether treatment with EGCG increases the rate of cardiac response following chemotherapy in patients with AL amyloidosis. The primary endpoint is cardiac response at 6 months., 6 months
Secondary Outcome Measures: Rate of adverse events, The secondary objectives are to assess the safety of EGCG in cardiac AL amyloidosis, to determine whether EGCG can prevent or delay cardiac progression and to compare survival of patients receiving EGCG compared to subjects receiving SST., 6 months|Rate of cardiac progression, The secondary objectives are to assess the safety of EGCG in cardiac AL amyloidosis, to determine whether EGCG can prevent or delay cardiac progression and to compare survival of patients receiving EGCG compared to subjects receiving SST., 6 months|Time to cardiac progression, The secondary objectives are to assess the safety of EGCG in cardiac AL amyloidosis, to determine whether EGCG can prevent or delay cardiac progression and to compare survival of patients receiving EGCG compared to subjects receiving SST., 6 months|Rate of cardiac events, The secondary objectives are to assess the safety of EGCG in cardiac AL amyloidosis, to determine whether EGCG can prevent or delay cardiac progression and to compare survival of patients receiving EGCG compared to subjects receiving SST., 6 months|Time to cardiac events, The secondary objectives are to assess the safety of EGCG in cardiac AL amyloidosis, to determine whether EGCG can prevent or delay cardiac progression and

to compare survival of patients receiving EGCG compared to subjects receiving SST., 6 months|Survival, The secondary objectives are to assess the safety of EGCG in cardiac AL amyloidosis, to determine whether EGCG can prevent or delay cardiac progression and to compare survival of patients receiving EGCG compared to subjects receiving SST., 6 months
Other Outcome Measures:
Sponsor: IRCCS Policlinico S. Matteo
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 86
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: AC-006-IT
Start Date: 2012-01
Primary Completion Date: 2016-07
Completion Date: 2016-07
First Posted: 2012-01-18
Results First Posted:
Last Update Posted: 2018-03-21
Locations: Centro per lo Studio e la Cura delle Amiloidosi Sistemiche - Fondazione IRCCS Policlinico S.Matteo, Pavia, 27100, Italy
Study Documents:

NCT Number: NCT04996693
Study Title: On Dose Efficiency of Modern CT-scanners in Chest Scans
Study URL: https://beta.clinicaltrials.gov/study/NCT04996693
Acronym:
Study Status: RECRUITING
Brief Summary: CT scans of the chest / thorax are of great importance both in the initial diagnosis and in the follow-up of pulmonary or thoracic diseases. As an example, CT angiography of the pulmonary arteries (CTPA) is worldwide considered to be gold standard test in patients with a suspicion for pulmonary embolism.

The aim of this study is to measure and compare dose efficiency of modern CT scanners for unenhanced and contrast-enhanced scan protocols of the chest/thorax. Patients who are referred for a CT of the chest/thorax will be randomly assigned to one of the three CT scanners currently in use at our institution.
Study Results: NO
Conditions: Pneumonia|Lung Cancer|Pulmonary Embolism|Pulmonary Disease|Aortic Stenosis
Interventions: DIAGNOSTIC_TEST: Imaging on Scanner with Spectral Imaging Capabilities|DIAGNOSTIC_TEST: CT Scan using an Energy-Integrating Detector CT (128 slice MDCT)|DIAGNOSTIC_TEST: CT Scan

using an Energy-Integrating Detector CT (20-slice MDCT)
Primary Outcome Measures: Parameters of Objective Image Quality, Measured as signal, image noise and modulation transfer function equivalent parameters, 1 year|Parameters of Radiation Dose, measured as x-ray tube parameters such as dose length product (DLP), 1 year
Secondary Outcome Measures: Subjective Image Quality Evaluation (entire cohort and for individual disease groups), measured by blinded evaluation by radiologists, 1 year
Other Outcome Measures:
Sponsor: University Hospital Augsburg
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 2400
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 21-0368
Start Date: 2021-10-07
Primary Completion Date: 2023-10-06
Completion Date: 2024-10-06
First Posted: 2021-08-09
Results First Posted:
Last Update Posted: 2022-03-08
Locations: University Hospital Augsburg, Augsburg, Bavaria, 86156, Germany
Study Documents:

NCT Number: NCT01150916
Study Title: B-type Natriuretic Peptide in the Diagnosis of Heart Failure Related Ascites
Study URL: https://beta.clinicaltrials.gov/study/NCT01150916
Acronym:
Study Status: COMPLETED
Brief Summary: The serum albumin ascites gradient (SAAG) is a recommended tool for ascites diagnosis since values ≥1.1 g/dl are found in nearly 97% of patients with portal hypertension. However, it mislabels chronic liver disease and heart failure as the cause of ascites. Because type-B Natriuretic Peptide (BNP) is increased in several body fluids of patients with both systolic and diastolic dysfunction, it was found to be a useful marker for diagnosing heart failure and pleural effusion due to heart failure. Nevertheless, to date, the performance of BNP testing for assessing the etiology of ascites has not been examined. The current prospective study is aimed at comparing the following strategies for diagnosing heart failure as the cause of ascites: 1) SAAG plus total protein concentration in ascitic fluid (gold standard); 2) SAAG plus BNP concentration in ascitic fluid; 3) SAAG plus BNP concentration in serum; 4) serum BNP

concentrations.

SAAG, ascitic fluid protein concentration, serum and ascites type-B Natriuretic Peptide and echocardiography will be performed in all patients. The final diagnosis of the cause of ascites will be adjudicated by independent physicians, blinded for the results of ascitic fluid biochemistry and BNP. Patients will be divided into four groups: Heart failure, Liver cirrhosis, concurrent heart failure and liver cirrhosis (mixed) and other causes of ascites.
Study Results: NO
Conditions: Heart Failure|Liver Cirrhosis|Ascites|Carcinomatosis
Interventions: PROCEDURE: BNP, SAAG, ascites total protein, echocardiography
Primary Outcome Measures: diagnostic accuracy of BNP for the diagnosis of ascites due to heart failure, * ROC curves of different strategies with and without BNP levels for diagnosing heart failure as the cause of ascites.
* Sensitivity, specificity, accuracy, predictive values, likelihood ratios., 6 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Sao Paulo
Collaborators: University of Sao Paulo General Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 278
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, CARE_PROVIDER)|Primary Purpose: DIAGNOSTIC
Other IDs: CapPesq0074/10
Start Date: 2010-06
Primary Completion Date: 2011-11
Completion Date: 2012-03
First Posted: 2010-06-28
Results First Posted:
Last Update Posted: 2012-12-20
Locations: Federal University of Espirito Santo, Vitoria, Espirito Santo, 29045-402, Brazil|Hospital das Clinicas. University of São Paulo, Sao Paulo, 05403-000, Brazil
Study Documents:

NCT Number: NCT01904903
Study Title: Cardiac Safety Study in Patients With HER2 + Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01904903
Acronym: SAFE-HEaRt
Study Status: COMPLETED

Brief Summary: HER2 positive breast cancer cells have more HER2 receptor (a protein on the surface of cells) than normal breast cells. Approximately 30% of patients with breast cancer have HER2 positive breast cancer. Before HER2 targeted therapies (i.e. treatments that directly block the receptor HER2) were developed, patients with HER2 positive breast cancer had a very aggressive form of disease. With the use of trastuzumab, an anticancer drug that directly targets the receptor HER2, and more recently, pertuzumab and ado-trastuzumab emtansine, patients are able to live longer and have better control of their cancer.

Unfortunately the use of HER2 targeted therapies can increase the risk of heart problems and for this reason these treatments were only studied and approved for patients with normal heart function.

In this study we plan to give HER2 targeted therapies to patients with HER2 positive breast cancer and mildly decreased heart function along with concomitant evaluation by a heart doctor (called cardiologist) and appropriate medications to strengthen the heart. We will do frequent monitoring of the heart function with a test called echocardiogram that will give us a detailed "picture" of the heart. We will also draw blood along with routine blood tests to try to understand why some patients develop heart problems and others do not. The study will take a maximum of 12 months and patients will be monitored for 6 additional months.

We hypothesize that it is safe to administer HER2 targeted therapies to patients with breast cancer and mildly decreased heart function, i.e. LVEF between 40 and 50%, while on appropriate heart medications.
Study Results: YES
Conditions: HER2 Positive Breast Cancer|Left Ventricular Function Systolic Dysfunction
Interventions: DRUG: Trastuzumab|DRUG: Pertuzumab|DRUG: Ado Trastuzumab Emtansine
Primary Outcome Measures: Percentage of Patients Who Complete Planned Oncologic Therapy Without the Development of a Cardiac Event or Asymptomatic Worsening of Cardiac Function., Cardiac events are defined as any of the following:

∗ Presence of symptoms attributable to heart failure as confirmed by a cardiologist
∗ Cardiac arrhythmia requiring pharmacological or electrical treatment
∗ Myocardial infarction
∗ Sudden cardiac death or death due to myocardial infarct, arrhythmia or heart failure

Asymptomatic worsening of cardiac function defined as:

- Asymptomatic decline in LVEF \> 10% points from baseline and/or EF \< 35% corroborated by a confirmatory echocardiogram in 2-4 weeks

Planned oncologic therapy is defined as:

* In the adjuvant setting: completion of 1 year total of HER2 targeted therapy. If a patient already received part of the planned HER2 targeted therapy prior to enrollment in this trial, planned oncologic therapy will be achieved when a total of 1 year is completed.
* In the metastatic setting: cessation of treating regimen due to progressive disease or non-cardiac toxicity or non-cardiac death., Up to 18 months.

Secondary Outcome Measures: Median Time to Development of an Event Defined as Cardiac Event or Asymptomatic Worsening of Left Ventricular Dysfunction, Among Patients Who Developed One Event., Up to 18 months.|Absolute Changes in LVEF During HER2 Targeted Therapy Between Baseline and End of Treatment, Difference in LVEF between end of treatment and baseline, Up to 18 months.|HER2 Therapy Holds Attributed to Proportion of Patients With Symptomatic or Asymptomatic Cardiotoxicity., Proportion of patients that had a hold because of symptomatic or asymptomatic cardiotoxicity.

Hold is defined as any delay or discontinuation of HER2 targeted therapy due to cardiac toxicity. One cycle of HER2 targeted therapy will be considered 3 weeks. One therapy hold will be defined as any 3-week HER2 targeted therapy missed dose or 1/3 if one weekly trastuzumab dose. For patients who had a hold and resumed HER2 targeted therapy, duration of treatment hold will be described., Up to 12 months.|Correlation of Global Longitudinal Myocardial Strain With Cardiac Events and Asymptomatic Worsening of Cardiac Function, Up to 18 months.|Correlation of Standard Cardiac Troponin I and Highly Sensitive Cardiac Troponin T With Cardiac Events and Asymptomatic Worsening of Cardiac Function, Up to 18 months.

Other Outcome Measures:
Sponsor: Medstar Health Research Institute
Collaborators: Genentech, Inc.
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 31
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: ML 28685
Start Date: 2013-10
Primary Completion Date: 2019-06
Completion Date: 2020-06
First Posted: 2013-07-22
Results First Posted: 2020-09-11
Last Update Posted: 2022-05-10
Locations: Washington Cancer Institute at MedStar Washington Hospital

Center, Washington, District of Columbia, 20010, United States|MedStar Georgetown University Hospital, Washington, District of Columbia, 20057, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT02996903
Study Title: Prospective Multicenter Registry On RadiaTion Dose Estimates Of Cardiac CT AngIOgraphy IN Daily Practice in 2017
Study URL: https://beta.clinicaltrials.gov/study/NCT02996903
Acronym: PROTECTION-VI
Study Status: COMPLETED
Brief Summary: The "Prospective Multicenter Registry On RadiaTion Dose Estimates Of Cardiac CT AngIOgraphy IN Daily Practice in 2017" (PROTECTION-VI) study is a prospective registry and investigator-initiated initiative without third-party funding, which will collect and analyze the radiation dose exposure of Cardiac Computed Tomography Angiographic (CCTA) studies in current daily practice worldwide. Particularly, the study will assess the use of strategies for dose reduction during CCTA.

A decade ago, the multicentre observational PROTECTION-I study has revealed that the dose-length-product of CCTA ranges between 568 - 1259 mGy x cm with a median of 885 mGy x cm. This corresponds to an estimated effective dose of approximately 12 mSv. Since then a variety of techniques have been developed and enhanced in order to reduce radiation exposure during CCTA. Recent studies demonstrated feasibility of dramatically reduced effective radiation doses during CCTA (0,1 - 0,3 mSv). This has been executed in small cohorts of patients at scientific expert centers. However, it remains unclear, if such low-level radiation dose exposure may be achieved in clinical routine and if diagnostic image quality is maintained. In order to analyze the magnitude of radiation dose exposure of CCTA in today's clinical practice and the current use of dose-saving techniques, we designed the PROTECTION-VI study. Eventually, this study may contribute to further improving radiation dose exposure for patients undergoing CCTA.
Study Results: NO
Conditions: Coronary Artery Disease|Cardiac Disease|Malignancy, Second
Interventions:
Primary Outcome Measures: Radiation dose estimates of cardiac CT angiographies in daily practice, Assessment after CT scan by radiologist or technical assistant, documented on questionnaire., Baseline
Secondary Outcome Measures: Use of dose-saving strategies, Use of Low tube potential imaging, Low tube current imaging, Automated Exposure Control, ECG-controlled tube current modulation (dose pulsing), Iterative image reconstruction techniques and Scan protocols (Prospective ECG-triggered axial scanning technique, Prospective ECG-triggered high-pitch spiral acquisition) will be assessed in the Core Lab according to information given by the CT-examiner on a

questionnaire., Baseline|Assessment of CCTA image quality in relation to radiation dose, Assessment after CT scan by CT-examiner on questionnaire (qualitative) or in the Core Lab (quantitative).

Quantitative Assessment includes Signal intensity, Image noise, Contrast-to-noise ratio, Signal-to-noise ratio. Qualitative assessment of each coronary artery is performed using a 3-point grading scale including excellent, intermediate or non-diagnostic as documented on a provided questionnaire., Baseline|Sufficient result of the first CCTA scan or need for repeated scans, According to information given by the CT-examiner on a questionnaire., Baseline|Cardiac CT scan length and relationship between scan and heart length, Assessment in Core Lab after analysis of CT scans., Baseline|Comparison of dose estimates between different continents, CT vendors and CT systems, Analysis done in the Core Lab according to information given by the CT-examiner on a questionnaire., Baseline
Other Outcome Measures:
Sponsor: LMU Klinikum
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 4502
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: MUC I002-16
Start Date: 2017-03-01
Primary Completion Date: 2017-10-31
Completion Date: 2017-12-31
First Posted: 2016-12-19
Results First Posted:
Last Update Posted: 2018-05-15
Locations: National Heart, Lung, and Blood Institute, Bethesda, Maryland, 20892-1061, United States|University of British Columbia, Department of Medical Imaging, Vancouver, British Columbia, Canada|Ludwig-Maximilians-Universitaet Muenchen, Medizinische Klinik I, Munich, Bavaria, 808303, Germany|Technion Israel Institute of Technology, The Ruth and Bruce Rappaport Faculty of Medicine, Haifa, Israel
Study Documents:

NCT Number: NCT03575650
Study Title: Early Detection of Imaging-derived Subclinical Cardiac Injuries
Study URL: https://beta.clinicaltrials.gov/study/NCT03575650
Acronym: EMIRA
Study Status: RECRUITING
Brief Summary: Breast cancer (BC) radiotherapy leads to incidental cardiac irradiation, resulting in an increased risk of various major

cardiac events (MCEs). In addition, recent studies indicate that for the treatment of BC, the addition of chemotherapy further enhances the risk of MCEs. Information regarding morphological and functional early subclinical cardiac injuries (ESCIs) induced by chemotherapy and radiotherapy that develop into MCEs is largely lacking in scientific literature. This information is essential towards the development of primary and secondary preventive strategies. The EMIRA prospective cohort has as main objective to identify morphological and functional ESCIs in BC patients treated with adjuvant radiotherapy and chemotherapy.
Study Results: NO
Conditions: Cardiovascular Diseases
Interventions: OTHER: Cardiac imaging modalities
Primary Outcome Measures: Left Ventricle Global Longitudinal Strain (LV-GLS) assessed by echocardiography, Increasement in left ventricle Global Longitudinal Strain (GLS) of at least 5%, 6 and 24 months after radiotherapy with reference to baseline
Secondary Outcome Measures: Changes in myocardial function assessed by echocardiography, Increasement of segmental strain measurements (unit of measures:%), 6 and 24 after completion of radiotherapy with reference to baseline|Anatomical changes in coronary arteries by cardiac CT, Increase in the number of coronary segments containing any plaque/stenosis, or increase in calcium score, 6 and 24 after completion of radiotherapy with reference to baseline|Myocardial tissue abnormalities assessed by cardiac MRI, Increase of the native mean myocardial T1 mapping value assessed by cardiac MRI, 6 and 24 after completion of radiotherapy with reference to baseline
Other Outcome Measures:
Sponsor: University Medical Center Groningen
Collaborators: Utrecht University
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 148
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2018-06
Start Date: 2019-01-24
Primary Completion Date: 2023-09-04
Completion Date: 2024-09-02
First Posted: 2018-07-02
Results First Posted:
Last Update Posted: 2023-05-22
Locations: UMCG, Groningen, 9713GZ, Netherlands
Study Documents:

NCT Number: NCT00501345
Study Title: Aspirin in Patients With Myocardial Infarction and Thrombocytopenia

Study URL: https://beta.clinicaltrials.gov/study/NCT00501345
Acronym:
Study Status: TERMINATED
Brief Summary: Primary Objective:

To determine the risk of bleeding from ASA therapy in thrombocytopenic patients who develop Acute Coronary Syndrome (ACS), and assess its effect on the overall morbidity and mortality in these patients as well as platelet functions.
Study Results: YES
Conditions: Thrombocytopenia|Myocardial Infarction
Interventions: DRUG: Aspirin
Primary Outcome Measures: Participants With 7 Days Observation Without Severe Bleeding, Blood samples collected at baseline before or after aspirin is given and at 24 hours, 72 hours and 7 days after treatment has been initiated for those that remain in the study after the first 24 hours., 7 Days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 5
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: ID01-674
Start Date: 2002-02
Primary Completion Date: 2008-02
Completion Date: 2008-02
First Posted: 2007-07-16
Results First Posted: 2009-09-24
Last Update Posted: 2012-08-01
Locations: U.T.M.D. Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT05215509
Study Title: Exercise-induced Cardiac Adaptions in Rheumatoid Arthritis Patients During Interleukin-6 vs. Tumor Necrosis Factor Antibody Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT05215509
Acronym: RABEX
Study Status: RECRUITING
Brief Summary: The present study will investigative the physiological effects of the cytokines interleukin-6 (IL-6) and tumor necrosis factor (TNF) on the adaptive changes to exercise in patients with

rheumatoid arthritis. The investigators hypothesize that blockage of IL-6 receptors will decrease the cardiac and metabolic adaptations to exercise training compared to the inhibition of TNF. 80 patients will be included in a 12-week investigator blinded randomised exercise training intervention study.
Study Results: NO
Conditions: Rheumatoid Arthritis
Interventions: BEHAVIORAL: Exercise|BEHAVIORAL: No exercise
Primary Outcome Measures: Change in left ventricular mass, measured by MRI scan, 12 weeks
Secondary Outcome Measures: Visceral adipose tissue mass, measured by MRI scan, 12 weeks|Stroke volume, Structural cardiac parameter: measured by MRI scan and echocardiography, 12 weeks|Left ventricular and atrial end-diastolic volume, Structural cardiac parameter: measured by MRI scan and echocardiography, 12 weeks|LVEF, Functional cardiac parameters: measured by MRI scan and echocardiography, 12 weeks|Global longitudinal strain, Functional cardiac parameters: measured by MRI scan and echocardiography, 12 weeks|E/A ratio, Functional cardiac parameters: measured by MRI scan and echocardiography, 12 weeks|E/é, Functional cardiac parameters: measured by MRI scan and echocardiography, 12 weeks|Left ventricular and atrial end-systolic volume, Structural cardiac parameter: measured by MRI scan and echocardiography, 12 weeks|Left atrial volume index, Structural cardiac parameter: measured by MRI scan and echocardiography, 12 weeks|Interventricular septum thickness, Structural cardiac parameter: measured by MRI scan and echocardiography, 12 weeks|Left ventricular posterior wall thickness, Structural cardiac parameter: measured by MRI scan and echocardiography, 12 weeks|Aortic and pulmonary distensibility and pulse wave velocity, Functional vascular parameter: measured by MRI, 12 weeks|Subcutaneous, visceral and epicardial adipose tissue, Measured by MRI and MR spectroscopy, 12 weeks|Intramyocardial triglyceride content, Measured by MRI and MR spectroscopy, 12 weeks|Cardiorespiratory fitness, Measured with an incremental VO2 protocol on exercise bike, 12 weeks|Dynamic spirometry, Pulmonary function testing, 12 weeks|Whole body plethysmography, Pulmonary function testing, 12 weeks|Diffusion capacity, Pulmonary function testing, 12 weeks|Body composition, Measured by a DXA scan, 12 weeks|Oral glucose tolerance test, 75g of glucose taken while fasting, 12 weeks|Axial accelerometer-based physical activity monitors, Free-living physical activity is measured using axial accelerometer-based physical activity monitors (AX3; Axivity, Newcastle upon Tyne, UK) for a 5-day period, 5 days in week 6 of the intervention/control|Dietary intake, Self reported intake of all foods and liquids, 3 days in the week 6 of intervention/control|Blood sample, Change in fasting total cholesterol, low-density lipoprotein (LDL)-cholesterol and high-density lipoprotein (HDL)-cholesterol (mmol/L). Following an overnight fast (10 hours), blood samples are collected and processed by a trained laboratory technician and analysed according to standard procedures., 12 weeks|Blood sample, Change in triglycerides (mmol/L).

Following an overnight fast (10 hours), blood samples are collected and processed by a trained laboratory technician and analysed according to standard procedures., 12 weeks|RA disease specific outcomes 1, Change in measures of the international Core Outcome Set for rheumatoid arthritis : 66/68 tender and swollen joint count, 12 weeks|RA disease specific outcomes 2, Change in visual analogue scale (VAS) pain, VAS physician global assessment, VAS patient global assessment

The Visual Analogue Scale (VAS) is a self-report measure consisting simply of a 100 mm horixontal line with a statement at each end representing one extreme (0mm = nothing, 100mm = extreme), 12 weeks|RA disease specific outcomes 3, Change in Health Assessment Questionnaire (HAQ-DI)

Total score is between 0-3.0. Increasing scores indicate worse functioning with 0 indicating no functional impairment and 3 indicating complete impairment., 12 weeks|RA disease specific outcomes 4, Change in Short Form 36 (SF-36) Health Survey Questionnaire

A 8-scale score within 8 domains.All items are scored so that a high score defines a more favorable health state., 12 weeks|RA disease specific outcomes 5, Change in the composite Disease Activity Score-28 ESR for Rheumatoid Arthritis (DAS28).

A DAS28 of greater than 5.1 implies active disease, less than 3.2 low disease activity, and less than 2.6 remission, 12 weeks|RA disease specific outcomes 6, Change in response criteria will be assessed according the clinical disease activity index (CDAI).

The CDAI composite index quantifies disease activity in RA, by utilising four clinical parameters including tender and swollen joints and global assessment from both patient and assessor on a vasual analogue scale.

CDAI interpretation score CDAI ≥ 22,1: High Activity CDAI \< 22,1 og ≥10,1: Moderate Activity CDAI \<10,0 og ≥ 2,9: Low Activity CDAI \<2,9: Remission, 12 weeks|RA disease specific outcomes 7, Change in response criteria will be assessed according the American College of Rheumatology (ACR 20/50/70) response, 12 weeks|RA disease specific outcomes 8, Change in response criteria will be assessed according the European League Against Rheumatism (EULAR none/good/moderate response), 12 weeks
Other Outcome Measures:
Sponsor: Rigshospitalet, Denmark
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 80

Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: SINGLE (INVESTIGATOR)|Primary Purpose:
HEALTH_SERVICES_RESEARCH
Other IDs: H-21010559
Start Date: 2021-12-01
Primary Completion Date: 2023-12-31
Completion Date: 2024-03-30
First Posted: 2022-01-31
Results First Posted:
Last Update Posted: 2023-04-05
Locations: Rigshospitalet, Copenhagen, 2100, Denmark
Study Documents:

NCT Number: NCT01448083
Study Title: Heart/Mediastinal Ratio Study for Potential Equivalence of Heart/Mediastinal Ratios at One and Two Hours to the Traditional Heart/Mediastinal Ratio Obtained at Four Hours
Study URL: https://beta.clinicaltrials.gov/study/NCT01448083
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to determine if the measurement (with a standard nuclear camera) of radioactivity normally present in the nervous system of your heart at four hours after the injection of radioactive drug for your diagnostic I-123 MIBG scan is any different than radioactivity measured in your heart at one and/or two hours after your diagnostic scan injection. If equivalent information to the conventional 4 hr H/M ratio could be collected by obtaining H/M ratios at 1 or 2 hour windows, it would greatly facilitate patient acceptance of the procedure since the requirements for obtaining a valid H/M ratio would be considerably less time-consuming.

One hour before being injected with the drug (I-123 MIBG) for your MIBG scan, you will be given a standard dose of non-radioactive iodine (Lugol's solution) to block your thyroid from receiving the small amount of radiation that is a normal part of the MIBG scan. You will then be injected with MIBG, and you will have 10 minute pictures of your chest at 15 minutes, 1 hour, 2 hours, and 4 hours in addition to the standard 24 hour pictures. These pictures will be taken in the Nuclear Medicine Section, Department of Radiology at Ochsner Medical Center-Kenner. The experimental (research) part of this study is having the extra 10-minute pictures of your chest at 15 minutes, 1 hour, 2 hours, and 4 hours. Normally, pictures are only taken 24 hours after the injection. Therefore the research is limited to the four extra pictures taken, and involve no additional injections or I-123 drug beyond that you will be receiving regardless of whether you are part of this research.
Study Results: NO

Conditions: Neuroendocrine Tumor
Interventions: OTHER: Standard of care diagnostic MIBG scan for neuroendocrine tumor diagnosis.
Primary Outcome Measures: The heart/mediastinal ratio (H/M) at one or two hours post injection of AdreView™ (I-123 MIBG) in neuroendocrine tumor patients is equivalent to the standard 4 hr calculation., Approximately 10 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Nuclear Medicine Consultants, Inc.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 40
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 11-MIBG-005
Start Date: 2011-10
Primary Completion Date:
Completion Date:
First Posted: 2011-10-07
Results First Posted:
Last Update Posted: 2012-09-18
Locations: Ochsner Medical Center - Kenner, Kenner, Louisiana, 70065, United States
Study Documents:

NCT Number: NCT05563883
Study Title: Atrial Fibrillation and Cancer: a Nationwide French Cohort Study
Study URL: https://beta.clinicaltrials.gov/study/NCT05563883
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Atrial fibrillation (AF) is a common complication associated with cancer but the risk of AF according to the cancer localization and status as well as the risk of thromboembolisms, bleedings and mortality are poorly known.

The objective of this study is to use a very large French nationwide cohort to adress thèses questions.
Study Results: NO
Conditions: Atrial Fibrillation|Cancer|Thromboembolism|Bleeding
Interventions: OTHER: event occurence
Primary Outcome Measures: atrial fibrillation, occurrence of atrial fibrillation, from inclusion in the cohort up to 10 years|cancer, occurrence of cancer, ffrom inclusion in the cohort up to 10 years
Secondary Outcome Measures: thromboembolism, occurrence of thromboembolism, from inclusion in the cohort up to 10 years|bleeding,

occurrence of bleeding, from inclusion in the cohort up to 10 years| mortality, occurrence of mortality, from inclusion in the cohort up to 10 years
Other Outcome Measures:
Sponsor: University Hospital, Caen
Collaborators: University Hospital, Tours
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 5000000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PMSI_092022
Start Date: 2022-09-22
Primary Completion Date: 2030-01
Completion Date: 2030-01
First Posted: 2022-10-03
Results First Posted:
Last Update Posted: 2022-10-03
Locations: Service de Cardiologie, Centre Hospitalier Universitaire Trousseau, Tours, 37000, France
Study Documents:

NCT Number: NCT04961307
Study Title: Evaluation of Heart Function in Breast Cancer Patients Using Trastuzumab
Study URL: https://beta.clinicaltrials.gov/study/NCT04961307
Acronym:
Study Status: UNKNOWN
Brief Summary: By dynamically observing the changes of echocardiogram and biomarkers in breast cancer patients using trastuzumab, evaluate the effect of trastuzumab on cardiac function; determine the sensitivity of echocardiography and biomarker indicators And specificity, explore effective and specific early warning indicators, and provide technical support for the evaluation of the cardiac safety of anti-tumor drugs.
Study Results: NO
Conditions: Cardiotoxicity|Antitumor Drugs|Breast Cancer|Trastuzumab
Interventions: DRUG: Trastuzumab
Primary Outcome Measures: Time ending, 180 days after chemotherapy, 6 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Peking University Third Hospital
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 30

Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Cardiac safety study
Start Date: 2019-07-05
Primary Completion Date: 2021-12-01
Completion Date: 2021-12-30
First Posted: 2021-07-14
Results First Posted:
Last Update Posted: 2021-07-14
Locations: Peking University Third Hospital, Peking, Beijing, 100191, China
Study Documents:

NCT Number: NCT02062983
Study Title: Early Predictor of Herceptin Cardio Toxicity in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02062983
Acronym:
Study Status: SUSPENDED
Brief Summary: Early identification of patients at risk for cardiotoxicity represent a primary goal for cardiologist and oncologist

From all adjuvant trials echocardiography is ideal for evaluating Left Ventricular function though its operator dependent. The use of other technique such as endomyocardial biopsy, is troublesome in clinical practice

Cardiac magnetic resonance imaging (MRI) have greater reproducibility in evaluating left ventricular ejection fraction (LVEF). This technique provides morphological, functional, perfusion, and viability information in one assessment. It is expensive and time consuming but id the diagnostic method of choice for patients with technically limited images from ECG and in patients with discordant information that is clinically significant from prior tests
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Herceptin
Primary Outcome Measures: Estimate the incidence /of Herceptin induced heart failure in our population, To evaluate the reversibility of damage in patients on long term follow- up for a period of up to three years.

To identify the applicability of troponin / cardiac natriuretic peptides (CNPS) as bio marker that can predict the occurrence of clinically significant left ventricular dysfunction.

To evaluate the role of MRI in identifying patient at risk to develop cardio toxicity.

Determine the frequency of elevated Troponin and B-type natriuretic peptide (BNP) in patient receiving adjuvant herceptin., 3 years
Secondary Outcome Measures: Determine the incremental diagnostic value of Trop and BNP in predicting incidence of Hem CMP., Determine the incremental diagnostic value of Trop and BNP in predicting incidence of Hem cardiac marker (CMP).

Determine the relation between prior myocardial scaling and incidence of herceptin induced cardiac marker (CMP).

Determine the correlation between myocardial edema, BNP and heart failure incidence of CMP, 3 years
Other Outcome Measures:
Sponsor: National Guard Health Affairs
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 50
Funder Type: OTHER_GOV
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Herceptin
Start Date: 2012-06
Primary Completion Date: 2016-08
Completion Date: 2016-08
First Posted: 2014-02-14
Results First Posted:
Last Update Posted: 2016-05-13
Locations: National Guard Health Affairs, Riyadh, 11426, Saudi Arabia
Study Documents:

NCT Number: NCT04632407
Study Title: Can Flaxseed Prevent Broken Hearts in Women With Breast Cancer Study?
Study URL: https://beta.clinicaltrials.gov/study/NCT04632407
Acronym: CANFLAX
Study Status: UNKNOWN
Brief Summary: The main goal of the current research program is to examine the use of nutraceuticals, in particular flaxseed (FLX), in the prevention of Doxorubicin and Trastuzumab (DOX+TRZ) mediated cardiotoxicity in the clinical setting. As Manitoba continues to be one of the top FLX producers in the world, there is an increasing public awareness of the importance of the consumption of this whole grain commodity in the prevention of cancer and cardiovascular disease. In North America, approximately 1 in 8 women will develop breast cancer and will receive treatment with DOX+TRZ. Although women with breast cancer are at risk of developing heart failure due to chemotherapy, FLX has the capacity to prevent this outcome. The

purpose of the CANFLAX study is to establish FLX "milk" as an effective method in preventing heart failure in women with breast cancer.
Study Results: NO
Conditions: Cardiotoxicity
Interventions: DIETARY_SUPPLEMENT: Flax "milk"|DIETARY_SUPPLEMENT: Oat fibre "milk"
Primary Outcome Measures: Left ventricular ejection fraction (LVEF) change, Left ventricular ejection fraction (LVEF %) will be evaluated using transthoracic echocardiography at baseline and 12 month follow-up. A difference in LVEF\>10% from baseline will be considered significant., 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: St. Boniface Hospital
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: CT/2019/CANFLAX
Start Date: 2020-10-21
Primary Completion Date: 2022-12-31
Completion Date: 2022-12-31
First Posted: 2020-11-17
Results First Posted:
Last Update Posted: 2020-11-17
Locations: St. Boniface Albrechtsen Research Centre, Winnipeg, Manitoba, R2E1J7, Canada
Study Documents:

NCT Number: NCT05611307
Study Title: Late Subclinical Cardiovascular Disease in Testicular Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT05611307
Acronym:
Study Status: RECRUITING
Brief Summary: Late subclinical cardiovascular disease in testicular cancer survivors exposed to cisplatin-based chemotherapy and bone marrow transplant
Study Results: NO
Conditions: Testicular Cancer|Survivorship|ASCVD|Coronary Artery Disease|Lipid Disorder|Hypogonadism, Male|Cisplatin Adverse Reaction|Bone Marrow Transplant Complications
Interventions: DIAGNOSTIC_TEST: Lipid profile|DIAGNOSTIC_TEST:

Coronary artery assessment|DIAGNOSTIC_TEST: Hormone levels for hypogonadism
Primary Outcome Measures: Lipid profile, HDL, LDL, Tg, Cholesterol, Novel Lipid biomarkers using blood draws, More than 10 years after testicular cancer diagnosis, At recruitment|Coronary plaque assessment, Coronary calcium score, coronary artery anatomy and plaque assessment using CT scans, More than 10 years after testicular cancer diagnosis, At recruitment
Secondary Outcome Measures: Hormone levels, Measurement of testosterone, More than 10 years after testicular cancer diagnosis, At recruitment|Serum platinum, Measurement of residual serum platinum levels, More than 10 years after testicular cancer diagnosis, At recruitment
Other Outcome Measures:
Sponsor: Indiana University
Collaborators:
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 150
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 12751
Start Date: 2022-10-11
Primary Completion Date: 2025-12-31
Completion Date: 2025-12-31
First Posted: 2022-11-10
Results First Posted:
Last Update Posted: 2022-11-10
Locations: Indiana University, Indianapolis, Indiana, 46202, United States
Study Documents:

NCT Number: NCT01038583
Study Title: Aspirin in Reducing Events in the Elderly
Study URL: https://beta.clinicaltrials.gov/study/NCT01038583
Acronym: ASPREE
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: ASPREE-XT is a post-treatment, longitudinal observational follow-up study of ASPREE participants \[ASPREE Investigator Group, 2013; www.aspree.org; McNeil et al 2017\]. Although the ASPREE trial medication was ceased, the study activity was not stopped and ASPREE participants are continuing with scheduled visits and phone calls. An observational follow-up phase (ASPREE-XT), began in January, 2018. This will enable the monitoring of possible delayed effects of aspirin treatment, primarily on cancer incidence, metastases and mortality. In addition to monitoring the incidence of malignancy within the ASPREE cohort, the opportunity will be taken to observe any other residual effects of aspirin on the endpoints being

monitored in the cohort. Continuity of contact with study participants is the key to retention of the cohort for any ongoing or future studies.
Study Results: NO
Conditions: Functional Disability|Dementia|Heart Disease|Stroke|Cancer|Bleeding|Depression
Interventions: DRUG: 100 mg enteric-coated aspirin|DRUG: Placebo
Primary Outcome Measures: The primary endpoint is death from any cause or incident, dementia or persistent physical disability., Dementia will be diagnosed based on DSM-IV criteria. Significant physical disability will be defined as a confirmed, and persisting for at least 6 months, self-report of 'a lot of difficulty', or 'inability to perform independently' any one of the 6 Katz basic Activities of Daily Living (ADLs).75, every 6 months
Secondary Outcome Measures: All-cause mortality, every 6 months|Fatal and non fatal cardiovascular events including a) coronary heart disease death, b) non-fatal MI, c) fatal and non-fatal stroke and d) any hospitalization for heart failure, every 6 months|Fatal and non-fatal cancer, excluding non-melanoma skin cancer, every 6 months|Dementia, every 6 months|Mild Cognitive Impairment (MCI; assessed using the Modified Mini-Mental State Examination or 3MS 70 and other cognitive function measures - see below), every 6 months|Physical disability, every 6 months|Major hemorrhagic events, every 6 months|Depression, Annually
Other Outcome Measures:
Sponsor: Hennepin Healthcare Research Institute
Collaborators: National Health and Medical Research Council, Australia|Bayer|Monash University|Berman Center for Outcomes and Clinical Research|National Institute on Aging (NIA)|National Cancer Institute (NCI)
Sex: ALL
Age: OLDER_ADULT
Phases:
Enrollment: 19114
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: HSR#09-3029|3U01AG029824-07S2
Start Date: 2010-01
Primary Completion Date: 2017-12
Completion Date: 2024-04
First Posted: 2009-12-24
Results First Posted:
Last Update Posted: 2021-04-05
Locations: The University of Alabama at Birmingham, Birmingham, Alabama, 35294, United States|Palo Alto Medical Foundation Research Institute, Palo Alto, California, 94301, United States|Howard University, Washington, District of Columbia, 20060, United States|University of Florida Department of Aging and Geriatrics, Gainesville, Florida, 32611, United States|Morehouse School of Medicine, Atlanta,

Georgia, 30310, United States|Emory/ Atlanta VAMC, Atlanta, Georgia, 30322, United States|Georgia Health Sciences University, Augusta, Georgia, 30912, United States|Rush Alzheimer's Disease Center, Chicago, Illinois, 60612, United States|University of Iowa, Iowa City, Iowa, 52242, United States|Kansas University Medical Center, Kansas City, Kansas, 66106, United States|Pennington Biomedical Research Center, Baton Rouge, Louisiana, 70808, United States|Mary Bird Perkins Our Lady of the Lake Cancer Center, Baton Rouge, Louisiana, 70809, United States|LSU Health Sciences- New Orleans, New Orleans, Louisiana, 70112, United States|Tulane Medical Center, New Orleans, Louisiana, 70112, United States|LSU Health Sciences- Shreveport, Shreveport, Louisiana, 71130, United States|University of Michigan, Ann Arbor, Michigan, 48109, United States|Wayne State University, Detroit, Michigan, 48201, United States|Henry Ford Health System, Detroit, Michigan, 48202, United States|Detroit Clinical Research Center, Novi, Michigan, 48377, United States|HealthPartners Research Institute, Minneapolis, Minnesota, 55425, United States|Phalen Village Clinic, Saint Paul, Minnesota, 55106, United States|Central Jersey Medical Center, Elizabeth, New Jersey, 07202, United States|Winthrop University Hospital, Mineola, New York, 11501, United States|Wake Forest University Baptist Medical Center, Greensboro, North Carolina, 27408, United States|The Brody School of Medicine at ECU, Greenville, North Carolina, 27834, United States|Albert Einstein Medical Center, Philadelphia, Pennsylvania, 19141, United States|University of Pittsburgh Health Sciences Research Center, Pittsburgh, Pennsylvania, 15260, United States|Memorial Hospital of Rhode Island, Pawtucket, Rhode Island, 02860, United States|University of Tennessee Health Science Center, Memphis, Tennessee, 38105, United States|University of Texas Southwestern Medical Center at Dallas, Dallas, Texas, 75390, United States|University of TX Medical Branch, Galveston, Texas, 77555, United States|Regional Academic Health Center, Harlingen, Texas, 78550, United States|UT Health Science Center at San Antonio, San Antonio, Texas, 78229, United States|Clinical Trials Unit, The Canberra Hospital, Garran, Australian Capital Territory, 2605, Australia|Illawarra Health and Medical Research Institute, University of Wollongong, Wollongong, New South Wales, 2522, Australia|Discipline of General Practice, School of Population Health, University of Adelaide, Adelaide, South Australia, 5005, Australia|Greater Green Triangle University, Mount Gambier, South Australia, 5290, Australia| University of Tasmania Rural Clinical School, Burnie, Tasmania, 7320, Australia|The Menzies Institute for Medical Research, University of Tasmania, Hobart, Tasmania, 7000, Australia|University of Tasmania Newnham Campus, Launceston, Tasmania, 7250, Australia|Bendigo Regional Clinical School, Bendigo, Victoria, 3550, Australia|Geelong Hospital, Geelong, Victoria, 3220, Australia|Monash Mildura Regional Clinical School, Mildura, Victoria, 3500, Australia|University of Ballarat, Mount Helen, Victoria, 3350, Australia|Monash Gippsland Regional Clinical School, Traralgon, Victoria, 3844, Australia|The South West Alliance of Rural Health (SWARH), Warrnambool, Victoria, 3280, Australia|Gateway Community Health, Wodonga, Victoria, 3690, Australia

Study Documents:

NCT Number: NCT04190433
Study Title: Autophagy Activation for the Alleviation of Cardiomyopathy Symptoms After Anthracycline Treatment, ATACAR Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT04190433
Acronym:
Study Status: WITHDRAWN
Brief Summary: This phase II trial compares two drug therapy plans for the correction of heart function changes (reduced ejection function) in patients who have undergone anthracycline-based treatment for lymphoma, sarcoma, or breast cancer. "Reduced ejection fraction" means the left ventricle of the heart is pumping a reduced blood volume with each heartbeat. Treatment is recommended, and the purpose of this research is to compare two different drug therapy plans (standard therapy with carvedilol and lisinopril and standard therapy with carvedilol and lisinopril plus pravastatin and spironolactone) and their effects on improvement of heart function. All of these drugs are heart medications, and carvedilol and lisinopril are commonly used to improve heart function. Adding pravastatin, a cholesterol lowering drug with additional beneficial effects on the cardiovascular system, and spironolactone, a water pill with additional beneficial effects on the cardiovascular system, may lead to even better (and faster) improvements in heart function.
Study Results: NO
Conditions: Breast Carcinoma|Hematopoietic and Lymphoid Cell Neoplasm|Lymphoma|Sarcoma
Interventions: DRUG: Carvedilol|DRUG: Lisinopril|DRUG: Pravastatin|DRUG: Spironolactone
Primary Outcome Measures: Delta change in left ventricular ejection fraction [LVEF]), Will be a comparison of the average delta change in LVEF from start to six months of therapy between group 1 and 2 via an independent groups t-test or Wilcoxon as appropriate after testing distributional assumptions., Baseline up to 6 months
Secondary Outcome Measures: Cardiac function recovery rates between group 1 and group 2, Incidence rates will be compared using a simple test for equality of binomial proportions ($\chi \^ 2$ -test or Fisher Exact)., Baseline up to 6 months|Time to recovery of cardiac function between group 1 and group 2, Will be a comparison of the average delta change in LVEF from start to six months of therapy between group 1 and 2 via an independent groups t-test or Wilcoxon as appropriate after testing distributional assumptions., Baseline up to 6 months
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 0
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 19-007547|NCI-2021-13928
Start Date: 2020-09-01
Primary Completion Date: 2023-04-18
Completion Date: 2023-04-18
First Posted: 2019-12-09
Results First Posted:
Last Update Posted: 2023-05-24
Locations:
Study Documents:

NCT Number: NCT03987633
Study Title: EMPOWER-1: A Multi-site Clinical Cohort Research Study to Reduce Health Inequality
Study URL: https://beta.clinicaltrials.gov/study/NCT03987633
Acronym:
Study Status: RECRUITING
Brief Summary: Health inequality and genetic disparity are a significant issue in the United Kingdom (UK).

This study focuses on diseases that are associated with significant morbidity and mortality in the UK, and specifically examines the extent and basis of treatment failure in different patient populations.

The vast majority of drug registration clinical trials have under-representation of ethnic minority populations. In addition, the wider Caucasian populations have reasonably different clinical characteristics to the population that participated in the drug licencing clinical trials. A consequence of this is that drugs are licensed for use in real-world general patient populations where the clinical trial results are simply not statistically significant to specifically demonstrate efficacy or safety in populations that were either absent or under-represented in the drug registration clinical trials. When these facts are considered alongside data that supports significant under-reporting of adverse events in the real-world setting within the UK (and globally, e.g the USA and Europe), it highlights that pharmacovigilance systems are unable to capture drug effectiveness and safety data in a manner that can reasonably assure appropriate prescribing in the wider patient populations.

This large real-world research study aims to identify whether commonly prescribed drugs are effective in treating illnesses that cause significant poor health and death in the different patient populations that represent the UK.

The goal of this study is to generate large quantitative data-sets

that may inform clinical practice to reduce the existing health inequality and genetic disparity in the UK.
Study Results: NO
Conditions: Atrial Fibrillation|Coronary Heart Disease|Cardiovascular Diseases|Heart Failure|Hypertension|Peripheral Arterial Disease|Stroke, Ischemic|Asthma|Chronic Obstructive Pulmonary Disease|Obesity|Cancer|Chronic Kidney Diseases|Diabetes Mellitus|Dementia|Depression|Epilepsy|Mental Health Disorder|Rheumatoid Arthritis|Blood Pressure
Interventions:
Primary Outcome Measures: Ethnic disparities in treatment failure, Identify ethnic disparities in treatment failures for any of the 19 disease states under investigation. The primary outcome is treatment failure, as measured by the discontinuation of a treatment regimen by a clinician in the absence of the cure of the disease, for the most common treatment in each of the 19 diseases., Ongoing review of data, anticipated completion of primary outcome analysis 4 years post launch
Secondary Outcome Measures: Ethnic disparities in disease incidence, Identifying ethnic disparities in disease incidence. The corresponding secondary outcome measure for this is, for each of the 19 diseases under consideration, the diagnosis of the disease. We will use time to diagnosis to examine ethnic disparities in incidence., Ongoing review of data, anticipated completion of analysis 5 years post launch|Identification of candidate genetic variants associated with observed disparities in treatment failure., Another secondary outcome is identifying candidate genetic variants that may underpin observed disparities in treatment failure, for treatments in the 19 diseases under consideration. The corresponding secondary outcome measures used for this are genotypes as identified through whole genome sequencing (WGS) of patient saliva or peripheral blood that are associated with the phenotypes corresponding to the treatment failure previously described as the primary outcome measure., Ongoing review of data, anticipated completion of analysis 5 years post launch
Other Outcome Measures:
Sponsor: Future Genetics Limited
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 200000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: EMPOWER-1
Start Date: 2021-02-01
Primary Completion Date: 2026-02-01
Completion Date: 2028-02-01
First Posted: 2019-06-17
Results First Posted:
Last Update Posted: 2023-02-15
Locations: Future Genetics, The Science Centre, Wolverhampton Science

Park, Wolverhampton, West Midlands, WV10 9RU, United Kingdom
Study Documents:

NCT Number: NCT02344433
Study Title: Using Virtual Counselors to Overcome Genetic Literacy Barriers
Study URL: https://beta.clinicaltrials.gov/study/NCT02344433
Acronym: VICKY
Study Status: COMPLETED
Brief Summary: A Relational Agent (RA) "virtual counselor" (VICKY: VIrtual Counselor for Knowing Your Family History) has been developed to collect family health history information for common health conditions including heart disease, stroke, diabetes, hypertension and various cancers. In this study, the investigators will conduct a randomized controlled trial (RCT) to compare the efficacy of using VICKY to the existing My Family Health Portrait (MFHP) tool for collecting family health history information among an underserved primary care patient population. The primary aims of the study are to 1) evaluate the efficacy of VICKY versus MFHP for collecting accurate family health histories and 2) determine whether accuracy varies as a function of health literacy. This project will obtain validation data on the efficacy of both VICKY and MFHP for collecting accurate family history data among an underserved patient population, in two languages (English and Spanish). The study will determine whether a virtual counselor can overcome many of the existing barriers to using traditional web-based family history tools.
Study Results: NO
Conditions: Heart Disease|Stroke|Diabetes|Cancer
Interventions: BEHAVIORAL: VICKY|BEHAVIORAL: MFHP
Primary Outcome Measures: Accuracy of health conditions id'd (interview w/ genetic counselor gold standard. health conditions id'd by VICKY or MFHP id'd by genetic counselor (true +) divided by health conditions captured by genetic counselor (false - plus true +), Sensitivity will be calculated using an interview with a genetic counselor as the gold standard. Sensitivity will be defined as the health conditions identified by the family health history tool (VICKY or MFHP) that were also identified by the genetic counselor (true positive) divided by the health conditions not captured by the tool but captured by the genetic counselor (false negatives) plus the true positives., Computed value derived from baseline assessments of family health history (both tool and counselor-obtained histories).|Accuracy of family members identified (defined as the agreement of first and second degree relatives identified by both the tool (VICKY or MFHP) and the genetic counselor), Accuracy of family members identified will be defined as the agreement of first and second degree relatives identified by both the tool (VICKY or MFHP) and the genetic counselor., Computed value derived from baseline assessments of family health history (both tool and counselor-obtained histories).
Secondary Outcome Measures: Family and provider communication (Communication of family health history with family members and health

care providers), Communication of family health history with family members and health care providers., Baseline and 3 month follow-up
Other Outcome Measures:
Sponsor: Boston University
Collaborators: Northeastern University|National Human Genome Research Institute (NHGRI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 279
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: SCREENING
Other IDs: H-32767|1R01HG007746-01
Start Date: 2016-11
Primary Completion Date: 2019-10
Completion Date: 2019-10
First Posted: 2015-01-26
Results First Posted:
Last Update Posted: 2019-10-24
Locations:
Study Documents:

NCT Number: NCT05344547
Study Title: Women With Polycystic Ovary Syndrome Are at High Risk for Cardiac Insults
Study URL: https://beta.clinicaltrials.gov/study/NCT05344547
Acronym:
Study Status: COMPLETED
Brief Summary: Objectives: Evaluation of the cardiovascular (CV) risk in a sample of CV asymptomatic infertile women with polycystic ovary syndrome (PCOS).

Patients \& Methods: 100 infertile PCOS women older than 30 years (PCOS group) and 50 fertile non-PCOS women (Non-PCOS group) underwent gynecological and laboratory diagnosis and then underwent a diagnostic protocol consisting of determination of body mass index (BMI), Homeostasis model assessment of insulin resistance (HOMA-IR) scoring and cardiologic evaluation using echocardiography, estimation of carotid artery intima-media thickness (CIMT), coronary artery calcium (CAC) score using multi-slice non-contrast cardiac CT and cardiac risk ratio (CRR). Study outcomes included the incidence of abnormal cardiac risk parameters and the determination of the best minimally invasive modality to be used as a screening test for these women.
Study Results: NO
Conditions: Cardiac Disease
Interventions: DIAGNOSTIC_TEST: Cardiac risk ratio (CRR)
Primary Outcome Measures: Abnormal Cardiac Outcomes, incidence of abnormal cardiac risk parameters among PCOS women who were apparently

cardiac free women, 1 to 3 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Tanta University
Collaborators:
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 150
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 35179/1/22
Start Date: 2020-03-21
Primary Completion Date: 2021-08-15
Completion Date: 2021-11-17
First Posted: 2022-04-25
Results First Posted:
Last Update Posted: 2022-04-25
Locations: Tanta university, Tanta, El-Gharbyia, 13511, Egypt
Study Documents:

NCT Number: NCT01281787
Study Title: PREvention of Atrial Fibrillation in patientS Undergoing thorAcic surGEry for Lung Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01281787
Acronym: PRESAGE
Study Status: COMPLETED
Brief Summary: The aim of this study is to assess whether prophylactic treatment with metoprolol or losartan is able to reduce the incidence of atrial fibrillation (AF) in patients undergoing thoracic surgery for lung cancer, showing elevated plasma levels in NT probrain natriuretic peptide (NT-proBNP), measured in the perioperative period.
Study Results: NO
Conditions: Lung Cancer|Atrial Fibrillation
Interventions: DRUG: Metoprolol|DRUG: Losartan
Primary Outcome Measures: Incidence of postoperative atrial fibrillation, up to 10 days
Secondary Outcome Measures: Evaluation of NT-proBNP in the days following the start of treatment and post surgery duration of hospital stay, up to 10 days
Other Outcome Measures:
Sponsor: European Institute of Oncology
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 320
Funder Type: OTHER
Study Type: INTERVENTIONAL

Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: PREVENTION
Other IDs: IEO S365/407|2007-003856-12
Start Date: 2008-04
Primary Completion Date: 2013-06
Completion Date: 2013-10
First Posted: 2011-01-24
Results First Posted:
Last Update Posted: 2014-06-18
Locations: European Institute of Oncology, Milan, 20141, Italy
Study Documents:

NCT Number: NCT01016886
Study Title: Multidisciplinary Approach to Novel Therapies in Cardiology Oncology Research
Study URL: https://beta.clinicaltrials.gov/study/NCT01016886
Acronym: MANTICORE
Study Status: UNKNOWN
Brief Summary: While trastuzumab has been shown to prevent recurrences of breast cancer, some women may also experience damage to their heart muscle (including heart failure) as a result of their treatment. The investigators hope to learn if standard medications used in heart failure can prevent heart damage caused by trastuzumab in women with breast cancer. The investigators would also like to know if there are any ways to detect this damage earlier using magnetic resonance imaging (MRI) and blood tests.
Study Results: NO
Conditions: Breast Cancer|Heart Failure
Interventions: DRUG: perindopril OR bisoprolol OR placebo
Primary Outcome Measures: The primary objective is to determine if conventional heart failure pharmacotherapy can prevent trastuzumab-mediated left ventricular (LV) remodeling among women with HER2+ early breast cancer., 3.5 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Alberta
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE1|PHASE2
Enrollment: 99
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|
Masking: DOUBLE (CARE_PROVIDER, INVESTIGATOR)|Primary Purpose: DIAGNOSTIC
Other IDs: 00027 / Ethics 25253
Start Date: 2010-09
Primary Completion Date: 2015-09
Completion Date: 2016-09

First Posted: 2009-11-20
Results First Posted:
Last Update Posted: 2016-02-09
Locations: University of Alberta/ Cross Cancer Institute, Edmonton, Alberta, Canada
Study Documents:

NCT Number: NCT02632786
Study Title: The PRONTO Study, a Global Phase 2b Study of NEOD001 in Previously Treated Subjects With Light Chain (AL) Amyloidosis
Study URL: https://beta.clinicaltrials.gov/study/NCT02632786
Acronym: PRONTO
Study Status: COMPLETED
Brief Summary: This is a global, multicenter, Phase 2b, randomized, double-blind, placebo-controlled, two-arm, parallel-group efficacy and safety study of NEOD001 as a single agent administered intravenously in adults with AL amyloidosis who had a hematologic response to previous treatment for their amyloidosis (e.g., chemotherapy, autologous stem cell transplant \[ASCT\]) and have persistent cardiac dysfunction.
Study Results: YES
Conditions: AL Amyloidosis
Interventions: DRUG: NEOD001|DRUG: Placebo
Primary Outcome Measures: Number of Participants With Cardiac Response and Non-Response, N-terminal pro-brain natriuretic peptide (NT-proBNP) best response (Response or Non-Response \[Stable, Progression\]) from baseline through 12 months of treatment. Cardiac best response, as assessed by NT-proBNP alone, is defined as the most favorable category among response (ie, decrease in NT-proBNP from baseline of \>30% and \>300 ng/L), stable (ie, neither response nor progression), and progression (ie, increase in NT-proBNP from baseline of \>30% and \>300 ng/L) across all visits after the first infusion of study drug up to and through the end of the study. Subjects are considered non-responders until a response is achieved. Non-response is defined as either stable or progression., Baseline through 12 months of treatment
Secondary Outcome Measures: SF-36v2 PCS Score, Change in Short Form-36 (SF-36 version 2) questionnaire Physical Component Summary \[PCS\] Score. PCS scores are calculated based on responses to specific Short Form-36 (version 2) questions using a weight scoring method. The lower the PCS score the more disability, the higher the score the less disability. A score of 50 is the mean in the US General Population and the standard deviation is 10. Minimum is 0 and maximum value is 100., Baseline to 12 months of treatment|6MWT Distance, Change in 6 Minute Walk Test (6MWT) Distance (meters), Baseline to 12 months of treatment|Number of Participants With Renal Best Response and Non-Response, Proteinuria and estimated Glomerular Filtration Rate (eGFR) response (Response or Non-Response \[Stable, Progression\]) from baseline through 12 months of treatment in subjects with renal involvement. Renal best response, as assessed by proteinuria, is

defined as the most favorable category among response (ie, ≥30% decrease from baseline or \<0.5 g/24 hours postbaseline result if subject does not meet criteria for progression), stable (ie, neither response nor progression), and progression (ie, ≥25% decrease in eGFR from baseline) across all visits after the first infusion of study drug up to and through the end of the study. Subjects are considered non-responders until a response is achieved. Assessments that qualify as both a response and progression are counted as progression.

Non-response is defined as either stable or progression., Baseline through 12 months of treatment|NIS-LL Total Score, Change in Neuropathy Impairment Score-Lower Limb (NIS-LL) Total Score in subjects with peripheral nerve involvement. NIS-LL is a scoring system graduated from 0 points to a maximum of 88 points (the absence of all motor, sensory, and reflex activity in the lower extremities). The scale is an additive of all deficits (64 potential points for muscle strength, 8 points for reflexes, and 16 points for sensory function) in the lower extremities. A score of 0 is normal and score of 88 is total impairment., Baseline to 12 months of treatment|NT-proBNP Slope, Rate of change in NT-proBNP (ng/L per infusion). Estimates of the intercept, slope, SE, and associated 95% CI for each treatment group, and the NEOD001 and placebo group difference comparisons are estimated using a general linear mixed effects model. The model fits a random intercept and slope for each subject and includes fixed effects for treatment group, time, treatment group by time interaction, IWRS stratification factors (hematologic response to first-line therapy: CR/VGPR, PR and NT-proBNP \<1800 ng/L, ≥1800 ng/L), and an unstructured covariance structure to model the within-subject errors. Time is represented in months as a continuous variable and includes all scheduled time points, including baseline. The p-value is associated with the visit by treatment group interaction term., Baseline through 12 months of treatment|Hepatic Best Response, Alkaline Phosphatase response (Response or Non-Response \[Stable, Progression\]) from baseline through 12 months of treatment in subjects with hepatic involvement, Baseline through 12 months of treatment
Other Outcome Measures:
Sponsor: Prothena Biosciences Ltd.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 129
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: NEOD001-201
Start Date: 2016-03

Primary Completion Date: 2018-03
Completion Date: 2018-03
First Posted: 2015-12-17
Results First Posted: 2018-10-03
Last Update Posted: 2019-04-05
Locations: City of Hope, Duarte, California, 91010, United States| Stanford Cancer Institute (SCI), Stanford, California, 94305, United States|Colorado Blood Cancer Institute, Denver, Colorado, 80218, United States|Mayo Clinic, Jacksonville, Florida, 32224, United States|University of Chicago Medicine, Chicago, Illinois, 60637, United States|Indiana University Simon Cancer Center, Indianapolis, Indiana, 46202, United States|Tufts Medical Center, Boston, Massachusetts, 02111, United States|Boston University School of Medicine, Boston, Massachusetts, 02118, United States|Karmanos Cancer Institute, Detroit, Michigan, 48201, United States|Mayo Clinic - Minnesota, Rochester, Minnesota, 55905, United States|Memorial Sloan-Kettering Cancer Center, New York, New York, 10065, United States|Duke University Medical Center, Durham, North Carolina, 27705, United States|The Cleveland Clinic, Cleveland, Ohio, 44195, United States| Oregon Health & Science University, Portland, Oregon, 97239, United States|Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States|Vanderbilt University Medical Center, Nashville, Tennessee, 37232, United States|University of Texas; MD Anderson Cancer Center, Houston, Texas, 77030, United States|University of Washington/Seattle Cancer Care Alliance, Seattle, Washington, 98109, United States|Froedtert & Medical College of Wisconsin, Cancer Center - Froedtert Hospital, Milwaukee, Wisconsin, 53226, United States|Westmead Hospital, Sydney, New South Wales, 2145, Australia|The University of Queensland - Princess Alexandra Hospital (PAH), Woolloongabba, Queensland, 4102, Australia|Eastern Health (Box Hill Hospital), Box Hill, Victoria, 3128, Australia|Medizinische Universität Wien, Allgemeines Krankenhaus der Stadt Wien, Vienna, Austria|Hôpital Dupuytren - CHU Limoges, Limoges, 87042, France| Hôpital Pitié-Salpêtrière, Paris, 75013, France|Hopitaux Lyon Sud, Pierre-Benite Cedex, 69495, France|CHU Rennes, Service de Medecine Interne, Rennes Cedex 2, France|Charite-Universitatsmedizin, Berlin, 12203, Germany|Universitätsklinikum Essen, Essen, 45147, Germany| Universitatsklinikum Hamburg-Eppendorf (UKE, Hamburg, 20246, Germany| Universitatsklinikum Heidelberg, Heidelberg, 69120, Germany|Alexandra General Hospital of Athens, Athens, 11528, Greece|University Hospital of Patras, Patras, Greece|Hadassah University Medical Center, Jerusalem, 91120, Israel|Policlinica San Matteo, Pavia, 27100, Italy| Hospital Clinic de Barcelona, Barcelona, 08036, Spain|Hospital Universitario Puerta de Hierro - Majadahonda, Majadahonda, 28222, Spain|Centre for Clinical Haematology, Birmingham, B15 2TH, United Kingdom|The Royal Free London NHS Foundation Trust - The Royal Free Hospital, London, NW3 2PF, United Kingdom|Southampton General Hospital, Southampton, United Kingdom
Study Documents: Study Protocol|Statistical Analysis Plan

NCT Number: NCT00106886
Study Title: HOPE-2 Study (Heart Outcomes Prevention Evaluation-2 Study)
Study URL: https://beta.clinicaltrials.gov/study/NCT00106886
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of the HOPE-2 study is to determine whether long term supplementation with folic acid, vitamins B6 and B12 aimed at homocyst(e)ine reduction reduces the rates of major fatal and nonfatal cardiovascular events in patients with established cardiovascular disease and/or diabetes mellitus.
Study Results: NO
Conditions: Cardiovascular Disease|Myocardial Infarction|Stroke|Cancer
Interventions: DRUG: Folic acid, vitamin B6 and B12 or placebo
Primary Outcome Measures: The composite of cardiovascular death, myocardial infarction (MI) and stroke
Secondary Outcome Measures: Total major ischemic events (includes CV [cardiovascular] death, MI, stroke, hospitalizations for UA [unstable angina] and revascularizations)|Hospitalization for unstable angina|Hospitalization for congestive heart failure (CHF)|Hospitalization for revascularization procedures|Total mortality|Other hospitalizations|Diabetic complications (laser therapy, dialysis, nephropathy or new diagnosis of diabetes)|The composite of death due to cancer, hospitalization for cancer and new diagnosis of cancer
Other Outcome Measures:
Sponsor: Hamilton Health Sciences Corporation
Collaborators: Canadian Institutes of Health Research (CIHR)|Population Health Research Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 5000
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: DOUBLE|Primary Purpose: PREVENTION
Other IDs: HOPE-2, CIHR FRN # MT-15428
Start Date: 1999-12
Primary Completion Date:
Completion Date: 2005-10
First Posted: 2005-04-01
Results First Posted:
Last Update Posted: 2005-09-20
Locations: McMaster University and Hamilton Health Sciences Corporation, Hamilton, Ontario, L8L 2X2, Canada
Study Documents:

NCT Number: NCT01022086
Study Title: Assessment of Cardiotoxicity by Cardiac Magnetic Resonance (CMR) in Breast Cancer Patients Receiving Trastuzumab

Study URL: https://beta.clinicaltrials.gov/study/NCT01022086
Acronym:
Study Status: UNKNOWN
Brief Summary: Herceptin has shown significant improvement in breast cancer therapy and improved survival of patients over-expressing the HER-2 protein by 50%. However, Herceptin has shown to negatively affect the heart, and frequent heart monitoring with multiple gated acquisition (MUGA) scans is required. MUGA scans use radiation and are not very accurate. This study will use cardiac magnetic resonance images (CMRs) to evaluate heart function and compare to MUGA scans in patients receiving Herceptin for early-stage breast cancer. In addition, novel biomarkers will also be assessed at the same time to help identify possible patients at risk for developing heart toxicities.
Study Results: NO
Conditions: Stage I-IV Breast Cancer (Neo-adjuvant, Adjuvant, Locally Advanced and Metastatic)
Interventions: PROCEDURE: Cardiac MRI|BIOLOGICAL: Biomarker Testing
Primary Outcome Measures: To compare CMR with MUGA scans for determining LVEF and LV volumes in breast cancer patients treated with trastuzumab., Five years
Secondary Outcome Measures: To examine the association between changes in biomarker levels and changes in cardiac structure and function as measured by CMR in breast cancer patients receiving trastuzumab., Five years
Other Outcome Measures: To determine the long-term prognostic significance of reduced LVEF and myocardial injury detected by CMR and biomarkers in breast cancer patients treated with trastuzumab., Five years
Sponsor: Unity Health Toronto
Collaborators: Hoffmann-La Roche
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 50
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Cardiac CMR
Start Date: 2009-11
Primary Completion Date: 2019-12
Completion Date: 2019-12
First Posted: 2009-12-01
Results First Posted:
Last Update Posted: 2017-07-12
Locations: Odette Cancer Centre/Sunnybrook Health Sciences Centre, Toronto, Ontario, M4N 3M5, Canada|St. Michael's Hospital, Toronto, Ontario, M5B 1W8, Canada
Study Documents:

NCT Number: NCT04663685
Study Title: MoveStrong at Home
Study URL: https://beta.clinicaltrials.gov/study/NCT04663685
Acronym:
Study Status: UNKNOWN
Brief Summary: Sufficient muscle strength helps to get out of a chair and can prevent falls. Up to 30% of older adults experience age-related loss of muscle strength, which can lead to frailty and health instability. Exercise helps to build muscle, maintain bone density and prevent chronic disease, especially during the aging process. In older adults at risk of mobility impairment, exercise greatly reduced incidence and effects did not vary by frailty status. However, more than 75% of Canadian adults ≥18 years of age are not meeting physical activity guidelines. In addition, it is known that malnutrition, including low protein intake, may lead to poor physical function. While there are services to support exercise and nutrition, barriers to implementing them persist. The COVID-19 pandemic has exacerbated the potential for physical inactivity, malnutrition, and loneliness among older adults, especially those with pre-existing health or mobility impairments. Now and in future, alternate ways to promote exercise and proper nutrition to the most vulnerable are needed. The investigators propose to adapt MoveStrong, an 8-week education program combining functional and balance training with strategies to increase protein intake. The program was co-developed with patient advocates, Osteoporosis Canada, the YMCA, Community Support Connections and others. MoveStrong will be delivered by telephone or web conference to older adults in their homes, using mailed program instructions, 1-on-1 training sessions through Physitrack®, as well as online nutrition seminars and support groups over Microsoft® Teams. The primary aim of this study is to assess feasibility as determined by recruitment (≥ 25 people in 3 months), retention (≥80%), adherence of (70%) and participant experience.
Study Results: NO
Conditions: Arthritis|Cancer|Cardiovascular Diseases|Chronic Lung Disease|Congestive Heart Failure|Diabetes|Hypertension|Kidney Diseases|Obesity|Osteoporosis|Stroke|Frailty
Interventions: OTHER: Exercise program|OTHER: Nutrition education
Primary Outcome Measures: Recruitment, The number of participants recruited at the end of rollout and participant experience., Through study completion, an average of 12 weeks|Retention, The number of participants retained at post-rollout end, Through study completion, an average of 12 weeks|Adherence, Attendance - The average proportion of exercise sessions completed will be ≥70% and the average proportion of nutrition seminars completed will be ≥ 67%., Through study completion, an average of 12 weeks|Participant experience, A semi-structured interview guide has been designed to conduct exit interviews and follow-up interviews with each participant over the phone or web conference. Interviews will be audio-recorded and transcribed verbatim. One researcher will perform Qualitative Description and Quantitative Content Analysisusing NVivo version 12

Pro or higher (QSR International Pty Ltd, 2019) to describe participant experience, satisfaction, learning needs and suggested adaptations to the program. In addition, the exercise physiologist will be given a spreadsheet to record any protocol adaptations, challenges, and successes to inform future trials., Week 12
Secondary Outcome Measures: Physical activity, A Physical Activity Screen (PAS) will be used to capture average minutes of moderate-to-vigorous physical activity each week(Clark et al., 2020). This tool was created based on questions used by Exercise is Medicine in the Physical Activity Vital Sign questionnaire (Greenwood et al., 2010). The results will be compared to national exercise guidelines for older adults that promote ≥150 minutes and ≥2 session of muscle strengthening per week (Tremblay et al., 2011)., Baseline, week 9, week 12, 6 month|Exercise self-efficacy scale, A modified version of the Exercise Self-Efficacy Scale will be used to capture levels of planning and execution of exercise related activities (Resnick \& Jenkins, 2000). The lowest response option to each question is "Not true at all", while the highest is "Exactly true". Responses closer to "Exactly true" indicate a better outcome., Baseline, week 9, week 12, 6 month|30-second Chair Stand, The 30-second Chair Stand will be used to access lower extremity muscle function (Bohannon, 1995; Jones et al., 1999). The instructions for this test have been adapted and will be self-administered under the remote supervisor supervision of the exercise physiologist. A higher score on this test indicates a better outcome., Baseline, week 9, week 12|Static balance, Static balance will be measured using the 3-point scale from the Short Performance Physical Battery (J. M. Guralnik et al., 1994). The instructions for this test have been adapted and will be self-administered under the remote supervisor supervision of the exercise physiologist. A higher score on this test indicates a better outcome., Baseline, week 9, week 12|Fatigue, Fatigue will be assessed with the Center for Epidemiologic Studies Depression Scale-fatigue questions (CES-D) Depression Scale (Radloff, 1977). Only two questions on the CES-D will be used: "I felt that everything I did was an effort, "I could not get going". The lowest response option is "Rarely (\<1 day)", and the highest response option is "Nearly every day". Responses closer to the lowest response option indicate a better outcome., Baseline, week 9, week 12|Mental health and social isolation, Warwick-Edinburgh Mental Well-being Scale focuses on positive aspects of mental health. It is short, yet robust and showed high correlations with other mental health and well-being scales. The lowest response option is "None of the time", and the highest response option is "All of the time". Responses closer to the highest response option indicate a better outcome., Baseline, week 9, week 12, 6 month|Quality of life score, The EuroQol Group 5 Dimension 5 Level questionnaire is a multi-attribute health related quality of life tool (Herdman et al., 2011). The system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems to extreme problems five dimensions can be combined into a 5-digit number that describes the self rated patient's health state. Responses to

each dimension are scored as a number from 1-5. Responses scored as 1 indicate a better outcome., Baseline, week 9, week 12|Nutritional risk, The SCREEN tool is a valid and reliable nutrition questionnaire designed specifically for older adults (Keller et al., 2005). This tool will be used to assess changes in weight, appetite, eating habits and promote viable self-management., Baseline, week 9, week 12|Nutrition tracking, ASA24®-Canada is a guided web-based tool used for 24-hour diet recalls. All food and drinks consumed by the participant on two weekdays and one weekend day (3 days in total) will be reported to track protein intake (Subar et al., 2012)., Baseline, week 9, week 12|Number of adverse events, We will ask participants to report adverse events, using Health Canada definitions. We will report all serious and non-serious adverse events and identify those attributable to intervention. Safety outcomes will include all falls, fractures, and serious and non-serious adverse events. Any fractures or falls that are attributable to intervention will be considered under both fall or fracture outcomes, and harms., Through study completion, an average of 12 weeks
Other Outcome Measures:
Sponsor: University of Waterloo
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 30
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: 42206
Start Date: 2020-10-05
Primary Completion Date: 2021-04-09
Completion Date: 2021-10-12
First Posted: 2020-12-11
Results First Posted:
Last Update Posted: 2021-07-13
Locations: University of Waterloo, Waterloo, Canada
Study Documents:

NCT Number: NCT01817686
Study Title: Study of Default Options in Advance Directives
Study URL: https://beta.clinicaltrials.gov/study/NCT01817686
Acronym:
Study Status: COMPLETED
Brief Summary: Default options represent the events or conditions that are set into place if no alternatives are actively chosen. The setting of default options has well-established effects on a broad range of human decisions, but its influence on patients' preferences for end-of-life care is only beginning to be understood.

This is a 3-armed randomized clinical trial in Veterans at high risk for critical illness, assessing the impact of Advance Directive (AD) forms framed with different default options. The central goals are to assess how default options in ADs influence the end-of-life care choices made by patients at risk for critical care, and these patients' hospital and ICU utilization.

The investigators hypothesize that setting defaults in real ADs will increase the proportion of Veterans selecting comfort-oriented plans of care, decrease selections of life-extending therapies such as mechanical ventilation and dialysis, and reduce the proportion of time during follow-up that Veterans spend in the hospital and/or ICU, without affecting patient satisfaction with end-of-life care planning.
Study Results: NO
Conditions: COPD|Severe or Very Severe Airflow Obstruction and/or Receiving or Eligible to Receive Long-term Oxygen Therapy|Idiopathic Pulmonary Fibrosis|Other Interstitial Lung Disease Without Curative Therapy|Congestive Heart Failure|NYHA Class IV or NYHA Class III Plus 1 Hospitalization in the Past Year|Malignancy|Any Stage 3B or 4 Solid Tumor
Interventions: OTHER: Comfort Default AD forms|OTHER: Life Extension Default AD forms|OTHER: Standard Default AD forms
Primary Outcome Measures: Evaluate how the setting of defaults influences the proportion of Veterans selecting comfort-oriented plans of care in real ADs, The primary outcome is the proportion of patients in each of the 3 groups who select a general plan of care that prioritizes comfort over life extension., 18 months
Secondary Outcome Measures: Assess the influence of default options in ADs on Veterans' selections of specific life-extending therapies, The proportions of patients electing to receive each of the 5 specific life-extending interventions, 18 months|Determine whether setting defaults in ADs influences the proportion of time during follow-up that Veterans spend in the hospital or ICU, The proportion of time during a 6-18 month follow-up (median 1 year) that patients spend in the hospital or ICU for each AD group, 18 months
Other Outcome Measures: To document feasibility of a study of Advance Directives in the Veteran population, To document our ability to recruit and retain patients with advanced diseases, we will measure the proportions of patients approached for consent who enroll (consent rate), the proportion of such patients who complete their AD (completion rate), and the proportion who subsequently complete their advance care satisfaction interview (retention rate)., 18 months
Sponsor: Corporal Michael J. Crescenz VA Medical Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 62
Funder Type: FED
Study Type: INTERVENTIONAL

Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: SINGLE (PARTICIPANT)|Primary Purpose:
HEALTH_SERVICES_RESEARCH
Other IDs: 01381
Start Date: 2013-03
Primary Completion Date: 2015-06
Completion Date: 2015-06
First Posted: 2013-03-25
Results First Posted:
Last Update Posted: 2015-06-30
Locations: Philadelphia Veterans Affairs Medical Center, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT02645786
Study Title: Thyrotropin Over-suppression and Heart
Study URL: https://beta.clinicaltrials.gov/study/NCT02645786
Acronym:
Study Status: COMPLETED
Brief Summary: The investigators evaluated the cardiac effects of Thyroid-stimulating hormone (TSH) over-suppression in women with differentiated thyroid cancer (DTC) frequently encountered during suppression therapy.
Study Results: NO
Conditions: Malignant Neoplasm of Thyroid|Heart Diseases|
Thyrotoxicosis on Thyroxine Therapy
Interventions:
Primary Outcome Measures: comparison of cardiac fucntion and structure between groups, In DTC group, the investiagtors measured cardiac function and structure by echocardiography at 2009 (receiving TSH suppressive therapy for 5 to 9 years after thyroidectomy). As each DTC patient was enrolled, control subjects were selected from persons who visited endocrinology department for thyroid nodule work-up. The control group had to meet the following criteria: 1) the subject matched to a patient by age (±2 years), sex, and body mass index (BMI) (±2 kg/m2), 2) within the reference range of serum TSH (0.3-4.6 mU/L), 3) no history of structural heart disease, arrhythmia, or cardiac symptoms, 4) no history of comorbid diseases which affect thyroxine metabolism and cardiac structure, including hepatic or renal disease, anemia, and hypertension.The cardiac function and structure were evaluated by echocardiography at 2010., measure cardiac function and struture at 2009 in case (DTC group) and at 2010 in control group
Secondary Outcome Measures: comparison of heart rate between groups, In DTC group, the investiagtors measured heart rate at 2009 (receiving TSH suppressive therapy for 5 to 9 years after thyroidectomy). As each DTC patient was enrolled, control subjects were selected from persons who visited endocrinology department for thyroid nodule work-up. The control group had to meet the following criteria: 1) the subject matched to a patient by age (±2 years), sex, and body mass index (BMI) (±2 kg/m2), 2) within the reference range of serum TSH (0.3-4.6 mU/L),

3) no history of structural heart disease, arrhythmia, or cardiac symptoms, 4) no history of comorbid diseases which affect thyroxine metabolism and cardiac structure, including hepatic or renal disease, anemia, and hypertension.Heart rate were evaluated at 2010 in control group., measure heart rate at 2009 in case (DTC group) and at 2010 in control group.|comparison of N-terminal pro-brain natriuretic peptide (NT-pro-BNP) between groups, In DTC group, the investiagtors measured NT-Pro-BNP at 2009 (receiving TSH suppressive therapy for 5 to 9 years after thyroidectomy). As each DTC patient was enrolled, control subjects were selected from persons who visited endocrinology department for thyroid nodule work-up. The control group had to meet the following criteria: 1) the subject matched to a patient by age (±2 years), sex, and body mass index (BMI) (±2 kg/m2), 2) within the reference range of serum TSH (0.3-4.6 mU/L), 3) no history of structural heart disease, arrhythmia, or cardiac symptoms, 4) no history of comorbid diseases which affect thyroxine metabolism and cardiac structure, including hepatic or renal disease, anemia, and hypertension.NT-Pro-BNP was evaluated at 2010 in control group., measure NT-pro-BNP at 2009 in DTC group and at 2010 in control group| thyroid function test (TSH, free T4, free T3), In DTC group, the investiagtors measured thyroid function test at 2009 (receiving TSH suppressive therapy for 5 to 9 years after thyroidectomy). As each DTC patient was enrolled, control subjects were selected from persons who visited endocrinology department for thyroid nodule work-up. The control group had to meet the following criteria: 1) the subject matched to a patient by age (±2 years), sex, and body mass index (BMI) (±2 kg/m2), 2) within the reference range of serum TSH (0.3-4.6 mU/L), 3) no history of structural heart disease, arrhythmia, or cardiac symptoms, 4) no history of comorbid diseases which affect thyroxine metabolism and cardiac structure, including hepatic or renal disease, anemia, and hypertension.Thyroid function test was evaluated at 2010 in control group., comparison of thyroid function at 2009 in case (DTC) and 2010 in control group
Other Outcome Measures:
Sponsor: Chuncheon Sacred Heart Hospital
Collaborators:
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 31
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2009-19
Start Date: 2009-09
Primary Completion Date: 2013-11
Completion Date: 2014-04
First Posted: 2016-01-05
Results First Posted:
Last Update Posted: 2016-01-05

Locations:
Study Documents:

NCT Number: NCT03909386
Study Title: Non-interventional Study on Patients With Atrial Fibrillation and Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03909386
Acronym: BLITZ-AFCancer
Study Status: COMPLETED
Brief Summary: AF and cancer frequently coexist. Since these patients are usually excluded from randomized trials, information on their management and outcome is scarce. Occurrence of relevant clinical events, such as ischemic and hemorrhagic and all-cause mortality and cardiovascular (CV) mortality occurring in patients treated or not with antithrombotic agents needs to be clarified.

A prospective observational registry collecting information, in a real world setting, on the clinical profile of patients with these clinical conditions and on the use of antithrombotic drugs in patients with AF and cancer could improve our knowledge on the management of these high risk patients.
Study Results: NO
Conditions: Atrial Fibrillation|Cancer
Interventions:
Primary Outcome Measures: Patients with AF and cancer treated with oral anticoagulant therapy and with other antithrombotic therapy, Number of patients with AF and cancer treated with oral anticoagulant therapy and with other antithrombotic therapy, Baseline|Patients with AF and cancer treated with oral anticoagulant therapy and with other antithrombotic therapy, Number of patients with AF and cancer treated with oral anticoagulant therapy and with other antithrombotic therapy, 12 Months
Secondary Outcome Measures: Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing all cause stroke, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing all cause stroke, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing transient ischemic attacks, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing transient ischemic attacks, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing major adverse cardiovascular events (non fatal MI, non fatal stroke, non fatal systemic embolic events, cardiovascular death), Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing major adverse cardiovascular events (non fatal MI, non fatal stroke, non fatal systemic embolic events, cardiovascular death), Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not

treated experiencing systemic embolic events, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing systemic embolic events, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing acute coronary syndrome, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing acute coronary syndrome, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing venous thromboembolic events, defined as composite of deep vein thrombosis and pulmonary embolism, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing venous thromboembolic events, defined as composite of deep vein thrombosis and pulmonary embolism, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing deep vein thrombosis, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing deep vein thrombosis, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing pulmonary embolism, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing pulmonary embolism, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing major bleeding (Fatal bleeding, Non-fatal bleeding,Intracranial hemorrhage, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing major bleeding (Fatal bleeding, Non-fatal bleeding,Intracranial hemorrhage, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing clinically relevant non-major bleeding, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing clinically relevant non-major bleeding, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing composite of major and CRNM bleeding, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing composite of major and CRNM bleeding, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing all-cause death, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing all-cause death, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing cardiovascular death, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing cardiovascular death, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing death due to malignancy, Number of patients treated with oral anticoagulant therapy, other antithrombotic

therapy or not treated experiencing death due to malignancy, Baseline and 12 months|Patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing sudden and unexplained death, Number of patients treated with oral anticoagulant therapy, other antithrombotic therapy or not treated experiencing sudden and unexplained death, Baseline and 12 months|Association of various antithrombotic treatments (or lack of) on hospital admissions due to CV or non CV causes, Number of hospital admissions (defined as ≥ 24 h stay in a hospital) due to CV or non CV causes, Baseline and 12 months|Association of various antithrombotic treatments (or lack of) on hospital admissions due to CV or non CV causes, Length of hospital admissions (defined as ≥ 24 h stay in a hospital) due to CV or non CV causes;, Baseline and 12 months|Treatment satisfaction, Treatment satisfaction as assessed by the Perception Anticoagulant Treatment Questionnaire (PACT-Q), Baseline and 12 months|Quality of life satisfaction, Health related quality of life as assessed by the EuroQol (EQ-5D-5L) questionnaire, Baseline and 12 months
Other Outcome Measures:
Sponsor: Heart Care Foundation
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1514
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: K21
Start Date: 2019-06-26
Primary Completion Date: 2021-09-30
Completion Date: 2022-09-30
First Posted: 2019-04-10
Results First Posted:
Last Update Posted: 2023-01-12
Locations: OLV ZIEKENHUIS AALST - Cardiology, Aalst, Belgium|AZ IMELDA - Cardiology, Bonheiden, Belgium|AZ ST-JAN - Cardiology, Brugge, Belgium|Hôpital Erasme - Cardiology, Brussels, Belgium|UCL Cliniques universitaires Saint-Luc - Cardiolgy, Brussels, Belgium|UZ Brussel - Cardiology, Brussel, Belgium|Ziekenhuis Oost-Limburg - Cardiology, Genk, Belgium|JESSA HASSELT - Cardiology, Hasselt, Belgium|AZ GROENINGE - Cardiology, Kortrijk, Belgium|UZ LEUVEN - Cardiovascular diseases, Leuven, Belgium|AZ DELTA ROESELARE - Cardiology, Roeselare, Belgium|AZ TURNHOUT - Cardiology, Turnhout, Belgium|Bon Secours Hospital Cork - Oncology Department, Cork, Ireland|Beacon Hospital, Cardiology, Dublin, Ireland|Tallaght University Hospital - Geriatric and Stroke Medicine Department, Dublin, Ireland|Ospedale San Giovanni Di Dio - Uo Cardiologia E Utic, Agrigento, AG, 92100, Italy|Ospedale Barone Lombardo - Cardiologia E Utic, Canicattì, AG, 92024, Italy| Ospedale Santo Spirito - Sc Cardiologia, Casale Monferrato, AL, 15033, Italy|Ospedale Civile Profili - U.O. Cardiologia, Fabriano, AN, 60044,

Italy|Ospedale San Donato - U.O. Cardiologia, Arezzo, AR, 52100, Italy|Ospedale San Paolo - Cardiologia-Utic, Bari, BA, 70123, Italy| Istituto Tumori Giovanni Paolo Ii - U.O. Di Cardiologia, Bari, BA, 70124, Italy|Ospedali Treviglio-Caravaggio - Cardiologia, Treviglio, BG, 24047, Italy|Ospedale Civile - Sc Cardiologia, Belluno, BL, 32100, Italy|Ospedale Santa Maria Del Prato - U.O. Di Cardiologia, Feltre, BL, 32032, Italy|Ospedale Maggiore - U.O. Di Cardiologia, Bologna, BO, 40133, Italy|Ospedale Policlinico S. Orsola-Malpighi - U.O. Cardiologia-Rapezzi, Bologna, BO, 40138, Italy|Ospedale Bellaria - U.O. Di Cardiologia, Bologna, BO, 40139, Italy|Ospedale A. Businco - Servizio Di Cardiologia, Cagliari, CA, 09121, Italy|Ospedale Roberto Binaghi - Servizio Di Cardiologia, Cagliari, CA, 09126, Italy|Az. Ospedaliera S. Anna E S. Sebastiano - Cardiologia Clinica Universitaria - Utic, Caserta, CE, 81100, Italy|Ospedale San Giuseppe E Melorio - U.O.C. Cardiologia Utic, Santa Maria Capua Vetere, CE, 81055, Italy|Ospedale Regina Montis Regalis - U.O. Cardiologia-Utic, Mondovì, CN, 12084, Italy|Ospedale Maggiore Ss. Annunziata - Sc Cardiologia, Savigliano, CN, 12038, Italy|Ospedale Civile Ferrari - U.O.C. Cardiologia-Utic, Castrovillari, CS, 87012, Italy|Ospedale Spoke Paola- Cetraro Po Paola - Utic Cardiologia, Paola, CS, 87027, Italy|P.O. Garibaldi-Nesima - U.O.C. Di Cardiologia, Catania, CT, 95122, Italy|Azienda Ospedaliera Cannizzaro - Uoc Cardiologia Con Utic Ed Emodinamica, Catania, CT, 95126, Italy|Humanitas Centro Catanese Di Oncologia - Servizio Di Cardiologia, Catania, CT, 95126, Italy| Ospedali Riuniti - S.C. Di Cardiologia Univ.-Utic, Foggia, FG, 71100, Italy|Ospedale Civile San Giuseppe - Cardiologia, Empoli, FI, 50053, Italy|Ospedale San Giovanni Di Dio - Cardiologia, Firenze, FI, 50124, Italy|Aou Careggi - Cardiologa Diagnostica, Firenze, FI, 50134, Italy| Aou Careggi - Diagnostica Cardiovascolare, Firenze, FI, 50139, Italy| Ospedale Policlinico San Martino - Clinica Malattie Cardiovascolari, Genova, GE, 16132, Italy|Ospedale Padre Antero Micone - Sc Cardiologia - Utic, Genova, GE, 16153, Italy|Ospedale San Giuseppe Da Copertino - U.O. Di Cardiologia-Utic, Copertino, LE, 73043, Italy|Ospedale Ignazio Veris Delli Ponti - Uoc Cardiologia-Utic, Scorrano, LE, 73020, Italy| Nuovo Ospedale Versilia - Sc Cardiologia, Lido Di Camaiore, LU, 55043, Italy|Policlinico G. Martino - U.O. Medicina Interna, Messina, ME, 98124, Italy|Istituto Nazionale Tumori - Struttura Complessa Di Cardiologia, Milano, MI, 20133, Italy|Istituto Europeo Di Oncologia - Cardiologia, Milano, MI, 20141, Italy|Asst Ospedale Metropolitano Niguarda - Cardiologia 4 -Diagnost. E Riabilitativa, Milano, MI, 20162, Italy|Ospedale Di Vizzolo Predabissi - Uo Cardiologia E Ucc, Vizzolo Predabissi, MI, 20077, Italy|Ospedale Ramazzini - U.O. Cardiologia, Carpi, MO, 41013, Italy|Ospedale Di Sassuolo - Cardiologia, Sassuolo, MO, 41049, Italy|Ospedale San Francesco - Cardiologia - Utic, Nuoro, NU, 08100, Italy|Fondazione G. Giglio - U.O. Cardiologia E Utic, Cefalù, PA, 90015, Italy|Aor Villa Sofia-Cervello P.O. Cervello, Uo Cardiologia - Cervello, Palermo, PA, 90146, Italy|Istituto Oncologico Veneto - Cardiologia Oncologica, Padova, PD, 35128, Italy|Ospedale Civile Dello Spirito Santo - Utic E Cardiologia Interventistica, Pescara, PE, 65124, Italy|Azienda Ospedaliera

Universitaria Pisana - U.O. Malattie Cardiovasc. I - Cisanello, Pisa, PI, 26124, Italy|Centro Di Riferimento Oncologico (Cro) - Cardiologia, Aviano, PN, 33081, Italy|Presidio Ospedaliero San Salvatore - Cardiologia E Utic, Pesaro, PU, 61121, Italy|Fondazione Irccs Policlinico San Matteo - Cardiologia, Pavia, PV, 27100, Italy|Ics Maugeri Spa Societa' Benefit - U.O. Di Riabilitazione Cardiologica, Pavia, PV, 27100, Italy|Ospedale Civile Santa Maria Delle Croci - U.O. Di Cardiologia, Ravenna, RA, 48100, Italy|Ospedale Santa Maria Degli Ungheresi - Uoc Cardiologia-Utic, Polistena, RC, 89024, Italy|Grande Ospedale Metropolitano-Bianchi Melacrino Morelli - Divisione Di Cardiologia, Reggio Calabria, RC, 89124, Italy|Ospedale Civile - Sc Cardiologia Area Nord, Guastalla, RE, 42016, Italy|Arcispedale Santa Maria Nuova - S.C. Cardiologia, Reggio Emilia, RE, 42100, Italy|Ospedale Giovanni Paolo Ii - U.O.C. Cardiologia-Utic, Ragusa, RG, 97100, Italy|Nuovo Ospedale Dei Castelli - U.O.C. Di Cardiologia E Utic, Ariccia, RM, 00072, Italy|Campus Biomedico - Cardiologia, Roma, RM, 00128, Italy|P.O. San Filippo Neri - Asl Roma 1 - Uoc Cardiologia E Utic, Roma, RM, 00135, Italy|Ospedale San Camillo - Uosd Servizi Cardiologici Integrati, Roma, RM, 00151, Italy|Ifo- Istituto Naz. Tumori Regina Elena - Uo Cardiologia, Roma, RM, 00152, Italy|Policlinico Agostino Gemelli - Uo Cardiologia Per Sc E Riab. Cardiolog., Roma, RM, 00168, Italy|Ospedale G. Ceccarini - Cardiologia-Utic, Riccione, RN, 47838, Italy|Aou S. Giovanni Di Dio-Ruggi D'Aragona - Cardiologia Intensiva, Salerno, SA, 84131, Italy|Ospedale Dell'Alta Val D'Elsa - Uosd Cardiologia-Utic, Poggibonsi, SI, 53036, Italy|Ospedale San Bartolomeo - U.O. Cardiologia Clinica-Riabilitativa, Sarzana, SP, 19038, Italy|Ospedale E. Muscatello - U.O. Di Cardiologia - Utic, Augusta, SR, 96011, Italy|Ospedale Di Castellaneta - S.C. Cardiologia, Castellaneta, TA, 74011, Italy|Ospedale Civile M. Giannuzzi - Cardiologia E Utic, Manduria, TA, 74024, Italy|Presidio Ospedaliero Della Valle D'Itria - Struttura Complessa Di Cardiologia, Martina Franca, TA, 74015, Italy|Ospedale Civile G. Mazzini - Cardiologia Utic Ed Emodinamica, Teramo, TE, 64100, Italy|Ospedale Santa Maria Del Carmine - Cardiologia, Rovereto, TN, 38068, Italy|Ospedale San Luigi Gonzaga - S.C.D.O. Cardiologia, Orbassano, TO, 10043, Italy|Ospedale Civile E. Agnelli - Sc Di Cardiologia, Pinerolo, TO, 10064, Italy|Ospedale Degli Infermi, Sc Cardiologia, Rivoli, TO, Italy|Aou Citta' Della Salute E Della Scienza - S.C.D.U. Cardiologia, Torino, TO, 10126, Italy|Ospedale Mauriziano Umberto I - Sc Cardiologia, Torino, TO, 10128, Italy|Ospedale Humanitas Gradenigo - Cardiologia, Torino, TO, 10153, Italy|Ospedale Giovanni Bosco - Sc Cardiologia, Torino, TO, 10155, Italy|Ospedale Ss. Vito E Spirito - U.O.S. Di Cardiologia, Alcamo, TP, 91011, Italy|Azienda Ospedaliera Santa Maria - S.C. Di Cardiologia, Terni, TR, 05100, Italy|Asui Trieste - S.C. Centro Cardiovascolare, Trieste, TS, 34125, Italy|Pou Santa Maria Della Misericordia - S.O.C. Cardiologia, Udine, UD, 33100, Italy|Presidio Ospedaliero Di Saronno - U.O.C. Di Cardiologia, Saronno, VA, 21047, Italy|Ospedale Civile - U.O. Cardiologia, Mirano, VE, 30035, Italy|Ospedale Civile - U.O.C. Cardiologia, Arzignano, VI, 36071, Italy|Ospedale Sacro Cuore - U.O.

Di Cardiologia, Negrar, VR, 37024, Italy|Ospedale Miulli - U.O.C. Cardiologia - Utic, Acquaviva Delle Fonti, Italy|Ospedale Ss. Trinita' - S.C. Di Cardiologia, Borgomanero, 28021, Italy|Az. Ospedaliera S. Anna E S. Sebastiano - Uoc Medicina E Chirurgia D'Urgenza, Caserta, Italy|Ospedale Policlinico Ss. Annunziata - Medicina Generale Ii, Chieti, Italy|Arcispedale Sant'Anna - U.O. Cardiologia - Utic, Ferrara, Italy|Ospedale Generale Di Zona - U.O. Cardiologia - Utic, Giugliano In Campania, 80014, Italy|Fondazione Pascale - S.C. Cardiologia, Napoli, 80131, Italy|Ospedale San Gennaro - U.O. Cardiologia E Riabilitazione Card., Napoli, 80136, Italy|Aou Maggiore Della Carita' - Cardiologia Ii, Novara, 28100, Italy|Ospedale Ss. Cosma E Damiano - U. O. Cardiologia - Utic, Pescia, Italy|Ospedale Santa Maria Delle Grazie - U.O. Cardiologia - Utic, Pozzuoli, 80078, Italy|Ospedale Sandro Pertini, Uoc Cardiologia, Roma, Italy|Rijnstate Ziekenhuis - Afdeling Cardioresearch, Arnhem, Netherlands|Tergooi - Poli cardiologie / poli 2, Blaricum, Netherlands|Amphia Ziekenhuis - Research Cardiologie, Breda, Netherlands|Jeroen Bosch Ziekenhuis - Research Cardiologie, Den Bosch, Netherlands|Martini Ziekenhuis - Dept. Cardio Research Noord BV, Groningen, Netherlands|Diakonessenhuis - Research Cardiologie, Utrecht, Netherlands|University Medical Center Utrecht - Cardiologie, Utrecht, Netherlands|Máxima Medisch Centrum - Poli Cardiologie, Veldhoven, Netherlands|Prof. Doutor Fernando Fonseca EPE Hospital, Cardiologia, Amadora, Portugal|Hospital Nossa Senhora do Rosário, Cardiology, Barreiro, Portugal|Hospital da Luz, Lisboa, Portugal|Hospital de Santa Cruz, Cardiology, Lisboa, Portugal|Hospital Santa Maria, Cardiology, Lisboa, Portugal|Hospital del Mar (Parc de Salut Mar),Cardiologa I Unitat Coronaria, Barcelona, Spain|Hospital Médico-Quirúrgico, Cardiology, Jaén, Spain|Clínica Anderson, Oncología Médica, Madrid, Spain|Clínica Medicentro, Cardiología, Madrid, Spain|Hopsital Puerta de Hierro, Madrid, Spain|Hospital La Moraleja, Servicio de Cardiología, Madrid, Spain|Hospital La Paz, Madrid, Spain|Hospital La Zarzuela, Madrid, Spain|Hospital Montepríncipe, Cardiología, Madrid, Spain|Hospital Ramón y Cajal, Madrid, Spain|Hospital Rúber Internacional, Oncología, Madrid, Spain|Hospital Universitario Gregorio Marañón, Servicio de Cardiología, Madrid, Spain|Hospital Virgen de Arrixaca - Cardiologia, Murcia, Spain|Hospital de Salamanca, Cardiología, Salamanca, Spain|Hospital Universitario Virgen Macarena, Cardiologia, Sevilla, Spain|Hospital de Torrejón, Torrejón De Ardoz, Spain|Hospital Universitario Río Hortega, Cardiología, Valladolid, Spain|University Clinical Hosp. de Valladolid, Cardiología, Valladolid, Spain|Hospital Clínico "Lozano Blesa", Cardiologia, Zaragoza, Spain
Study Documents:

NCT Number: NCT04338386
Study Title: Detection and Pathogenesis of Novel Protein F
Study URL: https://beta.clinicaltrials.gov/study/NCT04338386
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: From December 6, 2019 to March 23, 2020, the research

group of Qingkun Fan found a novel protein(temporarily named protein F) in heparin anticoagulant plasma of three patients with heart disease. One patient was diagnosed with multiple myeloma.However, protein F cannot be detected by serum protein electrophoresis. Preliminary studies have shown that this novel protein F have an obvious absorption peak at about 600nm. Placed at 2-8 degrees for 7 days, protein F will be isolated from heparin plasma. To the naked eye, protein F appear to be transparent jelly between the red blood cells and the plasma. The specific protein F, how it is produced, how it causes disease are still unknown. This study will explore how to detect protein F and how it is produced.
Study Results: NO
Conditions: Cardiac Disease|Multiple Myeloma
Interventions:
Primary Outcome Measures: Concentration of plasma protein F content, the protein F content was measured by turbidimetric assay in automatic biochemical analyzer, six month
Secondary Outcome Measures: Number of Participants with Multiple myeloma, Develop or be diagnosed with multiple myeloma, 3 years
Other Outcome Measures:
Sponsor: Wuhan Asia Heart Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: YX-2020-B002
Start Date: 2020-04-15
Primary Completion Date: 2025-03-14
Completion Date: 2028-03-14
First Posted: 2020-04-08
Results First Posted:
Last Update Posted: 2020-04-10
Locations:
Study Documents:

NCT Number: NCT05023785
Study Title: The HIMALAYAS Trial and Lifestyle Changes in Pediatric, Adolescent and Young Adult Cancer Survivors Study: A Multicentre Randomized Controlled Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT05023785
Acronym: HIMALAYAS
Study Status: NOT_YET_RECRUITING
Brief Summary: Cardiovascular disease (CVD) is a major contributor to morbidity and mortality in pediatric, adolescent and young adult (AYA) cancer survivors (hereafter referred to as AYA-CS). Exercise is a cornerstone of CVD prevention and treatment; yet, exercise has not

been adopted as a standard of care in AYA-CS at high CVD risk. The HIMALAYAS trial is designed to evaluate the impact of an exercise-based cardiac rehabilitation program on cardiovascular (CV) and psychosocial health, as well as CVD risk, in AYA-CS with mild heart dysfunction (stage B heart failure (SBHF)). The primary objective of the HIMALAYAS study is to determine whether supervised Cardio-oncology Rehabilitation \[CORE; Group 1A\], consisting of moderate to high-intensity aerobic exercise training, CVD risk factor modification and enhanced online behavioural support, improves cardiorespiratory fitness (VO2peak; primary outcome), cardiac function, CVD risk factors and biomarkers, and patient-reported outcomes (PROs) at 6, 12, and 24 months compared to standard of care \[CON1; Group 1B\] in AYA-CS with SBHF. Additionally, AYA-CS with and without SBHF will participate in a secondary randomized controlled trial (RCT) to assess the independent effects of two passive behavioural support strategies based on the attainment of the personal activity intelligence (PAI) score \[PAI; Group 2A\] or the exercise guidelines for cancer survivors \[ExGL; Group 2B\] on cardiorespiratory fitness, cardiac function, CVD risk factors and biomarkers, and PROs at 24 months compared to standard of care \[CON2; Group 2C\].
Study Results: NO
Conditions: Heart Failure|Cardiotoxicity|Cancer
Interventions: BEHAVIORAL: Cardio-oncology Rehabilitation (CORE)|BEHAVIORAL: PAI Group (PAI)|BEHAVIORAL: Exercise Guidelines for Cancer Survivors (ExGL)
Primary Outcome Measures: Cardiorespiratory fitness, Assessed via cardiopulmonary exercise test and quantified as VO2peak, Baseline to 6-month follow-up (Primary RCT)
Secondary Outcome Measures: Cardiorespiratory fitness, Assessed via cardiopulmonary exercise test and quantified as VO2peak, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Ventilatory threshold, Estimated using the V-slope method and according to the following criteria: i) an exaggerated response in the volume of carbon-dioxide (i.e., VCO2) relative to the volume of oxygen (i.e., VO2), and ii) the first identifiable break-point in in the minute ventilation (i.e., VE/VO2 vs work rate relationship)., Baseline to 6-month follow-up (Primary RCT)|Ventilatory threshold, Estimated using the V-slope method and according to the following criteria: i) an exaggerated response in the volume of carbon-dioxide (i.e., VCO2) relative to the volume of oxygen (i.e., VO2), and ii) the first identifiable break-point in in the minute ventilation (i.e., VE/VO2 vs work rate relationship)., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Anaerobic threshold, Estimated according to the three-criterion discrimination technique: i) an excess VCO2 response relative to the VO2 response identified per the modified V-slope criteria; ii) the VE/VO2 to VO2 relationship having been flat or decreasing begins to increase without returning to baseline; and iii) there is no reciprocal decrease in PETCO2 at the point where PETO2 starts to rise systematically., Baseline to 6-month follow-up (Primary RCT)|Anaerobic threshold, Estimated according to the three-criterion discrimination

technique: i) an excess VCO2 response relative to the VO2 response identified per the modified V-slope criteria; ii) the VE/VO2 to VO2 relationship having been flat or decreasing begins to increase without returning to baseline; and iii) there is no reciprocal decrease in PETCO2 at the point where PETO2 starts to rise systematically., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Post-exercise heart rate recovery, One-minute HR recovery (HRR; an index of post-exercise parasympathetic reactivation) will be calculated as the HR-difference between peak exercise and following one minute of quiet standing on the treadmill immediately post-test., Baseline to 6-month follow-up (Primary RCT)|Post-exercise heart rate recovery, One-minute HR recovery (HRR; an index of post-exercise parasympathetic reactivation) will be calculated as the HR-difference between peak exercise and following one minute of quiet standing on the treadmill immediately post-test., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Left ventricular ejection fraction (LVEF), Assessed via 2D and 3D echocardiography, Baseline to 6-month follow-up (Primary RCT)|Left ventricular ejection fraction (LVEF), Assessed via 2D and 3D echocardiography, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Global longitudinal strain (GLS), Assessed via 2D echocardiography, Baseline to 6-month follow-up (Primary RCT)|Global longitudinal strain (GLS), Assessed via 2D echocardiography, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Early (E) and late (A) diastolic mitral inflow velocities and deceleration time, Assessed via echocardiography, Baseline to 6-month follow-up (Primary RCT)|Early (E) and late (A) diastolic mitral inflow velocities and deceleration time, Assessed via echocardiography, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Early diastolic mitral septal and lateral annular velocities (e'), Assessed via tissue Doppler imaging (TDI), Baseline to 6-month follow-up (Primary RCT)|Early diastolic mitral septal and lateral annular velocities (e'), Assessed via tissue Doppler imaging (TDI), Baseline to 24-month follow-up (Primary and Secondary RCTs)|TR velocity, Assess via spectral Doppler, Baseline to 6-month follow-up (Primary RCT)|TR velocity, Assess via spectral Doppler, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Left atrial volume, Assess via 2D echocardiography, Baseline to 6-month follow-up (Primary RCT)|Left atrial volume, Assess via 2D echocardiography, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Diastolic function - E/e' ratio, Calculated using the average of the TDI septal and lateral annular velocities (e'), Baseline to 6-month follow-up (Primary RCT)|Diastolic function - E/e' ratio, Calculated using the average of the TDI septal and lateral annular velocities (e'), Baseline to 24-month follow-up (Primary and Secondary RCTs)|Left ventricular hypertrophy, Assessed via Devereux formula and quantified as LV mass/body surface area: \>95 g/m2 for women or \>115 g/m2 for men, Baseline to 6-month follow-up (Primary RCT)|Left ventricular hypertrophy, Assessed via Devereux formula and quantified as LV mass/body surface area: \>95 g/m2 for women or \>115 g/m2 for men, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Concentric cardiac remodeling, Assessed as \>0.42 relative wall

thickness, Baseline to 6-month follow-up (Primary RCT)|Concentric cardiac remodeling, Assessed as \>0.42 relative wall thickness, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Resting heart rate, Measured with an average of 2 readings taken via ECG during the resting period during the cardiac screening procedures., Baseline to 6-month follow-up (Primary RCT)|Resting heart rate, Measured with an average of 2 readings taken via ECG during the resting period during the cardiac screening procedures., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Resting systolic and diastolic blood pressure, Calculated as average of 3 readings measured via automated sphygmomanometer per the Hypertension Canada guidelines., Baseline to 6-month follow-up (Primary RCT)|Resting systolic and diastolic blood pressure, Calculated as average of 3 readings measured via automated sphygmomanometer per the Hypertension Canada guidelines., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Apolipoprotein B, Assessed via blood serum sample, Baseline to 6-month follow-up (Primary RCT)|Apolipoprotein B, Assessed via blood serum sample, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Total cholesterol, Assessed via blood serum sample, Baseline to 6-month follow-up (Primary RCT)|Total cholesterol, Assessed via blood serum sample, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Low density lipoprotein, Assessed via blood serum sample, Baseline to 6-month follow-up (Primary RCT)|Low density lipoprotein, Assessed via blood serum sample, Baseline to 24-month follow-up (Primary and Secondary RCTs)|High density lipoprotein, Assessed via blood serum sample, Baseline to 6-month follow-up (Primary RCT)|High density lipoprotein, Assessed via blood serum sample, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Whole body insulin sensitivity, Assessed via Matsuda index, Baseline to 6-month follow-up (Primary RCT)|Whole body insulin sensitivity, Assessed via Matsuda index, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Hepatic insulin sensitivity, Assessed via homeostasis model assessment insulin resistance (HOMA-IR), Baseline to 6-month follow-up (Primary RCT)|Hepatic insulin sensitivity, Assessed via homeostasis model assessment insulin resistance (HOMA-IR), Baseline to 24-month follow-up (Primary and Secondary RCTs)|Pancreatic beta-cell function, Assessed via the insulin secretion-sensitivity index-2 (ISSI-2), Baseline to 6-month follow-up (Primary RCT)|Pancreatic beta-cell function, Assessed via the insulin secretion-sensitivity index-2 (ISSI-2), Baseline to 24-month follow-up (Primary and Secondary RCTs)|Body mass index, Calculated as body weight (kg) divided by height (m) squared, Baseline to 6-month follow-up (Primary RCT)|Body mass index, Calculated as body weight (kg) divided by height (m) squared, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Objective physical activity, Objectively assessed via wrist-worn physical activity/heart rate monitor and reported as Personal Activity Intelligence (PAI) Score, Baseline to 6-month follow-up (Primary RCT)|Objective physical activity, Objectively assessed via wrist-worn physical activity/heart rate monitor and reported as Personal Activity Intelligence (PAI) Score, Baseline to 24-month follow-up (Primary and

Secondary RCTs)|Subjective physical activity, Subjectively assessed via Godin Leisure Time Physical Activity Questionnaire and reported as moderate-to-vigorous intensity physical activity (MVPA), Baseline to 6-month follow-up (Primary RCT)|Subjective physical activity, Subjectively assessed via Godin Leisure Time Physical Activity Questionnaire and reported as moderate-to-vigorous intensity physical activity (MVPA), Baseline to 24-month follow-up (Primary and Secondary RCTs)|Social support, Measured using the Social Support Survey-Clinical (SSS-C) form, a 5-item survey designed to measure five dimensions of social support + a single item to assess cancer-specific social support., Baseline to 6-month follow-up (Primary RCT)|Social support, Measured using the Social Support Survey-Clinical (SSS-C) form, a 5-item survey designed to measure five dimensions of social support + a single item to assess cancer-specific social support., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Exercise self-efficacy, Measured using the Multidimensional Self-Efficacy for Exercise Scale (MSES) to measure three behavioural subdomains: task, scheduling, and coping, Baseline to 6-month follow-up (Primary RCT)|Exercise self-efficacy, Measured using the Multidimensional Self-Efficacy for Exercise Scale (MSES) to measure three behavioural subdomains: task, scheduling, and coping, Baseline to 24-month follow-up (Primary and Secondary RCTs)|Anxiety, Measured using the Generalized Anxiety Disorder (GAD-7), a 7-item inventory that assesses 2-week anxiety symptom frequency on a 0-3 scale, with higher scores reflecting higher symptom frequency. A cut-off of ≥10 indicates some degree of clinical anxiety., Baseline to 6-month follow-up (Primary RCT)|Anxiety, Measured using the Generalized Anxiety Disorder (GAD-7), a 7-item inventory that assesses 2-week anxiety symptom frequency on a 0-3 scale, with higher scores reflecting higher symptom frequency. A cut-off of ≥10 indicates some degree of clinical anxiety., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Depression, Measured using the Patient Health Questionnaire (PHQ-9), a 9-item inventory that assesses 2-week depressive symptom frequency on a 0-3 scale, with higher scores reflecting higher symptom frequency. The PHQ-9 has been validated in cancer survivors using a cut-off of ≥8 to indicate some degree of clinical depression., Baseline to 6-month follow-up (Primary RCT)|Depression, Measured using the Patient Health Questionnaire (PHQ-9), a 9-item inventory that assesses 2-week depressive symptom frequency on a 0-3 scale, with higher scores reflecting higher symptom frequency. The PHQ-9 has been validated in cancer survivors using a cut-off of ≥8 to indicate some degree of clinical depression., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Health-related quality of life, Measured using the Medical Outcomes Survey Short-Form (SF-12)., Baseline to 6-month follow-up (Primary RCT)|Health-related quality of life, Measured using the Medical Outcomes Survey Short-Form (SF-12)., Baseline to 24-month follow-up (Primary and Secondary RCTs)|Health service utilization, Measured using the Health Service Utilization Inventory., Baseline to 6-month follow-up (Primary RCT)|Health service utilization, Measured using the Health Service Utilization Inventory., Baseline to 24-month follow-up

(Primary and Secondary RCTs)
Other Outcome Measures: Therapeutic alliance, Measured using the Working Alliance Inventory Short-Revised (WAI-SR) form., Baseline to 6-month follow-up (Primary RCT)|Testing Performance, Defined as the percent of tests that achieve 'peak' termination criteria relative to the total number of tests completed across all time points, Study initiation to end of 66-month study period (Primary and Secondary RCTs)|Serious and non-serious adverse events, Defined as the number and frequency of testing-, intervention-, and non-intervention-related serious (i.e. Grade 3 to 5; NCI-CTCAE criteria) and non-serious (i.e. Grade 1 to 2; NCI-CTCAE criteria), Study initiation to end of 66-month study period (Primary and Secondary RCTs)|Exercise Adherence, This variable applies only to CORE participants. Exercise adherence is defined as the relative dose intensity (i.e. the percent of total dose of exercise performed, relative to the total dose prescribed) and quantified according to metabolic equivalents., Study initiation to end of 48-month phase I intervention period (Primary RCT - CORE participants)|Medication Compliance, Defined as the percent of pharmaceutical doses taken based on the total number of doses prescribed (applicable only to those that are provided pharmaceutical therapy for CVD risk factor modification), Study initiation to end of 48-month phase I intervention period (Primary RCT - CORE participants)|Behavioural Compliance, Defined as the percent of behavioural support resources accessed, based on the number recommended (one per month), Study initiation to end of 66-month study period (Primary RCTs - CORE participants)|PA Behavioural Compliance, Defined as the average number of participants achieving their weekly PA goals of meeting and maintaining either a PAI-Score of ≥100 \[PAI\] or weekly cancer exercise guidelines \[ExGL\]., Study initiation to end of 66-month study period (Primary and Secondary RCTs - CORE, PAI and ExGL participants)|Oxygen utilization during HIIT, Quantified as timepoint measures of oxygen utilization assessed via portable metabolic measurement system within the final 30 seconds of the warm-up, work and recovery periods, and the cool down during pre-specified high-intensity interval training sessions, Study initiation to end of 48-month phase I intervention period (CORE substudy participants; Primary RCT)|Power output during HIIT, Quantified as power output (watts) assessed cycle ergometer within the final 30 seconds of the warm-up, work and recovery periods, and the cool down during pre-specified high-intensity interval training sessions, Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)|Heart rate response during HIIT, Quantified via heart rate monitor or single-lead ECG within the final 30 seconds of the warm-up, work and recovery periods, and the cool down during pre-specified high-intensity interval training sessions, Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)|Energy expenditure during HIIT, Quantified as total metabolic equivalent of task following HIIT sessions, Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)|Perceived exertion

during HIIT, Assessed via rating of perceived exertion scale (6-20) within the final 30 seconds of the warm-up, work and recovery periods, and the cool down during pre-specified high-intensity interval training sessions, Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)|Felt arousal during HIIT, Affective arousal is evaluated via the felt arousal scale that assesses energy/arousal level on a scale of 1 (low arousal) to 6 (high arousal) within the final 30 seconds of the warm-up, work and recovery periods, and the cool down during pre-specified HIIT sessions, Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)|Feeling affect during HIIT, The feeling scale is used to assess affective valence (pleasure/displeasure; feeling good/bad) on a scale of -5 (vey bad) to +5 (very good) within the final 30 seconds of the warm-up, work and recovery periods, and the cool down during pre-specified high-intensity interval training sessions, Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)|Resilience, Measured using the Brief Relilience Scale (BRS), a 6-item inventory that assesses recovery, resistance, adaptation, and thriving., Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)|Stress, Measured using two items based on the Canadian Community Health Survey assessing the average daily stress experienced that day and over the past week., Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)|Feeling states, Assessed via ecological momentary assessments using brief reports completed 6 times a day on intervention weeks 1, 7, 16, 22, four weeks post intervention, and 26 weeks post intervention, Study initiation to end of 48-month phase I intervention period (CORE sub-study participants; Primary RCT)
Sponsor: University Health Network, Toronto
Collaborators: Centre hospitalier de l'Université de Montréal (CHUM)|Queen Elizabeth II Health Sciences Centre|Alberta Health services|Vancouver General Hospital|Université de Montréal|Dalhousie University|University of Alberta|University of British Columbia|University of Toronto
Sex: ALL
Age: ADULT
Phases: NA
Enrollment: 696
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: TREATMENT
Other IDs: 21-5391
Start Date: 2021-09
Primary Completion Date: 2026-09
Completion Date: 2027-03
First Posted: 2021-08-27
Results First Posted:

Last Update Posted: 2021-08-27
Locations:
Study Documents:

NCT Number: NCT03480087
Study Title: Subclinical Cardio-toxicities Evaluation With Strain Rate Echocardiography After Chemotherapy and/or Mediastinal Radiotherapy in Patient With Lymphoma
Study URL: https://beta.clinicaltrials.gov/study/NCT03480087
Acronym: Cardiocare
Study Status: COMPLETED
Brief Summary: Treatments-related cardiotoxicity is a critical issue in long term lymphoma survivors, particularly at young age, and its early identification is important to prevent clinically relevant cardiac events. Complete echocardiographic assessment including 2-dimension global longitudinal strain (2D-GLS), seems to be an effective tools in detecting preclinical systolic changes to the cardiac function even when the ejection fraction is preserved. The aim of Cardiocare study is to investigate early detection of subclinical chemo and radiation-induced changes in left ventricular function using 2D-GLS.
Study Results: NO
Conditions: Lymphoma, Non-Hodgkin|Hodgkin Lymphoma|Toxicity, Cardiac
Interventions:
Primary Outcome Measures: Left ventricular ejection fraction (LVEF), Left ventricular ejection fraction measured by echocardiography, Baseline, Change of LVEF from Baseline at 4/6 month (end of chemotherapy), Change of LVEF from Baseline at 6/8 months (end of radiotherapy - if applicable), Change of LVEF from Baseline at 9/11 months (3 months after treatment completion)|Global Longitudinal Strain (GLS), Global Longitudinal Strain measured by strain-rate echocardiography, Baseline, Change of GLS from Baseline at 4/6 month (end of chemotherapy), Change of GLS from Baseline at 6/8 months (end of radiotherapy - if applicable), Change of GLS from Baseline at 9/11 months (3 months after treatment completion)
Secondary Outcome Measures: Anthracycline cumulative dose, Anthracycline cumulative dose, 4/6 month after baseline (end of chemotherapy)|T troponin, T troponin rate, Baseline, Before each chemotherapy administration, 4/6 month after baseline (end of chemotherapy), 6/8 months after baseline (end of radiotherapy - if applicable), 9/11 months after baseline (3 months after treatment completion)
Other Outcome Measures:
Sponsor: Azienda Ospedaliera Città della Salute e della Scienza di Torino
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 118

Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Cardiocare
Start Date: 2015-01
Primary Completion Date: 2022-07
Completion Date: 2022-07
First Posted: 2018-03-29
Results First Posted:
Last Update Posted: 2022-07-19
Locations: SC Ematologia - AOU Città della salute e della Scienza di Torino, Torino, 10126, Italy
Study Documents:

NCT Number: NCT02784587
Study Title: Feasibility of Perioperative Stellate Ganglion Blocks in Cardiac Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT02784587
Acronym:
Study Status: COMPLETED
Brief Summary: Based upon Northern New England Cardiovascular Study Group data, the rate of post operative atrial fibrillation (POAF) requiring treatment following coronary artery bypass grafting (CABG) at Maine Medical Center (MMC) is currently 30%. Nationally, POAF occurs in up to 40% of patients post CABG, 50% of patients after valve surgery, 64% of patients post mitral valve and CABG and 49% after aortic valve replacement. Atrial fibrillation worsens a patient's hemodynamic status and increases the risk of congestive heart failure (CHF), embolic events and longer ICU stays leading to increased patient morbidity and strain on financial resources. In the U.S., POAF carries a higher risk of stroke (37% OR 2.0 in-hospital mortality (OR = 1.7), worsened survival (74% versus 87%), and an additional 4.9 days and $10,000-$11,500 in hospital stay costs.

Atrial fibrillation requires both an initiation trigger and favorable environment for maintenance and the sympathetic and parasympathetic nervous systems play important roles in this regard. Unfortunately, the precise mechanisms of POAF are still being investigated. This postoperative complication has persisted in spite of efforts to mitigate it pharmacologically with beta blockers and amiodarone, an experience shared by most other cardiac surgery centers.

The stellate ganglion is formed by the fusion of the inferior cervical sympathetic ganglion and first thoracic sympathetic ganglion. By modulating the sympathetic component of the autonomic nervous system, stellate ganglion stimulation has been shown to facilitate induction of atrial fibrillation while ablation may reduce or prevent episodes. Human studies have further supported this model.

Preliminary studies of perioperative stellate ganglion block (SGB) in

cardiac surgery suggest that this technique may reduce or prevent episodes of POAF requiring treatment. The investigator's ultimate goal is to determine whether SGB reduces the incidence of POAF in specific cardiac surgery populations at MMC. First, however, the investigator proposes to test the hypothesis that SGB, performed perioperatively by cardiac anesthesiologists in a population of patients undergoing cardiac surgery, is both safe and clinically feasible.
Study Results: YES
Conditions: Atrial Fibrillation
Interventions: PROCEDURE: Stellate Ganglion Block
Primary Outcome Measures: Success of Stellate Ganglion Block, Correct placement of stellate ganglion block as measured by a temperature rise of at least 1 degree Celsius in the ipsilateral hand, day of surgery
Secondary Outcome Measures: Rate of Atrial Fibrillation, The current rate of atrial fibrillation is measured by the Northern New England Cardiac Database, this existing database will track a-fib rates until the patients are discharged from the hospital after surgery., Through study completion, approximately 1 year
Other Outcome Measures:
Sponsor: Christopher Connors, MD
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 25
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: #4624
Start Date: 2016-05-31
Primary Completion Date: 2016-12-06
Completion Date: 2016-12-07
First Posted: 2016-05-27
Results First Posted: 2019-04-22
Last Update Posted: 2019-07-08
Locations:
Study Documents:

NCT Number: NCT03535987
Study Title: Pilot Cohort Study of Rb-82 Myocardial PET Imaging to Evaluate Coronary Microvascular Dysfunction in Men With Prostate Cancer Receiving Androgen-Deprivation Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT03535987
Acronym:
Study Status: COMPLETED
Brief Summary: To determine the feasibility of using myocardial PET imaging as a means to assess cardiovascular risk in men with prostate cancer planned for androgen- deprivation therapy with external beam radiation therapy.

Study Results: NO
Conditions: Prostate Cancer
Interventions: DEVICE: myocardial PET imaging
Primary Outcome Measures: number of subjects who successfully complete Rb-82 myocardial PET Imaging assessments, 12-18 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 18
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 18817
Start Date: 2018-03-15
Primary Completion Date: 2019-04-19
Completion Date: 2019-10-19
First Posted: 2018-05-24
Results First Posted:
Last Update Posted: 2020-06-17
Locations: Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents: Informed Consent Form

NCT Number: NCT04655885
Study Title: Cardiac Output Optimization on Postoperative Complications in Major Hepatic Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT04655885
Acronym: OPTILIVER
Study Status: RECRUITING
Brief Summary: Major hepatectomies are high-risk surgeries offered more and more frequently for the curative treatment of primary or secondary liver cancer, and for complex cases, representing a real challenge for medical teams. The 1st peroperative phase of "hepatic resection" requires a minimum supply of filling fluids to limit perioperative bleeding (Low Central Venous Pressure). However this strategy exposes the risk of organ hypoperfusion due to low cardiac flow, secondary to hypovolaemia, which may lead to ischemic situations favoring the onset of postoperative complications. On the other hand, the hemodynamic management of the 2nd peroperative phase "post hepatic resection" is marked by the need to correct this hypoperfusion by optimizing cardiac output by suitable vascular filling.

The major challenge is thus to restore cardiac output by refilling without excess, by correcting the hypovolemia that arose during the "post resection of the hepatic parenchyma" phase.

Our hypothesis is that an individualized protocol for optimizing intraoperative cardiac flow by guided vascular filling during the "post hepatic resection" phase is accompanied by a reduction in postoperative complications in patients operated on for major hepatic surgery.
Study Results: NO
Conditions: Primary or Metastatic Hepatic Adenocarcinoma
Interventions: BEHAVIORAL: Optimization of cardiac flow by base water-electrolyte supply|BEHAVIORAL: Control arm
Primary Outcome Measures: Evaluation of the cardiac output optimization strategy on the occurrence of postoperative complications, Assessment of the impact of an individualized protocol for optimizing perioperative cardiac flow guided by monitoring of dynamic indices of preload dependence during the post-hepatic resection phase on the occurrence of postoperative complications in major hepatic surgery, for primary hepatic cancer or metastatic origin. We retain as the primary endpoint, the percentage of patients with at least one postoperative complication regardless of the grade in the Dindo-Clavien classification., From Day 1 to Day 30 post-surgery
Secondary Outcome Measures: Evaluation of grade III-IV postoperative complication in the Dindo-Clavien classification, To determine whether the strategy for optimizing cardiac output guided by dynamic dependence preload indices is associated with a difference in the incidence of occurrence of at least one grade III-IV postoperative complication in the Dindo-Clavien classification, From Day 1 to Day 30 post-surgery|Evaluation of length of stay in the hospital, To determine whether the cardiac output optimization strategy guided by the dynamic dependence preload indices is associated with a difference in the length of stay in the Continuing Care Unit, intensive care unit or length of hospital stay or on re-hospitalization rates, From Day 1 to Day 30 post-surgery|Evaluation of mortality, To determine whether the cardiac output optimization strategy guided by the dynamic dependence preload indices is associated with a difference in mortality at D30 and D90, On Day 1, Day 30 and Day 90 post-surgery|Evaluation occurrence of organ failures, To determine whether the cardiac output optimization strategy guided by dynamic dependence preload indices has an impact on the occurrence of organ failures, which will be evaluated by the SOFA score per device from Day 1 to Day 7 postoperatively, From Day 1 to Day 7 post-surgery|Evaluation of hemodynamic parameters, To determine whether the cardiac output optimization strategy guided by dynamic dependence preload indices is associated with a difference on hemodynamic parameters, From Day 0 to Day 1 post-surgery
Other Outcome Measures:
Sponsor: Institut Paoli-Calmettes
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA

Enrollment: 186
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: PREVENTION
Other IDs: OPTILIVER TRIAL-IPC 2018-022
Start Date: 2022-02-03
Primary Completion Date: 2024-03-03
Completion Date: 2024-05-03
First Posted: 2020-12-07
Results First Posted:
Last Update Posted: 2022-03-23
Locations: Institut Paoli Calmettes, Marseille, 13009, France
Study Documents:

NCT Number: NCT05932485
Study Title: Effect of Stellate Ganglion Block on New Atrial Fibrillation After Coronary Artery Bypass Grafting
Study URL: https://beta.clinicaltrials.gov/study/NCT05932485
Acronym:
Study Status: RECRUITING
Brief Summary: Post-operative new-onset atrial fibrillation (POAF) is one of the most common arrhythmias in adults after direct intracardiac surgery with extracorporeal circulation. The incidence of POAF in coronary artery bypass grafting (CABG) is approximately 30%. POAF can lead to an increased risk of complications such as stroke, heart failure, and acute kidney injury, which not only prolongs the patient's hospital stay, but also increases hospital costs and mortality. operation, extracorporeal circulation, and the patient's underlying conditions (such as age, gender, hypertension, and diabetes), which cause sympathetic activation, inflammatory response, and myocardial ischemia in the organism. The stellate ganglion block (SGB) regulates the sympathetic tone of the innervated nerves and thus the autonomic function of the body. SGB can effectively regulate the sympathetic-parasympathetic imbalance. Also, SGB may exert some anti-inflammatory effects. In this study, ultrasound-guided SGB was used in CABG patients to investigate its effect on the occurrence of POAF.
Study Results: NO
Conditions: Stellate Ganglion Block
Interventions: PROCEDURE: Stellate nerve block
Primary Outcome Measures: The occurrence of new atrial fibrillation was detected by ECG monitoring, ECG monitor shows atrial fibrillation. To be specific: 1)Irregular R-R interval (when atrioventricular conduction is present), 2) P wave disappearance, 3) irregular atrial activity., Within 5 days after surgery
Secondary Outcome Measures: Changes in the inflammatory factor interleukin-6, Detection of inflammatory factors by serum, It reflects the degree of inflammation in the body at different time points, Preoperatively, End of operation , The first day after surgery, The Third day after surgery|Changes in the Stress index cortisol,

Detection of Stress index by serum, It reflects the degree of stress in the body at different time points, Preoperatively, End of operation , The first day after surgery, The Third day after surgery
Other Outcome Measures:
Sponsor: Yangzhou University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 20230609
Start Date: 2023-06-01
Primary Completion Date: 2023-12-01
Completion Date: 2024-06-01
First Posted: 2023-07-06
Results First Posted:
Last Update Posted: 2023-07-06
Locations: the Affiliated Hospital of Yangzhou University, Yangzhou University, Yangzhou, Jiangsu, China
Study Documents:

NCT Number: NCT02175147
Study Title: Patient-centred Integrated Palliative Care Pathways in Advanced Cancer and Chronic Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT02175147
Acronym: InSup-C
Study Status: UNKNOWN
Brief Summary: Rationale: Palliative care integration in treatment pathways, palliative care networks and institutional collaborations in health services delivery seems a promising approach reducing fragmentation and discontinuity. Integrated Palliative Care (IPC) approaches in Europe are largely unknown and under-investigated. The investigators aim is to explore experiences of patients with advanced cancer, Chronic Obstructive Pulmonary Disease (COPD) and Chronic Heart Failure (CHF), family and professional caregivers within with IPC. This includes perceived quality of life, quality of care, burden/ rewards of care giving, symptoms and collaboration between caregivers in the patient's care network.

Objectives: To investigate how patients with advanced cancer, COPD and CHF, their family and professional caregivers within a selection of IPC initiatives in Belgium, Germany, Hungary, The Netherlands and United Kingdom experience care delivery in the last phase of disease.

* To investigate what opinions patients and family caregivers have on

the (continuity and) quality of care delivered
* To investigate how patients rate their symptoms and quality of life
* To investigate how family caregivers rate their burden / rewards of care giving
* To investigate how the care network of the patient is organised with respect to the type, properties and quality of relationships between patients and family / professional caregivers

Study design: Longitudinal multiple embedded case study.

Study population: Adult patients with advanced cancer, COPD, and CHF under the care of IPC initiatives in five participating countries, their family and professional caregivers. The investigators aim to enroll up to 288 patients, 288 family caregivers and 192 professional caregivers in total.

Study parameters: Experiences with IPC initiatives, quality of care, quality of life, perceived symptoms, perceived collaboration between professional caregivers, burden and rewards of care giving.

Methods: Semi-structured interviews, patient diary, Social Network Analysis and the following questionnaires: Palliative care Outcome Scale; Canhelp Lite, Caregiver Reaction Assessment. Patients and family caregivers will be followed over 3 months at 4 consecutive contact points. The diary (containing two questions) will be kept weekly by patients. There will be group or individual interviews with professional caregivers.

Analysis: The overall analysis will involve a synthesis of the qualitative and quantitative data. For more information see Detailed Description.
Study Results: NO
Conditions: COPD|Cancer|Heart Failure
Interventions:
Primary Outcome Measures: Change from baseline Experiences with IPC initiatives at 3 months, The semi-structured interviews will be used to explore views of patients and family caregivers about their experiences with the integrated palliative care initiative. Topics include:

* An exploration of problems and needs of the patient
* An exploration of the contacts and relationships of patients and family caregivers with professional caregivers
* An exploration of satisfaction and perceived deficits in service provision from the perspective of patients and family caregivers
* An exploration of the views of patients and family caregivers on collaboration between professional care providers in the care network of the patient., Baseline and Month 3|Change from baseline Quality of care at 1, 2 and 3 months, Quality of care/satisfaction will be measured using the Canhelp Lite and the Social Network Analysis (SNA)

method.

Outcomes will be explored in the interviews, see also "Experiences with IPC initiatives", Baseline, Month 1, Month 2, Month 3|Change from baseline Quality of life at 1, 2, and 3 months, Quality of Life will be measured using the Palliative Care Outcome Scale (POS) version 1.

Outcomes will be explored in the interviews, see also "Experiences with IPC initiatives", Baseline, Month 1, Month 2, Month 3|Change from baseline Perceived symptoms at 1, 2, and 3 months, Quality of Life will be measured using the Palliative Care Outcome Scale (POS) version 1.

Outcomes will be explored in the interviews, see also "Experiences with IPC initiatives"., Baseline, Month 1, Month 2, Month 3|Change from Perceived collaboration between professional caregivers at 3 months, Quality of Life will be measured using Social Network Analysis method (SNA). Outcomes will be explored in the interviews, see also "Experiences with IPC initiatives", Baseline, Month 3|Change from baseline Burden and rewards of care giving at 1, 2, and 3 months, Burden and rewards of care giving will be measured using the Caregiver Reaction Assessment., Baseline, Month 1, Month 2, Month 3
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Radboud University Medical Center
Collaborators: European Union|Medical University of Pecs|Lancaster General Hospital|University Hospital, Bonn|KU Leuven|World Health Organization|European Association for Palliative Care|University of Rotterdam, The Netherlands|University of Navarra|University of Sheffield|Icahn School of Medicine at Mount Sinai
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 576
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 305555
Start Date: 2014-06
Primary Completion Date: 2015-12
Completion Date: 2015-12
First Posted: 2014-06-26
Results First Posted:
Last Update Posted: 2014-06-26
Locations: Katholieke Universiteit Leuven, Leuven, Belgium|University Hospital Bonn, Bonn, Germany|Medical University of Pecs, Pecs, Hungary|Radboud University Medical Centre Palliative consultation team, Nijmegen, Gelderland, Netherlands|Lancaster General Hospital, Lancaster, United Kingdom
Study Documents:

NCT Number: NCT04552587
Study Title: The HEART Study (Healthy Eating and Recovery Together)
Study URL: https://beta.clinicaltrials.gov/study/NCT04552587
Acronym:
Study Status: COMPLETED
Brief Summary: Head and neck cancer survivors and their primary caregivers (N=25 dyads) will be enrolled to pilot test a nutrition support system with a care planning clinic visit and a caregiver mobile App. Participants will be asked to complete baseline and 6-week follow-up surveys. The clinic session (offered in person or remotely) will include a needs assessment and a tailored care plan with information, educational materials and referrals about participants' symptoms, behaviors, social concerns and caregiving tasks. After the visit, the program will provide an App for caregivers with follow-up resources and mobile support for one month.
Study Results: YES
Conditions: Head and Neck Cancer|Survivorship|Nutrition Aspect of Cancer
Interventions: BEHAVIORAL: Heart APP
Primary Outcome Measures: Number of Participants Meeting Patient-Caregiver Session and Care Plan Acceptability Criteria, Investigator developed questionnaire investigating acceptability of session intervention and care plan. Items were rated on a 6-point descriptive scale from strongly disagree to strongly agree. Participants that meet criteria are those that chose moderately or strongly agree. Items included: Session made me feel prepared, care plan information was helpful emotionally, care plan was helpful practically, amount of information in care plan provided was appropriate, timing of session of session was appropriate., 6 week follow-up visit|Intervention Delivery/ Fidelity, Number of caregivers receiving all session content and delivery of the intervention as planned (intro to session, nurse care plan discussion, viewed nutritional support video, app training)., 6 week follow up visit|Intervention Reach, Percentage of those recruited who completed baseline and 6 week follow up surveys and the intervention session., Baseline and 6 week follow up visit
Secondary Outcome Measures: Ease of Use/System Usability, System Usability Scale (SUS) - The SUS consists of a 10 item questionnaire with five response options for respondents; from Strongly agree to Strongly disagree. Scores range from 0-100, with higher scores indicating better usability., 6 week follow up visit only (no baseline comparison)|Mean Score of Unmet Needs, 30-item Cancer Survivors/ Partners Unmet Needs instruments (CaSUN/ CaSPUN). Needs were endorsed on a yes/no basis, with a range of 0-30 total endorsed needs. A higher score indicates more endorsed needs. Average number of needs is reported., Baseline and 6 week follow up visit|PROMIS Depression-Short Form (SF) v1.0 Form 8A, PROMIS Depression- SF v1.0 form 8A is an 8-item Patient-Reported Outcomes Measure Information System (PROMIS) short-form instrument. Respondents are asked how often in the past 7 days they have experienced specific depression symptoms, using a 5-

point ordinal rating scale of "Never," "Rarely," "Sometimes," "Often," and "Always" whereby a higher score indicates higher depression. Raw score totals are converted to an item response theory-based T-scores. The T-score rescales the raw score into a standardized score with a mean of 50 and a standard deviation (SD) of 10 with a range of 38.2 to 81.3. Therefore, a person with a T-score of 40 is one SD below the mean. A decrease in change from baseline to 6 week followup indicates reduced depression., Baseline and 6 week follow-up visit|Mean Score of Survivorship Readiness/Caregiver Preparedness, The 11-item Preparing for Life As a New Survivor (PLANS) Knowledge Subscale, developed at the University of Michigan, is utilized to evaluate survivor and caregiver (1) knowledge of diagnosis, treatment and side effects, and (2) communication with the cancer team regarding diagnosis, treatment and side effects and 3) preparedness for what to expect over the next year. Items are rated on a 6-point scale where: strongly disagree=1, moderately disagree =2, slightly disagree=3, slightly agree= 4, moderately agree=5 and strongly agree=6. Items were averaged, with a range of 1-6 with higher scores indicating higher levels of agreement., Baseline and 6 week follow-up visit|Mean Score of Self-Efficacy, Based on the National Cancer Institute Follow-up Care Use Among Survivors (FOCUS) survey, two questions were asked: "How confident are you that you can get advice or information related to your/your loved one's cancer if you needed at this time?" and "How confident are you that you can (assist your loved one to) keep to the follow-up care schedule recommended by your doctors?" Participants rated items on a 5-point Likert scale where 0="Not at all confident" to 4= "Completely confident." Scores were averaged for each question, whereby higher scores indicated higher level of confidence. Change from baseline to 6 week follow up is also reported. Negative change indicates decline in self-efficacy., Baseline and 6 week follow-up visit|Mean Score of Dyadic Coping/ Dyadic Efficacy, Dyadic Coping was measured using a 5-item cancer-specific subscale version of the Dyadic Coping Inventory. Items are rated on a 5-point scale from 1 ("never") to 5 ("always"). Scores were averaged with a higher score indicating a better outcome. A decrease in change between baseline and 6 week followup visit indicates worsening outcome over time.

Dyadic Efficacy is an investigator developed 1-item question "How confident are you that you and your loved one can work together as a team to manage the cancer-related problems that come up?" Item was answered on a scale of 0 ("not at all confident") to 10 ("extremely confident"), with average score reported. A decrease in change between baseline and 6 week followup visit indicates worsening, where as an increase in change indicates improvement., Baseline and 6 week follow-up visit|Health-Related Quality-of-Life (PROMIS Scale v1.2 - Global Health), PROMIS Scale v1.2 - Global Health short form consists of 10 items that assess overall perceived quality of life and five general domains of health and functioning including overall physical health, mental health, social health, pain, and fatigue. Scoring uses a 5-point Likert scale with the response scores reversed (5=None to 1=Very

severe) so that higher scores for responses always indicate better health. Raw scores are summed and converted to a T-score (mean score of 50, SD ± 10), Therefore a person with a T-score of 40 is one SD below the mean. A decrease in the change from baseline to 6 week follow up indicates worsening quality of life, whereas an increase indicates improvement., Baseline and 6 week follow-up visit|Caregiver Burden, 4-item screening version of the Zarit Burden Interview is a self-report measure of caregiver burden. Caregivers rate each item on a 5-point Likert scale (0=never, 4= nearly always). Higher scores indicate greater caregiver distress. Total score range: 0 to 16, ≥ 8: high burden. An increase in change from baseline to 6 week follow up visit indicates increased caregiver distress., Baseline and 6 week follow up visit|Ease of Mobile App Use/User Engagement, Number of weekly prompt responses missed out of 184 total expected (23 caregivers given 2 prompts per week for 4 weeks)., 4 weeks during app use|Number of Participants With Care Plan Use Endpoints, Number of participants of use of care plan after session, including patient and caregiver report of "Referred to Care Plan again," "Used Care Plan," "Used educational materials," and "Shared Care Plan with others.", 6 week follow up visit|Percentage of Participants Rating App Satisfaction/ Perceived Importance, Ratings of satisfaction with app and prompts on a 6 point descriptive rating scale ranging from strongly agree to strongly disagree. Measurements reported below are count of participants who moderately or strongly agreed with individual prompts., 6 week follow up visit|Process Monitoring Data, Resources needed: Session length overall, length of nursing portion of session, length of app training- number of minutes, After session completion|Change From Baseline in Nutritional Status Scale, Investigator-developed 1 item: "During the past two weeks, how satisfied have you been with your nutritional status (from Extremely satisfied (1) to Not at all satisfied (5))?", Baseline and 6 week follow up visit|Change From Baseline in Symptom Distress/Symptom Management, Adapted Symptom Distress Scale 1 item scaled to assess how distressing symptoms are to participant. 0= not at all distressing, 10= extremely distressing

1 item to assess patient and caregiver perceptions concerning patient ability to manage symptoms. 0= can manage extremely well, 10= cannot manage at all, Baseline and 6 week follow up visit|Change From Baseline in Emotional Support, PROMIS Short Form v2.0 - Emotional Support - 4a is a 4-item questionnaire. Item banks (currently adults only) assess perceived feelings of being cared for and valued as a person; having confidant relationships. PROMIS instruments are scored using item-level calibrations. Each question usually has five response options ranging in value from one to five. Raw scores are the sum of values of the response to each question then rescaled to to a standardized T-score with a mean of 50 and a standard deviation (SD) of 10. Therefore a person with a T-score of 40 is one SD below the mean., Baseline and 6 week follow up visit|Change From Baseline in Symptom Severity, MD Anderson Symptom Inventory (MDASI) Head and Neck

Module- Includes 13 core items and an additional 9 head and neck cancer module items which calculates a total score of symptom severity. The MDASI assesses the severity of symptoms at their worst in the last 24 hours on a 0-10 Numeric Rating Scale, with 0 being "not present" and 10 being "as bad as you can imagine." Core items and module symptom items are averaged into a mean module severity. A higher score always indicates an increase in severity. A decrease in change from baseline to 6 week follow up indicates improvement of symptoms., Baseline and 6 week follow up visit
Other Outcome Measures:
Sponsor: Medical University of South Carolina
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 51
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 0006621|R21CA215557-02
Start Date: 2020-12-04
Primary Completion Date: 2021-10-10
Completion Date: 2021-10-10
First Posted: 2020-09-17
Results First Posted: 2022-10-07
Last Update Posted: 2023-01-20
Locations: Medical University of South Carolina, Charleston, South Carolina, 29425, United States
Study Documents: Study Protocol and Statistical Analysis Plan|Informed Consent Form: Patient Consent|Informed Consent Form: Caregiver consent

NCT Number: NCT00651222
Study Title: Influence of Hormone Therapy on Heart Attack Incidence in Men Undergoing Prostate Brachytherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT00651222
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to review cause of death in patients undergoing prostate brachytherapy at a single institution. Furthermore, we are analyzing patients undergoing androgen deprivation therapy and whether or not this contributed to cardiovascular deaths, specifically myocardial infarction.
Study Results: NO
Conditions: Prostate Cancer|Cardiovascular Death
Interventions: OTHER: No intervention was required
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Prostate Cancer Foundation of Chicago

Collaborators:
Sex: MALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment:
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: MI-PB
Start Date:
Primary Completion Date:
Completion Date:
First Posted: 2008-04-02
Results First Posted:
Last Update Posted: 2008-04-02
Locations: Chicago Prostate Center, Westmont, Illinois, 60559, United States
Study Documents:

NCT Number: NCT02501707
Study Title: Echocardiography for RILI Prediction
Study URL: https://beta.clinicaltrials.gov/study/NCT02501707
Acronym:
Study Status: TERMINATED
Brief Summary: Severe radiation-induced lung injury (RILI) occurs in approximately 20% of the lung cancer patients, who are treated with curative chemoradiation. In this study the investigators want to evaluate the prognostic value of baseline cardiac function assessed with echocardiography for prediction of RILI.
Study Results: NO
Conditions: NSCLC
Interventions:
Primary Outcome Measures: Dyspnea score at three months after (chemo)radiotherapy, assessed by the patient version of the CTCv4.0, up to 3 months
Secondary Outcome Measures: Dyspnea score at six months after (chemo)radiotherapy, assessed by the patient version of CTCv4.0, up to 6 months|Changes in dyspnea score after radiotherapy, compared to baseline, up to 12 months|Change in Left Ventricle Ejection Fraction (LVEF) (baseline versus 3-month after chemo radiation), up to 3 months|Change in left atrial volume (2009 AHA/ESC guidelines)(baseline versus 3-month after chemo radiation), up to 3 months|Radiation pneumonitis at 3-months after start of radio(chemo)therapy, assessed on a follow-up 3D CT scan image., up to 3 months|Lung fibrosis score at 6-months after start of chemo radiation, assessed on a follow-up CT scan image, up to 6 months|Prevalence-based dyspnea measure, reflecting severity as well as duration of dyspnea, up to 12 months|Changes in physical activity levels and sedentary behavior, assessed by accelerometry, up to 12 months|Pulmonary function based on spirometry, up to 3 months|Change in left atrial ejection fraction

(from pts in SR)(2009 AHA/ESC guidelines)(baseline versus 3-month after chemo radiation), up to 3 months|Change in mitral inflow (2009 AHA/ESC guidelines)(baseline versus 3-month after chemo radiation), up to 3 months|Change in pulmonary vein inflow patterns (2009 AHA/ESC guidelines)(baseline versus 3-month after chemo radiation), up to 3 months|Change in tissue doppler patterns of the mitral annulus (2009 AHA/ESC guidelines)(baseline versus 3-month after chemo radiation), up to 3 months|Cardiac blood biomarkers at baseline and during treatment, Brain natriuretic peptide(BNP), troponin I (TnI) and troponin T(TnT), up to 3 months|Haemoglobin parameters in the blood at baseline and during treatment, up to 3 months|Inflammatory parameters (CRP, IL-6 and TNFa) in the blood at baseline and during treatment, up to 3 months|Time trends in physical activity and sedentary time from baseline till 12 months after radiotherapy, measured by accelerometers in four weekly periods, up to 12 months
Other Outcome Measures: Cardiac Comorbidity according to ICD v10, up to 12 months|Radiomics (the evolving field of texture analysis) of normal tissue(heart and lung), up to 3 months|Mitochondrial DNA (prognostic value of mtDNA for development of RILI), up to 12 months|Body composition, analysed by evaluation of muscle mass and fat mass on computed tomography (CT) scans at a standardized vertebral landmark (third lumbar vertebra), up to 12 months|Muscle strength, measured by respiratory mouth pressure measurement, maximum inspiratoire mouthpressure, (Pimax), up to 12 months|arterial inflammation as revealed by 18F-FDG PET . Standardized quantification parameters will be applied: Standardized uptake value (SUV), target-to-background ratio (TBR), most diseased segment analysis, up to 12 months|Calcification score of the coronary artery and thoracic aorta. The calcification will be quantified by using fully automated scoring and graded according to the Agatston score method, up to 3 months
Sponsor: Maastricht Radiation Oncology
Collaborators: Academisch Ziekenhuis Maastricht
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 15
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: echocardiographyRILI
Start Date: 2017-04-25
Primary Completion Date: 2019-09-12
Completion Date: 2019-09-12
First Posted: 2015-07-17
Results First Posted:
Last Update Posted: 2019-12-04
Locations: MAASTRO clinic, Maastricht, Limburg, 6229 ET, Netherlands|Maastricht University Medical Center, Maastricht, Limburg, 6229 HX, Netherlands
Study Documents:

NCT Number: NCT01230983
Study Title: Combination Chemotherapy in Treating Patients With Acute Lymphoblastic Leukemia or Advanced Lymphoblastic Non-Hodgkin's Lymphoma
Study URL: https://beta.clinicaltrials.gov/study/NCT01230983
Acronym: T-Cell #4
Study Status: COMPLETED
Brief Summary: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug may kill more tumor cells. Dexrazoxane may lessen the side effects of chemotherapy.

PURPOSE: Randomized phase III trial to compare combination chemotherapy with or without dexrazoxane and with or without high-dose methotrexate in patients with acute lymphoblastic leukemia or advanced lymphoblastic non-Hodgkin's lymphoma.
Study Results: NO
Conditions: Cardiac Toxicity|Leukemia|Lymphoma
Interventions: DRUG: asparaginase|DRUG: cytarabine|DRUG: dexrazoxane hydrochloride|DRUG: doxorubicin hydrochloride|DRUG: leucovorin calcium|DRUG: mercaptopurine|DRUG: methotrexate|DRUG: prednisone|DRUG: therapeutic hydrocortisone|DRUG: vincristine sulfate|RADIATION: radiation therapy
Primary Outcome Measures: Complete Continuous Remission, Since all patients receive the same induction, the endpoint will be CCR , i.e. complete continuous remission (the time to failure for any cause among patients achieving a complete response), Time to failure for any cause among patients achieving a complete response
Secondary Outcome Measures: Abnormalities in the 31 week and the year 3 echocardiograms, Endpoint will be abnormalities in the 31 week and the year 3 echocardiograms (i.e. year 1 off therapy). Secondarily, we shall compare the CCR rates for the two treatment regimens, in a two sided fashion., 1 year off therapy
Other Outcome Measures:
Sponsor: Children's Oncology Group
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE3
Enrollment: 573
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 9404|U10CA030969|POG-9404|CDR0000064664
Start Date: 1996-06
Primary Completion Date: 2001-09
Completion Date: 2004-10

First Posted: 2010-10-29
Results First Posted:
Last Update Posted: 2013-06-06
Locations:
Study Documents:

NCT Number: NCT02451007
Study Title: Evaluation of the Effect of Lurbinectedin (PM01183) on Cardiac Repolarization in Patients With Selected Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT02451007
Acronym:
Study Status: COMPLETED
Brief Summary: Study to assess the potential effects of lurbinectedin (PM01183) at a therapeutic dose on the duration of the QTc interval, measured by electrocardiograms (ECGs), to characterize the PM01183 plasma concentration/QTc relationship, and to explore related ECG parameters in patients with selected solid tumors.
Study Results: YES
Conditions: Solid Tumors
Interventions: DRUG: lurbinectedin (PM01183)
Primary Outcome Measures: Change in QTcF (QT Corrected According to Fridericia's Formula), ΔQTCF (Change in QTcF); EOI (end of infusion); LSM (Least Square Means); PK (Pharmacokinetic(s)).

On Day 1 (D1) of Cycle 1 (C1), LSM ΔQTcF should have low difference values, without any clear trend to change with time.

Therefore, the upper bound (UB) of the (two-sided) 90%Confidence Interval (CI) at all time points had to be less than the protocol-specified cut-off of 20 ms at each time point. If so, non-inferiority of any ECG time point to baseline with respect of QTc prolongation could be concluded, Scheduled post-baseline ECG time points were taken 5-10 min before their time-matched PK samples: i.e., 5 min before EOI, 30 min, 1, 3, 24, 72 and 168 hours after EOI of Cycle 1, and 5 min before EOI, 30 min, 1, 3 and 168 hours after EOI of Cycle 2.
Secondary Outcome Measures: Relationship Between ΔQTcF and Time-matched Lurbinectedin Plasma Concentrations (Plasma Concentration), ΔQTcF (Change from Baseline in QT Corrected According to Fridericia's Formula); CI (Confidence Interval); Cmax (Maximum Plasma Concentration).

Table below details the results of the linear mixed effects model to quantify the relationship between the lurbinectedin plasma concentrations and ΔQTcF and Predicted ΔQTcF and 90% CI at mean lurbinectedin Cmax., Through study completion, each patient had to be followed for 2 cycles (1 cycle =3 weeks)|Relationship Between ΔQTcF and Time-matched Lurbinectedin Plasma Concentrations (Predicted ΔQTcF), ΔQTcF (Change from Baseline in QT Corrected According to Fridericia's Formula); CI (Confidence Interval); Cmax (Maximum Plasma Concentration).

Table below details the results of the linear mixed effects model to quantify the relationship between the lurbinectedin plasma concentrations and ΔQTcF and Predicted ΔQTcF and 90% CI at mean lurbinectedin Cmax., Through study completion, each patient had to be followed for 2 cycles (1 cycle =3 weeks)|Relationship Between ΔQTcF and Time-matched Lurbinectedin Plasma Concentrations (Intercept), ΔQTcF (Change from Baseline in QT Corrected According to Fridericia's Formula); CI (Confidence Interval); Cmax (Maximum Plasma Concentration).

Table below details the results of the linear mixed effects model to quantify the relationship between the lurbinectedin plasma concentrations and ΔQTcF and Predicted ΔQTcF and 90% CI at mean lurbinectedin Cmax., Through study completion, each patient had to be followed for 2 cycles (1 cycle =3 weeks)
Other Outcome Measures:
Sponsor: PharmaMar
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 39
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: OTHER
Other IDs: PM1183-B-005-14-QT
Start Date: 2015-08-12
Primary Completion Date: 2016-08-19
Completion Date: 2016-08-19
First Posted: 2015-05-21
Results First Posted: 2018-10-17
Last Update Posted: 2019-11-19
Locations: Sarcoma Oncology Research Center, Santa Monica, California, 90403, United States|University of Colorado Cancer Center, Aurora, Colorado, 80045, United States|Dana Farber Cancer lnstitute, Boston, Massachusetts, 02215, United States|The University of Texas MD Anderson Cancer Center, Houston, Texas, 77030, United States|Cancer Therapy & Research Center, San Antonio, Texas, 78229, United States|Hospital Universitari Vall D'Hebron, Barcelona, 08035, Spain|Complejo Hospitalario Regional Reina Sofía, Córdoba, 14004, Spain|Hospital Universitario 12 de Octubre, Madrid, 280035, Spain|Hospital Ramón Y Cajal, Madrid, 28034, Spain|Hospital Universitario Fundación Jiménez Díaz, Madrid, 28040, Spain|Hospital Universitario Madrid Sanchinarro, Madrid, 28050, Spain|Hospital Universitario Puerta de Hierro Majadahonda, Majadahonda, 28222, Spain|Complejo Hospitalario de Especialidades Virgen de La Victoria, Málaga, 29010, Spain|Complexo Hospitalario Universitario de Santiago, Santiago De Compostela, 15706, Spain|Hospital Universitari I Politècnic La Fe, Valencia, 46026,

Spain|Hospital Universitario Miguel Servet, Zaragoza, 50009, Spain
Study Documents:

NCT Number: NCT02717507
Study Title: Carvedilol in Preventing Heart Failure in Childhood Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT02717507
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This phase IIb trial studies how well low-dose carvedilol works in preventing heart failure in cancer survivors exposed to high dose anthracyclines for management of childhood cancer. Patients who received high-dose anthracycline chemotherapy are at a much greater risk for developing heart failure compared to survivors who didn't get any anthracycline chemotherapy. Heart failure happens when the heart muscle has been weakened and can't pump blood as well as it should. Carvedilol may help lower the risk of cardiovascular complications.
Study Results: NO
Conditions: Hematopoietic and Lymphoid Cell Neoplasm|Malignant Solid Neoplasm
Interventions: DRUG: Carvedilol|OTHER: Laboratory Biomarker Analysis|OTHER: Pharmacogenomic Study|OTHER: Pharmacological Study|OTHER: Placebo Administration|OTHER: Quality-of-Life Assessment|OTHER: Questionnaire Administration
Primary Outcome Measures: Left ventricular (LV) thickness-dimension ratio (LVT-D) derived from echocardiogram, reported in terms of LV posterior wall dimension in systole and LV dimension based on the internal diameter in diastole, Z-scores appropriately transformed to normality as necessary. The analysis will be conducted accounting for correlation among repeated measurements within individuals. This may be done using the generalized estimating equation (GEE) approach or by linear mixed effects (LME) model with random effects. Various covariance structures will be assumed, including the unstructured, compound symmetry, and autoregressive lag-1 correlation. GEE and LME models will be implemented using GENMOD and MIXED procedures using the Statistical Analysis System (SAS) software. LV T-D z-scores will be modeled as a linear function of time. A treatment group by time interaction will be included and tested to assess the intervention effects., Up to 24 months
Secondary Outcome Measures: Afterload measurements, Evaluated in the manner described for primary outcome based on testing the significance of the interaction of time by group variables. The distribution of continuous variables will be examined graphically and appropriate transformations made before applying analytical methods based on normal assumption., Up to 24 months|Systolic measurements, Evaluated in the manner described for primary outcome based on testing the significance of the interaction of time by group variables. The distribution of continuous variables will be examined graphically and appropriate transformations made before applying analytical methods

based on normal assumption., Up to 24 months|Diastolic measurements, Evaluated in the manner described for primary outcome based on testing the significance of the interaction of time by group variables. The distribution of continuous variables will be examined graphically and appropriate transformations made before applying analytical methods based on normal assumption., Up to 24 months|Blood natriuretic peptide (BNP) level, Treated as continuous measures. The linear mixed effects model for between group comparisons of measures from the 5 time points will be applied. The unstructured mean model and linear in time model will be employed., Up to 24 months|Cardiac troponins (cTnT and cTnI) level, Treated as continuous measures. The linear mixed effects model for between group comparisons of measures from the 5 time points will be applied. The unstructured mean model and linear in time model will be employed., Up to 24 months|Galectin-3 level, Treated as continuous measures. The linear mixed effects model for between group comparisons of measures from the 5 time points will be applied. The unstructured mean model and linear in time model will be employed., Up to 24 months|Grade 2-4 adverse events, Will be assessed using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. The number of grade 2-4 toxicities observed will be tabulated by treatment arm. Differences by treatment arm will be evaluated using Fisher exact tests., Up to 24 months|Frequency of individuals with elevated liver function measurements (bilirubin, aspartate aminotransferase, alanine aminotransferase), Compared between treatment groups using an exact test on 2x2 tables, stratified on CYP2D6. Logistic regression analysis will also be used to compare the frequency of elevated liver function between treatments, adjusted for covariates. Linear mixed-effects model for normally distributed data will also be used to compare the trends in liver function levels between the treatment groups. Procs MIXED and GLIMMIX will be used for longitudinal analysis of normally and non-normally distributed data, respectively. Proc GENMOD will also be used for normally and non-normally distributed data., Up to 24 months|Treatment adherence as measured by pill counts, Voluntary withdrawals will be examined at the end of the study by comparing the percent of withdrawals between the treatment groups using a chi-square test or Fisher's exact test., Up to 24 months|Patient reported symptoms, Patient reported symptoms will be scored as a 5-point Likert-type scale in response to questions on how much patients are bothered by certain symptoms. The responses will be treated as normally distributed, as ordinal or dichotomized variable, and the linear mixed effects model or generalized linear mixed effects model will be applied to compare changes between treatment groups., Up to 24 months
Other Outcome Measures:
Sponsor: Children's Oncology Group
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 182

Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: ALTE1621|NCI-2016-00232|ALTE1621|COG-ALTE1621|ALTE1621|R01CA196854|UG1CA189955
Start Date: 2016-04-04
Primary Completion Date: 2022-06-30
Completion Date: 2023-09-30
First Posted: 2016-03-23
Results First Posted:
Last Update Posted: 2022-10-03
Locations: Children's Hospital of Alabama, Birmingham, Alabama, 35233, United States|Phoenix Childrens Hospital, Phoenix, Arizona, 85016, United States|Arkansas Children's Hospital, Little Rock, Arkansas, 72202-3591, United States|Kaiser Permanente Downey Medical Center, Downey, California, 90242, United States|City of Hope Comprehensive Cancer Center, Duarte, California, 91010, United States|Miller Children's and Women's Hospital Long Beach, Long Beach, California, 90806, United States|Children's Hospital Los Angeles, Los Angeles, California, 90027, United States|Kaiser Permanente-Oakland, Oakland, California, 94611, United States|Children's Hospital of Orange County, Orange, California, 92868, United States|University of California Davis Comprehensive Cancer Center, Sacramento, California, 95817, United States|Rady Children's Hospital - San Diego, San Diego, California, 92123, United States|Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center, Torrance, California, 90502, United States|Children's Hospital Colorado, Aurora, Colorado, 80045, United States|Rocky Mountain Hospital for Children-Presbyterian Saint Luke's Medical Center, Denver, Colorado, 80218, United States|Yale University, New Haven, Connecticut, 06520, United States|Alfred I duPont Hospital for Children, Wilmington, Delaware, 19803, United States|MedStar Georgetown University Hospital, Washington, District of Columbia, 20007, United States|Children's National Medical Center, Washington, District of Columbia, 20010, United States|Golisano Children's Hospital of Southwest Florida, Fort Myers, Florida, 33908, United States|University of Florida Health Science Center - Gainesville, Gainesville, Florida, 32610, United States|Nemours Children's Clinic-Jacksonville, Jacksonville, Florida, 32207, United States|AdventHealth Orlando, Orlando, Florida, 32803, United States|Nemours Children's Hospital, Orlando, Florida, 32827, United States|Nemours Children's Clinic - Pensacola, Pensacola, Florida, 32504, United States|Johns Hopkins All Children's Hospital, Saint Petersburg, Florida, 33701, United States|Tampa General Hospital, Tampa, Florida, 33606, United States|Saint Joseph's Hospital/Children's Hospital-Tampa, Tampa, Florida, 33607, United States|Saint Mary's Hospital, West Palm Beach, Florida, 33407, United States|Children's Healthcare of Atlanta - Egleston, Atlanta, Georgia, 30322, United States|Kapiolani Medical Center for Women and Children, Honolulu, Hawaii,

96826, United States|Lurie Children's Hospital–Chicago, Chicago, Illinois, 60611, United States|University of Illinois, Chicago, Illinois, 60612, United States|University of Chicago Comprehensive Cancer Center, Chicago, Illinois, 60637, United States|Advocate Children's Hospital–Oak Lawn, Oak Lawn, Illinois, 60453, United States|Advocate Children's Hospital–Park Ridge, Park Ridge, Illinois, 60068, United States|Saint Vincent Hospital and Health Care Center, Indianapolis, Indiana, 46260, United States|Blank Children's Hospital, Des Moines, Iowa, 50309, United States|University of Iowa/Holden Comprehensive Cancer Center, Iowa City, Iowa, 52242, United States|Norton Children's Hospital, Louisville, Kentucky, 40202, United States|Children's Hospital New Orleans, New Orleans, Louisiana, 70118, United States|Ochsner Medical Center Jefferson, New Orleans, Louisiana, 70121, United States|Sinai Hospital of Baltimore, Baltimore, Maryland, 21215, United States|C S Mott Children's Hospital, Ann Arbor, Michigan, 48109, United States|Children's Hospitals and Clinics of Minnesota – Minneapolis, Minneapolis, Minnesota, 55404, United States|University of Minnesota/Masonic Cancer Center, Minneapolis, Minnesota, 55455, United States|Mayo Clinic in Rochester, Rochester, Minnesota, 55905, United States|University of Mississippi Medical Center, Jackson, Mississippi, 39216, United States|Children's Mercy Hospitals and Clinics, Kansas City, Missouri, 64108, United States|Cardinal Glennon Children's Medical Center, Saint Louis, Missouri, 63104, United States|Children's Hospital and Medical Center of Omaha, Omaha, Nebraska, 68114, United States|University of Nebraska Medical Center, Omaha, Nebraska, 68198, United States|University Medical Center of Southern Nevada, Las Vegas, Nevada, 89102, United States|Sunrise Hospital and Medical Center, Las Vegas, Nevada, 89109, United States|Alliance for Childhood Diseases/Cure 4 the Kids Foundation, Las Vegas, Nevada, 89135, United States|Summerlin Hospital Medical Center, Las Vegas, Nevada, 89144, United States|Hackensack University Medical Center, Hackensack, New Jersey, 07601, United States|Saint Joseph's Regional Medical Center, Paterson, New Jersey, 07503, United States|Roswell Park Cancer Institute, Buffalo, New York, 14263, United States|NYU Winthrop Hospital, Mineola, New York, 11501, United States|The Steven and Alexandra Cohen Children's Medical Center of New York, New Hyde Park, New York, 11040, United States|Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States|University of Rochester, Rochester, New York, 14642, United States|Stony Brook University Medical Center, Stony Brook, New York, 11794, United States|Mission Hospital, Asheville, North Carolina, 28801, United States|Children's Hospital Medical Center of Akron, Akron, Ohio, 44308, United States|Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, 45229, United States|University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, 73104, United States|Legacy Emanuel Children's Hospital, Portland, Oregon, 97227, United States|Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, 19104, United States|Children's Hospital of Pittsburgh of UPMC, Pittsburgh, Pennsylvania, 15224, United States|Medical University of South Carolina, Charleston,

South Carolina, 29425, United States|BI-LO Charities Children's Cancer Center, Greenville, South Carolina, 29605, United States|Saint Jude Children's Research Hospital, Memphis, Tennessee, 38105, United States|Vanderbilt University/Ingram Cancer Center, Nashville, Tennessee, 37232, United States|Dell Children's Medical Center of Central Texas, Austin, Texas, 78723, United States|UT Southwestern/ Simmons Cancer Center-Dallas, Dallas, Texas, 75390, United States|El Paso Children's Hospital, El Paso, Texas, 79905, United States|Cook Children's Medical Center, Fort Worth, Texas, 76104, United States| Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center, Houston, Texas, 77030, United States|Methodist Children's Hospital of South Texas, San Antonio, Texas, 78229, United States|University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78229, United States|University of Virginia Cancer Center, Charlottesville, Virginia, 22908, United States|Virginia Commonwealth University/Massey Cancer Center, Richmond, Virginia, 23298, United States|Seattle Children's Hospital, Seattle, Washington, 98105, United States| Providence Sacred Heart Medical Center and Children's Hospital, Spokane, Washington, 99204, United States|Mary Bridge Children's Hospital and Health Center, Tacoma, Washington, 98405, United States| Princess Margaret Hospital for Children, Perth, Western Australia, 6008, Australia|Perth Children's Hospital, Perth, Western Australia, 6009, Australia|IWK Health Centre, Halifax, Nova Scotia, B3K 6R8, Canada|Starship Children's Hospital, Grafton, Auckland, 1145, New Zealand|Christchurch Hospital, Christchurch, 8011, New Zealand
Study Documents:

NCT Number: NCT00784095
Study Title: Outlook Quality of Life Intervention
Study URL: https://beta.clinicaltrials.gov/study/NCT00784095
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine whether discussions of life story, forgiveness, and future goals improve quality of life for patients with serious illness.
Study Results: YES
Conditions: Cancer|Congestive Heart Failure|Chronic Obstructive Pulmonary Disease
Interventions: OTHER: Life completion and preparation|OTHER: Attention Control
Primary Outcome Measures: Quality of Life - Preparation, Quality Of Life At The End Of Life (the QUAL-E 2009) is a 31 item measure of quality of life at the end of life assessing five domains: life completion, relationship with health care providers, preparation for death, physical symptoms and affective social support. The 4-item preparation sub-scale is a primary outcomes measure with each item scaled from 1 to 5 with a minimum of 5, maximum of 20 score with higher scores indicating better preparation., Baseline, 6 and 8 week follow up|QUAL-E Completion Sub-scale, A sub-scale of the QUAL-E quality of life at the end of life measures. The scale range was 5-35

with higher scores indicating more positive sense of completion., Baseline, 6 and 8 week follow up
Secondary Outcome Measures: Functional Status ADL, Rosow-Breslau Activities of Daily Living scale range 17-51 with higher scores indicating greater ability., Baseline, 6 and 8 week follow ups|Center for Epidemiology Studies - Depression Scale (CES-D), Center for Epidemiology Studies - Depression Scale (CES-D) is a 10-item measure of depression. Items are rated on a 4 point likert scale with total scores ranging from 0-30. Higher scores indicate greater depressive symptoms., Baseline, 6 and 8 week follow up|POMS Anxiety Sub-scale, The anxiety sub-scale from the modified Brief Profile of Mood States (POMS) is a 5-item measure of psychological distress.Items are on a 5-point likert scale with scoring ranging from 5-25. Higher scores indicate greater anxiety., Baseline, 6 and 8 week follow ups
Other Outcome Measures:
Sponsor: VA Office of Research and Development
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 36
Funder Type: FED
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose:
Other IDs: IAD 07-162
Start Date: 2008-12
Primary Completion Date: 2009-05
Completion Date: 2009-05
First Posted: 2008-11-02
Results First Posted: 2014-10-03
Last Update Posted: 2016-03-22
Locations: Durham VA Medical Center HSR&D COE, Durham, North Carolina, 27705, United States
Study Documents:

NCT Number: NCT05406635
Study Title: Imaging Versus Cardiac Biomarker Monitored HER2 Directed Therapy in Patients With Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05406635
Acronym: HER2BIC
Study Status: RECRUITING
Brief Summary: Due to a risk of heart failure during HER2 directed therapy in breast cancer, treatment is monitored with imaging of myocardial function, which is resource demanding for both patients and the health care system. The purpose of this study is to evaluate, if biomarkers can replace imaging based examinations of myocardial function during HER2 directed therapy.
Study Results: NO
Conditions: Cardiotoxicity|HER2-positive Breast Cancer

Interventions: DIAGNOSTIC_TEST: Biomarkers: Troponins and natriuretic peptides
Primary Outcome Measures: Left ventricular ejection fraction (LVEF), LVEF on cardiac MR., Three months after treatment has ended.
Secondary Outcome Measures: The number of treatment interruptions due to suspected cardiotoxicity, Number of times treatment was paused due to suspected cardiotoxicity either based on imaging or biomarkes as defined in the protocol., Through study completion, an average of 1 year.|The number of MUGA scans/echocardiograms, The number of MUGA scans/echocardiograms preformed during the study periode., Through study completion, an average of 1 year.|The cumulative doses of trastuzumab and pertuzumab, The cumulative doses of trastuzumab and pertuzumab in mg., After end of treatment, an average of 1 year after inclusion.|The proportion of patients treated for cardiotoxicity., Number of patients referred to tratment for heart failure in the department of cardiology., Through study completion, an average of 1 year|Change in self-reported health status measured with EQ-5D-5L questionnaire, An Index score and a Visual Analogue Scale (VAS)., At baseline, at treatment week 9, 18, 30 and 48 and three months after end of treatment.|Correlation between radiotherapy and cardiac function., Correlation between location and dose of the radiotherapy with changes in biomarkers, LVEF and ECG., Through study completion, an average of 1 year
Other Outcome Measures: Safty outcome of left ventricular ejection fraction, Drop in LVEF below 45 %, End of treatment
Sponsor: Odense University Hospital
Collaborators: Aarhus University Hospital|Aalborg University Hospital|University of Copenhagen
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 220
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, CARE_PROVIDER)|Primary Purpose: TREATMENT
Other IDs: OP_1413
Start Date: 2021-10-01
Primary Completion Date: 2024-09-01
Completion Date: 2025-09-01
First Posted: 2022-06-06
Results First Posted:
Last Update Posted: 2022-06-06
Locations: Aarhus University Hospital, Aarhus, Denmark|Herlev University Hospital, Herlev, Denmark|Odense University Hospital, Odense, 5000, Denmark
Study Documents:

NCT Number: NCT04138095

Study Title: Virtual Reality as an Adjunct to Management of Pain and Anxiety in Palliative Care
Study URL: https://beta.clinicaltrials.gov/study/NCT04138095
Acronym:
Study Status: UNKNOWN
Brief Summary: Virtual reality has been shown to be an effective way to treat pain and anxiety in various different settings. Palliative care is an area of medicine that often deals with patients suffering from pain and anxiety. The medication used to manage these symptoms are often opioids and benzodiazepines due to their rapid onset however they do have a significant side effect burden on patients. Very few studies have looked at the effect of virtual reality in this patient population. The goal of this study is to measure if virtual reality can decrease the required amount of medication used in managing pain and anxiety in palliative care. The secondary outcome will look at perceived benefit by patients
Study Results: NO
Conditions: Cancer|Heart Failure|Copd|ALS
Interventions: DEVICE: Virtual Reality
Primary Outcome Measures: Opioid and Benzodiazepine use, Number of additional doses of opioids and benzodiazepines used on standard of care days will be compared to additional doses of opioids and benzodiazepines used on standard of care and virtual reality days, 10 days
Secondary Outcome Measures: Patient perception of benefit, Patient will be asked to complete a Visual Analogue Scale for pain (scale from 0 to 10, 0 being no pain and 10 being worse pain imaginable) and and/or Visual Analogue Scale for anxiety (scale from 0 to 10, 0 being no anxiety/calm and 10 being extremely anxious/fearful) immediately prior to virtual reality use and immediately after use. The two values will be compared, 10 days
Other Outcome Measures:
Sponsor: Riverview Health Centre
Collaborators: Centre for Aging and Brain Health Innovation|Riverview Health Centre Foundation
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 8
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: RiverviewHC
Start Date: 2020-10-01
Primary Completion Date: 2020-12-31
Completion Date: 2021-03-30
First Posted: 2019-10-24
Results First Posted:
Last Update Posted: 2021-03-10

Locations: Riverview Health Centre, Winnipeg, Manitoba, R3L2P4, Canada
Study Documents:

NCT Number: NCT00122135
Study Title: A Culturally Sensitive Values-Guided Aid for End of Life Decision-Making
Study URL: https://beta.clinicaltrials.gov/study/NCT00122135
Acronym: Aim3
Study Status: COMPLETED
Brief Summary: The goal of this research agenda is to improve the quality of end-of-life care by explicitly identifying values that will guide the decision-making process, with a particular emphasis on the role of ethnic, racial and cultural factors.
Study Results: YES
Conditions: Congestive Heart Failure|Chronic Obstructive Pulmonary Disease|Cirrhosis|Colon Carcinoma|Lung Cancer|Chronic Kidney Disease
Interventions: OTHER: Values Inventory (VI)
Primary Outcome Measures: Presence of Discussions About End of Life Care Goals/Wishes, Qualitative content analysis of physician-patient encounters regarding presence of any type of discussion about end of life care goals/wishes, immediate
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: VA Office of Research and Development
Collaborators: Baylor College of Medicine
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: FED
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: IIR 02-224
Start Date: 2004-12
Primary Completion Date: 2009-09
Completion Date: 2009-09
First Posted: 2005-07-21
Results First Posted: 2015-07-10
Last Update Posted: 2015-12-14
Locations: Michael E DeBakey VA Medical Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT01047735
Study Title: The TRIABETES - ARMMS-T2D Study: A Randomized Trial to Compare Surgical and Medical Treatments for Type 2 Diabetes
Study URL: https://beta.clinicaltrials.gov/study/NCT01047735
Acronym: TRIABETES
Study Status: ACTIVE_NOT_RECRUITING

Brief Summary: This research study is being performed to begin to determine the effectiveness of two dominant bariatric surgery procedures versus an intensive lifestyle intervention to induce weight loss in patients and promote improvements in Type 2 diabetes mellitus (T2DM) in moderately obese patients.

T2DM is currently the 6th leading cause of mortality in the United States and is a major cause of kidney failure, blindness, amputations, heart attack, and other vascular and gastro-intestinal dysfunctions. Traditionally, treatments include intensive lifestyle modifications with or without glucose lowering agents. Neither treatment alone, or in combination, results in complete resolution of diabetes and its potential long-term complications. Bariatric surgery has been proven as an effective treatment to accomplish sustained and significant weight loss for those with severe obesity and has been shown to induce long-term remission of T2DM. However, despite enthusiasm for these potential treatment options, it is not clear whether diabetes is influenced by the type of surgery or by the amount of weight lost or if bariatric surgery is more effective than non-surgical weight loss induced by diet and physical activity in T2DM patients with moderate BMIs (30-40kg/m2; Class I and Class II obesity, or approximately 65-95 pounds overweight depending on your height). More well-controlled studies are needed to more completely inform health care decision making and clinical practice in this area. This research study aims to obtain preliminary information regarding the effectiveness of two major types of bariatric surgery, Laparoscopic Roux-en-Y Gastric Bypass and Laparoscopic Adjustable Gastric Banding versus an intensive lifestyle intervention to induce weight loss with diet and increased physical activity.
Study Results: NO
Conditions: Type 2 Diabetes Mellitus|Obesity
Interventions: PROCEDURE: Roux-en-Y Gastric Bypass Surgery|PROCEDURE: Laparoscopic Adjustable Gastric Banding|BEHAVIORAL: Lifestyle Weight Loss Intervention
Primary Outcome Measures: Feasibility of performing a randomized trial comparing two major types of bariatric surgery versus a lifestyle weight loss intervention (LWLI) induced by diet and increased physical activity in moderately obese patients with T2DM., 6 months, 1 year
Secondary Outcome Measures: Preliminary information regarding the effectiveness of two dominant bariatric surgery procedures versus an intensive lifestyle intervention to induce weight loss with diet and increased physical activity., 6 months, 1 year
Other Outcome Measures:
Sponsor: University of Pittsburgh
Collaborators: National Institutes of Health (NIH)|National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Sex: ALL
Age: ADULT
Phases: NA
Enrollment: 69

Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: RC1DK086037|RC1DK086037|R01DK095128-01
Start Date: 2009-09-01
Primary Completion Date: 2024-07-01
Completion Date: 2024-07-01
First Posted: 2010-01-13
Results First Posted:
Last Update Posted: 2023-07-11
Locations: William F Gourash, Pittsburgh, Pennsylvania, 15213, United States
Study Documents:

NCT Number: NCT00300495
Study Title: Study of Amiodarone Given Before Lung Surgery to Prevent Atrial Fibrillation After Lung Resection
Study URL: https://beta.clinicaltrials.gov/study/NCT00300495
Acronym:
Study Status: TERMINATED
Brief Summary: Atrial fibrillation is a very common complication of pulmonary resection. Patients who develop atrial fibrillation require additional treatment and are more likely to stay in the hospital for longer period of time increasing the costs associated with the operation. We propose a randomized controlled trial to see if oral amiodarone given for one week before surgery can prevent atrial fibrillation after pulmonary resection. We plan to evaluate the incidence of atrial fibrillation in patients who received preoperative amiodarone and compare them to the incidence of atrial fibrillation in patients who did not received preoperative amiodarone.
Study Results: YES
Conditions: Atrial Fibrillation|Lung Cancer
Interventions: DRUG: Amiodarone|OTHER: Control arm, standard care
Primary Outcome Measures: Incidence of Post-operative Atrial Fibrillation, Number of patients with post-operative atrial fibrillation, 30 days
Secondary Outcome Measures: Length of Post-operative Hospital Stay, Length of hospital stay after the operation, 1 week on average
Other Outcome Measures:
Sponsor: Beth Israel Deaconess Medical Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 19
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: PREVENTION

Other IDs: 2005P000376
Start Date: 2006-02
Primary Completion Date: 2009-10-13
Completion Date: 2009-10-13
First Posted: 2006-03-09
Results First Posted: 2017-03-20
Last Update Posted: 2017-04-28
Locations: Beth Israel Deaconess Medical Center, Boston, Massachusetts, 02215, United States
Study Documents:

NCT Number: NCT02722525
Study Title: Cardiac MRI in Measuring the Impact of Anti-androgen Treatment on Cardiac Function in Patients With Prostate Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02722525
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Learning about the impact of anti-androgen treatment has on cardiac function in patients with prostate cancer may help plan treatment and help patients live more comfortably. This pilot clinical trial will utilize cardiac magnetic resonance imaging (MRI) before a patient starts hormone therapy and after 4 to 7 months of hormone therapy. The objective is to measure the impact of hormone therapy (anti-androgen treatment) on cardiac function in patients with prostate cancer.
Study Results: NO
Conditions: Cardiovascular Injury|Prostate Carcinoma
Interventions: PROCEDURE: Magnetic Resonance Imaging|BEHAVIORAL: Exercise Intervention|PROCEDURE: Perfusion Magnetic Resonance Imaging|BEHAVIORAL: Exercise Intervention|PROCEDURE: Spectroscopy|OTHER: Laboratory Biomarker Analysis
Primary Outcome Measures: Heart rate (bpm), Up to 7 months post ADT initiation|Maximal rate of oxygen consumption, Up to 7 months post ADT initiation|Cardiac muscle mass, Up to 7 months post ADT initiation|Ventricular performance assessed by cardiac stress MRI, Up to 7 months post ADT initiation|Myocardial perfusion reserve assessed by cardiac stress MRI, Up to 7 months post ADT initiation|Skeletal muscle energetics assessed by PMRS, Up to 7 months post ADT initiation
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Ohio State University Comprehensive Cancer Center
Collaborators: Pelontonia
Sex: MALE
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 23
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC

Other IDs: OSU-14186|NCI-2015-00029
Start Date: 2014-12
Primary Completion Date: 2017-11-13
Completion Date: 2022-12-31
First Posted: 2016-03-30
Results First Posted:
Last Update Posted: 2022-05-20
Locations: Arthur G. James Cancer Hospital and Solove Research Institute at Ohio State University Medical Center, Columbus, Ohio, 43210, United States
Study Documents:

NCT Number: NCT03232125
Study Title: Effect of Ramosetron on Heart Rate-corrected QT Interval During Robot-assisted Laparoscopic Prostatectomy With Steep Trendelenburg Position
Study URL: https://beta.clinicaltrials.gov/study/NCT03232125
Acronym:
Study Status: COMPLETED
Brief Summary: Intraperitoneal insufflation of carbon dioxide may affect the sympathetic activity that leads to changes in ventricular re-polarization. This in turn can result in changes of heart rate-corrected QT (QTc) interval. Ramosetron is a 5-hydroxytryptamine three receptor antagonist and widely used anti-emetics. However, QTc interval prolongation has been observed in a number of patients after administration of 5-HT3 receptor antagonists. The aim of this study is to evaluate the effects of ramosetron on QTc interval and possible cardiovascular adverse effects during robot-assisted laparoscopic prostatectomy with steep Trendelenburg position.
Study Results: NO
Conditions: Prostate Cancer
Interventions: DRUG: Ramosetron|DRUG: Normal saline
Primary Outcome Measures: Maximum change of QTc interval, Maximum change of QTc interval from continuous ECG monitoring in lead V5 were collected by using the LabChart software., Before induction of anesthesia in the supine position (Baseline)|Maximum change of QTc interval, Maximum change of QTc interval from continuous ECG monitoring in lead V5 were collected by using the LabChart software., 10 minutes after tracheal intubation (Intu-10 min.)|Maximum change of QTc interval, Maximum change of QTc interval from continuous ECG monitoring in lead V5 were collected by using the LabChart software., immediately after steep Trendelenburg position with CO2 pneumoperitoneum (T-on)|Maximum change of QTc interval, Maximum change of QTc interval from continuous ECG monitoring in lead V5 were collected by using the LabChart software., 30 minutes after steep Trendelenburg position with CO2 pneumoperitoneum (T-30 min)|Maximum change of QTc interval, Maximum change of QTc interval from continuous ECG monitoring in lead V5 were collected by using the LabChart software., 60 minutes after steep Trendelenburg position with CO2 pneumoperitoneum (T-60 min)|Maximum change of QTc interval, Maximum

change of QTc interval from continuous ECG monitoring in lead V5 were collected by using the LabChart software., 90 minutes after steep Trendelenburg position with CO2 pneumoperitoneum (T-90 min)|Maximum change of QTc interval, Maximum change of QTc interval from continuous ECG monitoring in lead V5 were collected by using the LabChart software., immediately after a supine position with CO2 desufflation (T-off)|Maximum change of QTc interval, Maximum change of QTc interval from continuous ECG monitoring in lead V5 were collected by using the LabChart software., at the end of surgery (Surgery end)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Yonsei University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 54
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: 4-2017-0487
Start Date: 2017-08-01
Primary Completion Date: 2020-06-09
Completion Date: 2020-06-12
First Posted: 2017-07-27
Results First Posted:
Last Update Posted: 2020-08-25
Locations: Professor, Department of Anesthesiology and Pain Medicine, Severance Hospital, Yonsei University College of Medicine, Seoul, 03722, Korea, Republic of
Study Documents:

NCT Number: NCT05184725
Study Title: CARINAE for Stress Relief in Perioperative Care
Study URL: https://beta.clinicaltrials.gov/study/NCT05184725
Acronym: CARINAE
Study Status: COMPLETED
Brief Summary: Preventing pre-surgical stress can help patients achieve positive outcomes on health and well-being. However, very few patients receive adequate stress relief support prior to a surgical procedure. Provision of education and information about the surgery can be a crucial component of the preoperative experience and is inversely related to levels of preoperative anxiety. However, resource constraints make face-to-face education sessions untenable, given cost considerations and time investment by trained health personnel. Interventions based on mobile health (mHealth) technologies, geared towards increasing familiarity with surgical procedures and hospital environments have been shown to help patients feel informed about

possible benefits and risks of available treatment options. mHealth apps and Virtual Reality (VR) can offer patients experience in the perioperative environment that can be helpful in empowering patients and enhancing a more positive experience, while reducing stress. However, available applications focus only on providing informative content, neglecting the importance of patient empowerment with a more robust educational curriculum.

According to this, the Software as a Medical Device (SaMD) CARINAE, aims to support patients and caregivers during the whole perioperative process. SaMD CARINAE consists of an mHealth mobile application for patients and caregivers, a Virtual Reality headset for patients, and a web application for healthcare professionals.
Study Results: NO
Conditions: Psychological Stress|Cardiopulmonary Bypass Surgery|Coronary Artery Bypass Surgery|Cardiac Valve Replacement|Hip Replacement|Orthognathic Surgery|Scoliosis|Knee Replacement|Prostate Cancer|Kidney Cancer|Bladder Cancer
Interventions: DEVICE: SaMD CARINAE
Primary Outcome Measures: Visual Analog Scale for Stress, Patient and caregiver-reported visual analog scale question to assess subjective stress.

Along a 100 mm horizontal line, patient and caregiver indicate their perceived stress intensity. Rating varies from 0 (minimum values) to 100 (maximum value). Ratings of 0 to 4 mm can be considered no stress; 5 to 44 mm, mild stress; 45 to 74 mm, moderate stress; and 75 to 100 mm, severe stress., 2 months: from baseline to 14 days after the surgery|Visual Analog Scale for Pain, Patient-reported visual analog scale question to assess subjective pain. Along a 100 mm horizontal line, patient and caregiver indicate their perceived pain intensity. Rating varies from 0 (minimum values) to 100 (maximum value). Ratings of 0 to 4 mm can be considered no pain; 5 to 44 mm, mild pain; 45 to 74 mm, moderate pain; and 75 to 100 mm, severe pain., 2 months: from baseline to 14 days after the surgery|Hospital Anxiety and Depression Scale, Patient-reported questionnaire on anxiety and depression levels during the hospital stay. Hospital Anxiety and Depression Scale is a fourteen-item scale with seven items each for anxiety and depression subscales evaluated on a 0-3 Likert Scale. Rating varies from 0 to 21 and a subscale score \>8 denotes anxiety or depression., 45 days: From hospital admission to 14 days after the surgery|Health-related Quality of Life - EQ-5D-3L/-Y, Patient-reported questionnaire on quality of life. The questionnaire consists of five items related each to one dimension: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems (1), some problems (2), and extreme problems (3). The maximum score of 1 indicates the best health state, by contrast with the scores of individual questions, where higher scores indicate more severe or frequent problems. In addition, there is a visual analogue scale (VAS) to indicate the general health status with 100 indicating the best

health status., 45 days: From hospital admission to 14 days after the surgery|The Positive and Negative Affect Schedule, Patient-reported questionnaire on emotional status. It consists of 20 items that describe n emotions of a positive or negative nature, 10 of them positive and 10 negative. Each item is answered using an Likert-tscale with 5 response options (not at all, very little, somewhat, quite a lot, very much).

Scores can range from 10 - 50, with higher scores representing higher levels of positive or negative affect., 45 days: From hospital admission to 14 days after the surgery|The Short Warwick-Edinburgh Mental Well-Being Scale, Patient- and caregiver-reported questionnaire on mental well-being. It consists of 7 items and each item is answered using a 1-5 Likert scale. Scores range from 7 to 35 and higher scores indicate higher positive mental wellbeing., 2 months: from baseline to 14 days after the surgery|General Self-Efficacy Scale, Patient- and caregiver-reported questionnaire on self-efficacy perception. It consists of 10 items evaluated on a 1-4 Likert scale. Scores range from 10 to 40 amd higher scores indicate higher self-efficacy., 2 months: from baseline to 14 days after the surgery|Patient Activation Measure, Patient-reported questionnaire on the level of activation. It consists of 13 items that have four possible response options ranging from (1) strongly disagree to (4) strongly agree, and an additional "not applicable" option. To calculate the total score, the raw score is divided by the number of items answered (excepting non-applicable items) and multiplied by 13. Then, this score is transformed to a scale with a theoretical range 0-100, based on calibration tables, with higher scores indicating higher patient activation. The raw scores can be converted into four activation levels: 1 (≤47.0) not believing activation important, 2 (47.1-55.1) a lack of knowledge and confidence to take action, 3 (55.2-67.0) beginning to take action and 4 (≥67.1) taking action., 45 days: From baseline to hospital discharge
Secondary Outcome Measures: System Usability Scale, Questionnaire on SaMD CARINAE usability by patients, caregivers and healthcare professionals, 30 days: from hospital admission to 14 days after surgery|Usability questionnaire, Ad-hoc questionnaire for patients and healthcare professional on the digital solution usability, 30 days: from hospital admission to 14 days after surgery|Net Promoter Score, Net Promoter Score (NPS) is a questionnaire that measures patient and healthcare professionals experience and provides the core measurement for customer experience management programs., 30 days: from hospital admission to 14 days after surgery|Reliability, Ad-Hoc questionnaire for the healthcare professional on the digital solution, Day 60
Other Outcome Measures:
Sponsor: Adhera Health, Inc.
Collaborators: Maastricht University Medical Center|Hospital Sant Joan de Deu|Hospital Parc Taulí, Sabadell|Hospital Universitario Reina Sofia de Cordoba|Istituto Nazionale di Ricovero e Cura per Anziani
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT

Phases: NA
Enrollment: 50
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CAR-0320
Start Date: 2022-01-10
Primary Completion Date: 2022-04-30
Completion Date: 2022-05-31
First Posted: 2022-01-11
Results First Posted:
Last Update Posted: 2022-08-01
Locations: Istituto di Ricovero e Cura per Anziani, Ancona, Italy|Maastricht University Medical Center, Maastricht, Netherlands|Hospital Reina Sofía, Córdoba, Andalucía, 14004, Spain|Hospital San Joan de Deu, Esplugues De Llobregat, Catalunya, 08950, Spain|Hospital Parc Taulí, Sabadell, Catalunya, 08208, Spain
Study Documents:

NCT Number: NCT00921492
Study Title: Acupuncture and Gonadotropin-releasing Hormone Pulse Generator and Stress Axis in Polycystic Ovary Syndrome
Study URL: https://beta.clinicaltrials.gov/study/NCT00921492
Acronym: PCOSLFEA
Study Status: COMPLETED
Brief Summary: Hypothesis The overall hypothesis is that non-obese (BMI \<30) women with PCOS have high luteinising hormone (LH) and cortisol pulse frequency and amplitude and that repeated low-frequency EA restore these alterations and induce ovulation.
Study Results: NO
Conditions: Polycystic Ovary Syndrome
Interventions: DEVICE: Low-frequency electro-acupuncture (EA)|OTHER: Meeting a therapist - attention control
Primary Outcome Measures: Frequent blood sampling every 10th minute during an overnight stay in order to measure changes in LH and cortisol pulsatility before and after treatment. A third assessment will be made in those participants who ovulate during the 14 week study., 16 weeks
Secondary Outcome Measures: Ovulation, health related quality of life, 16 weeks
Other Outcome Measures:
Sponsor: Göteborg University
Collaborators:
Sex: FEMALE
Age: ADULT
Phases: NA
Enrollment: 28
Funder Type: OTHER
Study Type: INTERVENTIONAL

Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: PCOSLFEA-17611|2008-72VP-15445-01A|ALFFGBG-10984
Start Date: 2009-02
Primary Completion Date: 2010-12
Completion Date: 2010-12
First Posted: 2009-06-16
Results First Posted:
Last Update Posted: 2018-08-15
Locations: Institute of Neuroscience and Physiology, Sahlgrenska Academy, Göteborg University, Göteborg, 40530, Sweden
Study Documents:

NCT Number: NCT04461392
Study Title: Exercise Response After Revalidation in Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04461392
Acronym:
Study Status: UNKNOWN
Brief Summary: This study regarding oncological patients for rehabilitation after specific cancer therapy involves three aims: (1) to evaluate the predictive value of myocardial work parameters on the improvement of exercise performance after rehabilitation, (2) to determine which echocardiographic parameters are more suitable in predicting cardiac dysfunction, and (3) to evaluate the correlation between echocardiographic parameters and fibrosis detected by cardiac magnetic resonance imaging (CMR).
Study Results: NO
Conditions: Oncology|Cardiac Toxicity
Interventions: DIAGNOSTIC_TEST: Cardiorespiratory exercise test
Primary Outcome Measures: Change in peak volume oxygen - VO2 (L/min), represents the maximum oxygen consumption during incremental exercise that is measured during Cardiopulmonary Exercise test (CPET), being a measure of aerobic capacity of the subject, change from baseline (before rehabilitation) at 15 months (after rehabilitation)|Change in the minute ventilation/carbon dioxide production (VE/VCO2) slope, this parameter shows the increase in ventilation in response to CO2 production, thus it measures the ventilatory efficiency, change from baseline (before rehabilitation) at 15 months (after rehabilitation)|Change in the respiratory exchange ratio (RER), represents the ratio between exhaled CO2 and inhale O2 may quantify the grade of the effort, change from baseline (before rehabilitation) at 15 months (after rehabilitation)
Secondary Outcome Measures: Change in myocardial work (MW), Myocardial work (MW) is a non-invasive, less load-dependent echocardiographic parameter obtained during standard transthoracic echography using the pressure-strain loop data.

This parameter consists of the following measurements: Global constructive work (GCW) Global wasted work (GWW), Global work index (GWI), and Global work efficiency (GWE), change from baseline (before

rehabilitation) at 15 months (after rehabilitation)|Change in health status, Self-assessment of the generic health status using the EQ-5D-5L questionnaire. This questionnaire assesses health status in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, on a five-level scale.

In the evaluation part, the respondents evaluate their overall health status using the visual analogue scale (EQ-VAS) from 0 ('the worst health you can imagine') - 100 ('the best health you can imagine'), change from baseline (before rehabilitation) at 15 months (after rehabilitation)|Major adverse cardiovascular events (MACE), nonfatal stroke, nonfatal myocardial infarction, and cardiovascular death, through study completion, an average of 1 year
Other Outcome Measures:
Sponsor: Universitair Ziekenhuis Brussel
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 191
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: BC032020_1
Start Date: 2020-08
Primary Completion Date: 2021-07
Completion Date: 2022-08
First Posted: 2020-07-08
Results First Posted:
Last Update Posted: 2020-07-08
Locations: Universitair Ziekenhuis Brussel, Jette, 1090, Belgium
Study Documents:

NCT Number: NCT04749212
Study Title: Perioperative Troponin I and NT Pro-BNP in Lung Resection
Study URL: https://beta.clinicaltrials.gov/study/NCT04749212
Acronym:
Study Status: RECRUITING
Brief Summary: After lung resection, troponin elevation may be regulated by mechanisms other than myocardial ischemia. Perioperative natriuretic peptides measurement may help identify changes in ventricular function during thoracic surgery. Integrating both cardiac biomarkers may improve the predictive value for cardiovascular complications after lung resection.
Study Results: NO
Conditions: Cardiac Ischemia|Thoracic Cancer|Complication,Postoperative
Interventions: DIAGNOSTIC_TEST: serum high-sensitivity Troponin I (TnI) and NT-Pro-Brain Natriuretic Peptide (NT-proBNP)

Primary Outcome Measures: NT-proBNP perioperative changes, Perioperative change in NT-Pro-Brain Natriuretic Peptide (NT-proBNP) levels in patients undergoing pulmonary resection. Cutt-of values will be NT-proBNP ≥ 300 pg/ml pg/ml, Change from baseline NT-proBNP at two-days after surgery|TnI perioperative changes, Perioperative changes in high-sensitivity troponin I (TnI) levels in patients undergoing pulmonary resection. Cutt-of values will be TnI ≥45 ng/L, Change from baseline TnI at two-days after surgery|Major cardiovascular complications, Postoperative non-fatal cardiac arrest, acute myocardial infarction, angina, congestive heart failure, new clinically relevant cardiac arrhythmia, cardiovascular death, 30-days after surgery
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Hospital Universitari Vall d'Hebron Research Institute
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 345
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 621/2020
Start Date: 2021-05-19
Primary Completion Date: 2022-12-31
Completion Date: 2023-12-31
First Posted: 2021-02-11
Results First Posted:
Last Update Posted: 2022-09-06
Locations: Hospital Universitari Vall d'Hebron, Barcelona, Spain
Study Documents:

NCT Number: NCT02430012
Study Title: Quality Measurement and Improvement Study of Surgical Coronary Revascularization: Secondary Prevention
Study URL: https://beta.clinicaltrials.gov/study/NCT02430012
Acronym: MISSION-1
Study Status: COMPLETED
Brief Summary: The investigators have identified underuse of secondary prevention medications at discharge of patients underwent coronary artery bypass grafting (CABG) in China. The aim of this study is to develop series of quality improvement strategies focusing on secondary prevention medications for patients underwent CABG, and to evaluate their effectiveness and safety via a hospital-level cluster randomized clinical trial. The investigators established a network of 60 hospitals which have participated into Chinese Cardiovascular Surgery Registry and submitted 50 or more CABG surgeries already. The participating sites will be divided into intervention and control groups in a 1:1 ratio. The intervention group will undertake

intervention of quality improvement strategies, while the control group will maintain the routine practice pattern. All hospitals will consecutively enroll and submit data of CABG during the enrollment period, estimated for 6 months. The prescribing rates of angiotensin converting enzyme inhibitor (ACEI), angiotensin receptor blocker (ARB), beta-blockers, statins and aspirins will be compared between 2 groups.
Study Results: NO
Conditions: Coronary Artery Bypass Grafting|Secondary Preventions
Interventions: BEHAVIORAL: Quality improvement strategies
Primary Outcome Measures: statins use at discharge, Proportion of statins prescription at discharge among eligible patients, 14 days on average (during hospitalization)
Secondary Outcome Measures: ACEI/ARBs use at discharge, Proportion of β-blockers prescription at discharge among eligible patients, 14 days on average (during hospitalization)|β-blockers use at discharge, Proportion of β-blockers prescription at discharge among eligible patients, 14 days on average (during hospitalization)|aspirins use at discharge, Proportion of aspirins prescription at discharge among eligible patients, 14 days on average (during hospitalization)
Other Outcome Measures: education on smoking cessation at discharge, Proportion of education on smoking cessation at discharge among eligible patients, 14 days on average (during hospitalization)|education on glycemic control at discharge, Proportion of education on glycemic control at discharge among eligible patients, 14 days on average (during hospitalization)|education on moderate exercise at discharge, Proportion of education on moderate exercise at discharge among eligible patients, 14 days on average (during hospitalization)|education on weight control at discharge, Proportion of education on weight control at discharge among eligible patients, 14 days on average (during hospitalization)
Sponsor: China National Center for Cardiovascular Diseases
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 10009
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: MOST-2013BAI09B01-2
Start Date: 2015-06
Primary Completion Date: 2016-09-18
Completion Date: 2017-09
First Posted: 2015-04-29
Results First Posted:
Last Update Posted: 2019-03-21
Locations: China National Center for Cardiovascular Diseases, Beijing,

Beijing, 100037, China
Study Documents:

NCT Number: NCT03574012
Study Title: SmART Heart: Study of mHealth Apps to Reduce Cancer-Treatment Effects on the Heart
Study URL: https://beta.clinicaltrials.gov/study/NCT03574012
Acronym:
Study Status: COMPLETED
Brief Summary: This pilot trial studies how well education and mobile health applications work in reducing the effects of cancer treatment on the heart in participants with blood cancers that are in remission. Education and mobile health applications may be effective ways to manage heart health and to reduce future heart disease risk in participants with blood cancers.
Study Results: NO
Conditions: Acute Leukemia in Remission|Hematopoietic Cell Transplantation Recipient|Lymphoma
Interventions: DEVICE: Monitoring Device|OTHER: Informational Intervention|OTHER: Informational Intervention|OTHER: Questionnaire Administration
Primary Outcome Measures: Enrollment rate among participants approached, Up to 1 year|Retention rate among participants enrolled, Retention is defined as completion of patient questionnaire and in-person assessment after 4-month intervention, Up to 1 year|Participation in Facebook group, Number of participants who log onto the group page and participate at least one time (e.g., view a post, post something themselves, respond to a post \[e.g., "like" a post\], etc.), Up to 1 year|Participation in Fitbit physical activity tracking, Number of participants who submit step count data on at least 50% of eligible days, Up to 1 year|Participation in Healthwatch diet tracking, Number of participants who provide dietary data on at least 75% of eligible days, Up to 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Fred Hutchinson Cancer Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT
Phases: NA
Enrollment: 41
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (CARE_PROVIDER, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 10037|NCI-2018-01168|10037|P30CA015704|RG1001769
Start Date: 2018-08-31
Primary Completion Date: 2020-01-22
Completion Date: 2020-06-16

First Posted: 2018-06-29
Results First Posted:
Last Update Posted: 2020-09-10
Locations: Fred Hutch/University of Washington Cancer Consortium, Seattle, Washington, 98109, United States
Study Documents:

NCT Number: NCT03557255
Study Title: Levosimendan for Cardiac Patients Undergoing Major Abdominal Cancer Surgeries
Study URL: https://beta.clinicaltrials.gov/study/NCT03557255
Acronym:
Study Status: COMPLETED
Brief Summary: The objective of this pilot study is to evaluate the efficacy and safety of preoperative administration of levosimendan in patients with chronic heart failure scheduled for major abdominal cancer surgery assuming the reduction of both perioperative morbidity and mortality.
Study Results: NO
Conditions: Heart Failure
Interventions: DRUG: Levosimendan|DRUG: Saline
Primary Outcome Measures: Changes in mechanical ventilation, The total duration of postoperative ventilation in days, Baseline and after two weeks
Secondary Outcome Measures: Changes in Ejection fraction, The improvement in the ejection fraction in percentage., Baseline and after one week postoperative|Changes in cardiac index, The improvement in Cardiac index (Liters/minute/square meter), Baseline and after one week postoperative|Changes in Stroke volume index, The improvement in stroke volume index(milliliters/square meter), Baseline and after one week postoperative|Patient total hospital length of stay, Total hospital length of stay in days., Baseline and after two weeks postoperative
Other Outcome Measures:
Sponsor: National Cancer Institute, Egypt
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: Ehab-Raafat.Levo
Start Date: 2017-08-01
Primary Completion Date: 2018-02-01
Completion Date: 2018-04-23
First Posted: 2018-06-14

Results First Posted:
Last Update Posted: 2018-06-14
Locations: Department of Anesthesia and Pain medicine.National Cancer Institute, Cairo, 11796, Egypt
Study Documents:

NCT Number: NCT00321048
Study Title: Spect Analysis of Cardiac Perfusion Changes After Whole Breast/Chest Wall Radiation Therapy With ABC
Study URL: https://beta.clinicaltrials.gov/study/NCT00321048
Acronym:
Study Status: COMPLETED
Brief Summary: Cardiac perfusion changes have been seen after whole breast / chest wall irradiation for breast cancer. The Active Breathing Coordinator (ABC) device theoretically decreases radiation exposure to the heart during radiation for breast cancer. In this trial cardiac perfusion changes or lack thereof will be quantified in women treated with radiation for breast cancer while using the ABC device. The control group of the study will consist of patients randomized to radiation therapy without the ABC device.
Study Results: YES
Conditions: Breast Neoplasms|Carcinoma, Ductal|Adenocarcinoma
Interventions: DEVICE: Active Breathing Coordinator
Primary Outcome Measures: Efficacy of Active Breathing Coordinator (ABC) Device as Determined by the Mean Apical Perfusion Score, Efficacy of the ABC device in protecting the heart from radiation (XRT) damage in patients with L breast cancer is determined by the change in cardiac perfusion (mean apical perfusion score) as measured by SPECT between baseline and 6 month follow up. A score of 1 represents an equivocal or mild reduction in perfusion, 2 represents moderately reduced perfusion, 3 represents severely reduced perfusion, and 4 indicates absent perfusion., 6 months post-radiation
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
Collaborators: Breast Cancer Research Foundation
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 57
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: J0609|NA_00002394
Start Date: 2006-06
Primary Completion Date: 2010-01
Completion Date: 2010-01
First Posted: 2006-05-03
Results First Posted: 2019-05-24

Last Update Posted: 2019-06-19
Locations: The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, Maryland, 21205, United States
Study Documents:

NCT Number: NCT03089151
Study Title: Denver Garden Environment and Microbiome Study Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT03089151
Acronym: DGEM
Study Status: COMPLETED
Brief Summary: An interdisciplinary team with extensive garden study experience conducted a pilot randomized controlled clinical trial to see whether gardening reduced risk factors for diseases like cancer and heart disease. The pilot trial will provide preliminary data on associations between human microbiome, diet, physical activity, and social interactions and the outcomes of weight status and key inflammatory biomarkers.
Study Results: NO
Conditions: Diet Modification|Physical Activity|Weight Gain|Chronic Disease|Lifestyle, Sedentary|Health Behavior
Interventions: BEHAVIORAL: Community Garden Intervention
Primary Outcome Measures: Change in fruit and vegetable intake from baseline at 20 weeks, 6 24-hour diet recalls will be collected at random, Measurements will occur during weeks 1-2 (3 random recalls) and weeks 18-20 (3 random recalls)|Change in sedentary time behavior from baseline at 20 weeks, Accelerometers will be adhered to thigh and collect data for 7 days, 2 measurements over 6 months, T1 (Week 1) and T6 (Week 20)|Change in bacterial load from baseline at 20 weeks, Microbiome data will be collected six time points using 1 gut, 2 skin, and 1 oral samples, Every 3-4 weeks up to 20 weeks (Week 1, Week 4, Week 7, Week 10, Week 14, Week 18)|Change in moderate-to-vigorous physical activity (MVPA) from baseline at 20 weeks, Accelerometers will be adhered to thigh and collect data for 7 days, 2 measurements over 6 months, T1 (Week 1) and T6 (Week 20)|Change in weight (kg) from baseline at 20 weeks, Objective measurements of weight will be collected, 2 measurements over 6 months, T1 (Week 1) and T6 (Week 20)|Change in waist circumference from baseline at 20 weeks, Objective measurement of waist circumference, 2 measurements over 6 months, T1 (Week 1) and T6 (Week 20)|Change in pathogenic taxa from baseline at 20 weeks, Microbiome data will be derived from 1 gut, 2 skin, and 1 oral samples, Every 3-4 weeks up to 20 weeks (Week 1, Week 4, Week 7, Week 10, Week 14, Week 18)|Change in taxonomic diversity from baseline at 20 weeks, Microbiome data will be derived from 1 gut, 2 skin, and 1 oral samples, Every 3-4 weeks up to 20 weeks (Week 1, Week 4, Week 7, Week 10, Week 14, Week 18)|Change in relative dominance from baseline at 20 weeks, Microbiome data will be derived from 1 gut, 2 skin, and 1 oral samples, Every 3-4 weeks up to 20 weeks (Week 1, Week 4, Week 7, Week 10, Week 14, Week 18)|Change in indicator taxa from baseline at 20 weeks, Microbiome data will be derived from 1 gut, 2 skin, and 1 oral samples, Every 3-4 weeks up to 20 weeks (Week 1, Week 4, Week 7,

Week 10, Week 14, Week 18)|Change in Inflammatory biomarkers from baseline at 20 weeks, Samples include hs-CRP, TNF-alpha, IL1b, IL4, IL6, IL10, 20 weeks
Secondary Outcome Measures: Change in HbA1C from baseline at 20 weeks, 20 weeks|Change in blood pressure from baseline at 20 weeks, 20 weeks|Change in lipid profile from baseline at 20 weeks, Including LDL, HDL, total cholesterol, triglycerides, 20 weeks
Other Outcome Measures:
Sponsor: University of Colorado, Boulder
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 16
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 16-0138, 16-0424
Start Date: 2016-06-02
Primary Completion Date: 2017-12-15
Completion Date: 2017-12-30
First Posted: 2017-03-24
Results First Posted:
Last Update Posted: 2021-05-07
Locations: University of Colorado Boulder, Boulder, Colorado, 80303, United States
Study Documents:

NCT Number: NCT05732051
Study Title: Nicotinamide Riboside and Prevention of Cancer Therapy Related Cardiac Dysfunction in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05732051
Acronym: NARNIA
Study Status: RECRUITING
Brief Summary: Breast cancer is the most common form of cancer in women. Modern breast cancer treatments have led to increased survival, but at the same time, increased risk for cardiotoxicity and development of heart failure. In this study, the investigators want to evaluate whether nicotinamide riboside can prevent cancer-related cardiac dysfunction in metastatic breast cancer patients scheduled for anthracycline therapy. Further, the investigators will evaluate change in signs of skeletal muscle injury and functional capacity.
Study Results: NO
Conditions: Breast Cancer|Metastatic Breast Cancer|Cancer Therapy-Related Cardiac Dysfunction|Cardiotoxicity|Heart Failure
Interventions: DIETARY_SUPPLEMENT: Nicotinamide Riboside|DIETARY_SUPPLEMENT: Placebo
Primary Outcome Measures: Whether the administration of nicotinamide

riboside can prevent the reduction in left ventricular systolic function measured by cardiovascular magnetic resonance (CMR), compared to placebo., Change in left ventricular ejection fraction (LVEF), as determined by CMR from randomization to end of blinded therapy., Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy
Secondary Outcome Measures: Assess whether the administration of nicotinamide riboside is associated with less reduction in left ventricular systolic function measured by echocardiography, From randomization to the end of blinded therapy:

Change in LVEF, as determined by echocardiography, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Assess whether the administration of nicotinamide riboside is associated with less reduction in left ventricular systolic function measured by echocardiography, From randomization to the end of blinded therapy:

Change in left ventricular global longitudinal strain (GLS), as determined by echocardiography, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Assess whether the administration of nicotinamide riboside is associated with less reduction in left ventricular systolic function measured by CMR, From randomization to the end of blinded therapy:

Change in left ventricular global circumferential strain (GCS) and GLS, as determined by CMR, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Assess whether the administration of nicotinamide riboside is associated with less reduction in left ventricular systolic function measured by CMR, From randomization to the end of blinded therapy:

Change in left ventricular end-systolic volume measured by CMR, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|To assess whether the administration of nicotinamide riboside is associated with less myocardial injury measured by high-sensitive cardiac troponin T (hs-cTnT), From randomization to the end of blinded therapy:

Change in circulating hs-cTnT, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|To assess whether the administration of nicotinamide riboside is associated with less myocardial injury measured by high-sensitive cardiac troponin I (hs-cTnI), From randomization to the end of blinded therapy:

Change in circulating hs-cTnI, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|To assess whether the administration of nicotinamide riboside is associated with less worsening in functional capacity, From randomization to the end of blinded therapy:

Change in distance in meters during 6-minute walk test, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|To assess whether the administration of nicotinamide riboside is associated with less worsening in functional capacity, From randomization to the end of blinded therapy:

Change in force generated by handgrip strength test, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy
Other Outcome Measures: Pharmacological endpoint: Change in circulating Nicotinamide adenine dinucleotide (NAD+) concentration from baseline to end of blinded therapy., Changes in the amount of circulating NAD+ will be measured using commercial kits and Liquid chromatography-mass spectrometry analyses (LC-MS analyses), Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less myocardial injury expressed as oedema or fibrosis by CMR, Change in transverse relaxation time (T2) measured by CMR, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less myocardial injury expressed as oedema or fibrosis by CMR, Change in longitudinal relaxation time (T1) measured by CMR, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less myocardial injury expressed as oedema or fibrosis by CMR, Change in T1 rho measured by CMR, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less reduction in left ventricular diastolic function measured by echocardiography, Change in left ventricular diastolic function as measured by echocardiography, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less aortic stiffness measured by CMR, Change in the aortic pulse wave velocity measured by CMR, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less myocardial injury and dysfunction measured by cardiac biomarkers other than troponin, Chance in circulating N-terminal pro b-type natriuretic peptide (NT-proBNP), Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of

chemotherapy|Tertiary objective: Less myocardial injury and dysfunction measured by cardiac biomarkers other than troponin, Chance in circulating cardiac myosin binding protein C (cMyC), Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less skeletal muscle injury, Change in circulating creatine kinase (CK), Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less skeletal muscle injury, Change in circulating myoglobin, Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less worsening in health-related quality of life, Quality of life measured by Chalder Fatigue Scale. Items are rated on a 4-point Likert scale (0 = better than usual, 1 = no more than usual, 2 = worse than usual, 3 = much worse than usual), with higher scores indicating greater fatigue., Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less worsening in health-related quality of life, Quality of life measured by European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30). Range in score from 0 to 100. A high scale score represents a higher response level.

Thus a high score for a functional scale represents a high / healthy level of functioning, a high score for the global health status / Quality of life (QoL) represents a high QoL, but a high score for a symptom scale / item represents a high level of symptomatology / problems., Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy|Tertiary objective: Less worsening in health-related quality of life, Quality of life measured by European Quality of Life 5 Dimensions 5 Level Version (EQ-5D-5L). Each dimension in the EQ-5D-5L has five response levels: no problems (Level 1); slight; moderate; severe; and extreme problems (Level 5). There are 3,125 possible health states defined by combining one level from each dimension, ranging from 11111 (full health) to 55555 (worst health)., Baseline, 3 months, 6 months for patients receiving extended chemotherapy, and extended follow up 12 months after initiation of chemotherapy
Sponsor: University Hospital, Akershus
Collaborators: ChromaDex, Inc.|Norwegian Cancer Society|Norwegian Breast Cancer Association|Helse Sor-Ost
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|

Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 2021/156064(REK)
Start Date: 2023-03-16
Primary Completion Date: 2025-08-01
Completion Date: 2035-09-30
First Posted: 2023-02-16
Results First Posted:
Last Update Posted: 2023-03-17
Locations: Akershus University Hospital, Lørenskog, Akershus, 1478, Norway
Study Documents:

NCT Number: NCT00591851
Study Title: Phase II Study of Dose-Dense Doxurubicin and Cyclophosphamide (AC) Followed By Paclitaxel With Trastuzumab in HER2/NEU-Amplified Breast Cancer: Feasibility
Study URL: https://beta.clinicaltrials.gov/study/NCT00591851
Acronym:
Study Status: COMPLETED
Brief Summary: HER-2/neu (+) breast cancer is a more aggressive form of breast cancer. HER-2/neu is a protein that is overproduced by your tumor. It makes your cancer more aggressive. Standard treatments for this type of cancer will help some people, but there is a moderate to high chance that your cancer may come back.

The purpose of this study is to see if a new regimen will be effective in preventing cancer from coming back. This is a phase II trial. In this trial, patient get a drug regimen that has been tested in small groups of people to see what dose is safe. Researchers now wish to see how effective the drug is for HER-2/neu (+) breast cancer. The objective includes looking at short-term side effects and risks of the drug. All of the drugs on this regimen can affect the heart which can be a serious side effect. The drugs affect on heart function is a primary focus.
Study Results: YES
Conditions: Breast Cancer
Interventions: DRUG: AC [Adriamycin (A) (also known as doxorubicin) and Cyclophosphamide (C)] Followed By Paclitaxel (P)
Primary Outcome Measures: Cardiac Saftey, LVEF by Muga scan, Baseline-18 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators: Amgen|Genentech, Inc.
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 70
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 04-126
Start Date: 2004-12
Primary Completion Date: 2008-06
Completion Date: 2008-06
First Posted: 2008-01-11
Results First Posted: 2014-11-24
Last Update Posted: 2014-12-01
Locations: Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States
Study Documents:

NCT Number: NCT05600751
Study Title: Radiosurgery of Ganglion StELlatum In Patients With REFractory Angina Pectoris
Study URL: https://beta.clinicaltrials.gov/study/NCT05600751
Acronym: RELIEF-AP
Study Status: RECRUITING
Brief Summary: The core hypothesis to be tested is that the radiosurgery of stellate ganglion (left one or both if left-sided without full relief of symptoms) is an effective therapy of refractory angina pectoris in patients with no other therapeutic options - proof of concept study.
Study Results: NO
Conditions: Coronary Artery Disease|Angina Pectoris|Myocardial Ischemia
Interventions: PROCEDURE: Radiosurgery of ganglion stellatum
Primary Outcome Measures: Seattle Angina Questionnaire, The Seattle Angina Questionnaire is a cardiac disease-related quality-of-life measure with 19 items. A lower score corresponds to a lower level of functioning. The scores are classified as "minimal (scores 75-100), mild (50-74), moderate (25-49), and severe (0-24)., 24 months|Safety of radiosurgery of ganglion stellatum, Safety of radiosurgery of ganglion stellatum will be observed and assessed according to the occurrence of adverse events, 24 months
Secondary Outcome Measures: Usage of angina pectoris relief drugs, The change of angina pectoris relief drugs will be evaluated, 24 months|Six-minute walk test improvement, Change in the six-minute walk test will be evaluated before and after the procedure, 24 months
Other Outcome Measures:
Sponsor: University Hospital Ostrava
Collaborators: Nemocnice AGEL Trinec-Podlesi a.s.
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL

Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: RELIEF-AP Trial
Start Date: 2022-01-01
Primary Completion Date: 2024-12
Completion Date: 2024-12
First Posted: 2022-10-31
Results First Posted:
Last Update Posted: 2022-11-03
Locations: University Hospital Ostrava, Ostrava, Moravian-Silesian Region, 70852, Czechia|AGEL Podlesí Hospital Třinec, Třinec, Moravian-Silesian Region, 73961, Czechia
Study Documents:

NCT Number: NCT05198648
Study Title: Trigeminal Nerve Cardiac Reflex During Resection of Cerebellopontine Angle Tumors and Postoperative Myocardial Injury
Study URL: https://beta.clinicaltrials.gov/study/NCT05198648
Acronym:
Study Status: RECRUITING
Brief Summary: Myocardial injury after noncardiac surgery is significantly related to postoperative 30-day mortality. Trigeminal cardiac reflex is one of the main causes of perioperative cardiac emergency. Therefore, the investigators' aim is to test the hypothesis that trigeminal cardiac reflex associates postoperative myocardial damage in participants undergoing cerebellopontine angle tumor surgery. The investigators will observe the association between trigeminal cardiac reflex and myocardial injury by measuring the concentration of plasma high sensitivity cardiac troponin (hs-cTnT) in participants after cerebellopontine angle tumor surgery.
Study Results: NO
Conditions: Myocardial Injury|Trigeminal Cardiac Reflex
Interventions: OTHER: Trigeminal cardiac reflex|OTHER: Non-trigeminal cardiac reflex
Primary Outcome Measures: The incidence of postoperative myocardial injury, the elevation of plasma high sensitivity cardiac troponin I (hs-cTnI) caused by myocardial ischemia or injury (exclude other causes such as sepsis, pulmonary embolism, atrial fibrillation, etc). The blood samples before and within 24 hours after operation will be collected and measured by Roche's fourth generation hs-cTnI. It is commonly defined as an elevation as any value above the 99th percentile upper reference limit for each specific troponin I assay, Postoperative 1 day.
Secondary Outcome Measures: The duration time of trigeminal cardiac reflex during cerebellopontine angle tumor surgery., The duration time of trigeminal cardiac reflex during cerebellopontine angle tumor surgery., The whole cerebellopontine angle tumor surgery procedure.
Other Outcome Measures:
Sponsor: Beijing Tiantan Hospital
Collaborators:

Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 591
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2021-12-12
Start Date: 2022-07-01
Primary Completion Date: 2024-12-31
Completion Date: 2024-12-31
First Posted: 2022-01-20
Results First Posted:
Last Update Posted: 2022-10-05
Locations: Beijing Tian Tan Hospital, Capital Medical University, Beijing, Beijing, 100070, China
Study Documents:

NCT Number: NCT01738451
Study Title: A Study to Evaluate the Effect of Repeat Oral Dosing of GSK2118436 on Cardiac Repolarization in Subjects With V600 BRAF Mutation-Positive Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT01738451
Acronym:
Study Status: COMPLETED
Brief Summary: This is a Phase I, multicenter, 2-part study with Part 1 designed as a safety lead-in and Part 2 designed to evaluate the effect of GSK2118436 on cardiac repolarization (corrected QT interval \[QTc\] duration) as compared with placebo in subjects with V600 BRAF mutation-positive tumors.

Each part of the study will consist of screening (14 days prior to the start of the study treatment), treatment and follow-up period (14 days).

In Part 1 in Cohort 1 six subjects will receive GSK2118436 225 mg twice a day (BID) on study days 1 to 7 and a single 225 milligram (mg) dose on morning of Day 8. Based on the safety data of subjects in Cohort 1 subjects will be enrolled in Cohort 2 and the dose of GSK2118436 will be escalated to 300 mg BID. If the 225 mg dose of GSK2118436 is not well tolerated in Cohort 1 (i.e., 2 or more dose-limiting toxicities \[DLTs\]), then Cohort 2 of Part 1 will not be initiated and a dose of 150 mg BID of GSK2118436 will be administered in Part 2 of the study. In Cohort 2 six subjects will receive GSK2118436 300 mg BID on Study Days 1 to 7 and a single 300 mg dose on the morning of Day 8. Based on the safety data of subjects in Cohort 2 subjects will be enrolled in Part 2. If the 300 mg BID dose level of GSK2118436 is not well tolerated, then the highest tolerated dose will be selected for Part 2 of the study.

In Part 1 of the study the decision to proceed to the next cohort or Part 2 of the study will be based on the safety data of at least 6 evaluable subjects (\<=1 DLTs during the 14 days following the first dose of GSK2118436).

In Part 2 of the study eligible subjects will receive a single dose of GSK2118436/placebo (4 capsules of 75 mg/highest tolerated dose) orally on the first 2 days of the study followed by 2 doses daily for 6 days and a single dose on the 9th day. There will be 1 day when a placebo will be given.

In both the parts of the study serial blood samples for pharmacokinetic (PK) analysis for GSK2118436 and its metabolites (GSK2285403, GSK2298683 and GSK2167542) will be obtained at the same time points on the first and last day of dosing (2nd day of dosing also included for Part 2). Safety electrocardiogram (ECG)s will be performed at several timepoints during the study. In Part 2 Holter ECG monitoring will be performed for 24 hours on the 1st, 2nd and 9th days of dosing.
Study Results: NO
Conditions: Cancer
Interventions: DRUG: GSK2118436 75 mg|DRUG: Placebo
Primary Outcome Measures: Part 1: Safety and tolerability of GSK2118436 as assessed by changes in physical examination findings, Safety and tolerability parameter will include a complete (head, eyes, ears, nose, throat, skin, thyroid, neurological, lungs, cardiovascular, abdomen \[liver and spleen\], lymph nodes, extremities, height and weight) and brief (skin, lungs, cardiovascular system, abdomen \[liver and spleen\] and weight) physical examination at Baseline and at the end of Part 1 of the study., Screening, Day 1 and Week 6.|Part 1: Safety and tolerability of GSK2118436 as assessed by changes in vital signs measurements, Safety and tolerability parameter will include measurement of vital signs (recording of systolic and diastolic blood pressure, temperature, and pulse rate) at Baseline and at the end of Part 1 of the study., Screening, pre-dose and 8 hours post-dose on Study Day 1, 8, 15, and Week 6.|Part 1: Safety and tolerability of GSK2118436 as assessed by changes in ECG readings, Safety and tolerability parameter will include ECGs readings (heart rate and measurement of RR, PR, QRS, QT, and QTc intervals) at Baseline and at the end of Part 1 of the study., Screening, Day 1, 8 Day 15 and Week 6. On study days 1 and 8, ECG will be obtained at 30 minutes pre-dose and 2-hours (hrs) post-dose administration.|Part 1: Safety and tolerability of GSK2118436 as assessed by changes in clinical laboratory assessments, Safety and tolerability parameter will include laboratory values (hematology, clinical chemistry, coagulation, liver function tests, cardiac enzyme and beta-hCG/serum or urine pregnancy test for female subjects of childbearing potential only) at Baseline and at end of Part 1 of the study., Day 1, 8, 15 and and Week 6.|Part 2: Change from Baseline in QTcF interval at each time point for GSK2118436, Change from Baseline in QTcF interval at each

time point for GSK2118436 will be calculated as average of 3 Holter ECG replicates per time point minus the value at Baseline., Baseline (Study Day -1)/pre-dose (Study Days 1 and 8) (within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24-hrs post-dose. Day 2 and 9, 24 hr post dose Holter ECG. Secondary Outcome Measures: Part 1: Plasma concentration of GSK2118436 and its metabolites, Plasma concentrations of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542 will be recorded., On Day 1 and Day 8 at pre-dose (30 minutes (mins) prior to the administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, and 10-hours post-dose.|Part 1: The AUC(0-t)) of GSK2118436 and its metabolites, Pharmacokinetic data will include area under the time-concentration curve from time zero (pre-dose) to last time of quantifiable concentration (AUC(0-t)) of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542., On Day 1 and Day 8 at pre-dose (30 mins prior to the administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, and 10-hours post-dose.|Part 1: The Cmax of GSK2118436 and its metabolites, Pharmacokinetic data will include maximum plasma concentration (Cmax) of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542., Part 1: Day 1 and Day 8 pre-dose (30 mins prior to the administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, and 10-hours post-dose.|The Ctrough of GSK2118436 and its metabolites, Pharmacokinetic data will include predose concentration (Ctrough) of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542., Part 1: Day 8 pre-dose (30 mins prior to the administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, and 10-hours post-dose.|The tmax of GSK2118436 and its metabolites, Pharmacokinetic data will include time of occurrence of Cmax (tmax) of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542., Part 1: Day 1 and Day 8 pre-dose (30 mins prior to the administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, and 10-hours post-dose.|Part 2: Change from Baseline in slope of the relationships between the baseline-adjusted, placebo-corrected change in QTc interval and the plasma concentrations of GSK2118436 or its metabolites and predicted change in QTc, The relationship between plasma concentrations of GSK2118436 and its metabolites (GSK2285403, GSK2298683 and GSK2167542) and the baseline-adjusted, placebo-corrected, time-matched change from Baseline in QTc intervals will be assessed., Part 2: Baseline (pre-dose study Days 1 and 8 within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24-hrs post-dose (Day 1 and 8). On Day 2 and 9, 24-hr post-dose PK sample and Holter ECG.|Part 2: ECG parameters: and morphology assessments, ECG parameters: QT, QTcB, QTci, HR, RR interval, PR interval, QRS interval and morphology will be assessed in subjects receiving GSK2118436., Part 2: Baseline (pre-dose study Days 1 and 8 within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24-hrs post-dose (Day 1 and 8). On Day 2 and 9, 24-hr post dose Holter ECG.|Part 2: Plasma concentrations of GSK2118436 and its metabolites, The plasma concentration of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542

will be measured., On Days -1, 1 and 8 at pre-dose (within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hrs post-dose (Day 1 and 8). On Days 2 and 9 at 24-hr post dose PK sample.|The AUC(0-10) and AUC(0 t) of GSK2118436 and its metabolites (GSK2285403, GSK2298683 and GSK2167542), Pharmacokinetic data will include AUC from time zero (pre-dose) to 10 hours after the last dose of study treatment (AUC(0-10)) and AUC(0 t) of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542., Part 2: Days -1, 1 and 8: pre-dose (within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hrs post-dose (Day 1 and 8). On Day 2 and 9, 24-hr post dose PK sample.|The AUC(0-infinity) of GSK2118436 and its metabolites (GSK2285403, GSK2298683 and GSK2167542), Pharmacokinetic data will include AUC from time zero to infinity AUC(0-infinity) of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542 on Study Day 1, if data permit)., Part 2: Day 1: pre-dose (within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hrs post-dose (Day 1).|The $t_{\frac{1}{2}}$ of GSK2167542 and its metabolites, Pharmacokinetic data will include elimination half life (t1/2) of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542 if data permits., Part 2: Study Day 1 pre-dose (within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hrs post-dose.|Part 2: The Ctrough of GSK2167542 and its metabolites, Pharmacokinetic data will include C trough of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542., Part 2: Study Day 8 pre-dose (within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hrs post-dose.| Part 2: The Cmax, of GSK2167542 and its metabolites, Pharmacokinetic data will include Cmax of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542., Days -1, 1 and 8: pre-dose (within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hrs post-dose (Day 1 and 8). On Day 2 and 9, 24-hr post dose PK sample.|Part 2: The tmax, of GSK2167542 and its metabolites, Pharmacokinetic data will include tmax of GSK2118436 and its metabolites GSK2285403, GSK2298683 and GSK2167542., Days -1, 1 and 8: pre-dose (within 30 minutes prior to administration of study treatment) and 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hrs post-dose (Day 1 and 8). On Day 2 and 9, 24-hr post dose PK sample.|Part 2: Safety of GSK2118436 as assessed by number of subjects with adverse events (AE)s, Safety parameters will include recording of AEs, in Part 2 of the study., Continuous throughout the study.|Part 2: Safety of GSK2118436 as assessed by changes in vital signs measurements, Safety parameters will include measurement of vital signs (recording of systolic and diastolic blood pressure, temperature, and pulse rate) at Baseline and at the end of Part 2 of the study., Screening, Day -1, Day 1, Day 8, Day 9 and Week 5.|Part 2: Safety of GSK2118436 as assessed by changes in ECG readings, Safety parameters will include ECGs readings (heart rate and measurement of RR, PR, QRS, QT, and QTc intervals) at Baseline and at the end of Part 2 of the study., Screening, Day -1, Day 1, Day 2, Day 8, Day 9 and Week 5.|Part 2:

Safety of GSK2118436 as assessed by changes in clinical laboratory assessments, Safety parameters will include laboratory values (hematology, clinical chemistry, coagulation, liver function tests, cardiac enzyme and beta-hCG/serum or urine pregnancy test for female subjects of childbearing potential only) at Baseline and at end of Part 2 of the study., Screening, Day -1, Day 1, Day 8, Day 9 and Week 5.
Other Outcome Measures:
Sponsor: GlaxoSmithKline
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 50
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 113773
Start Date: 2013-01-22
Primary Completion Date: 2014-11-28
Completion Date: 2014-11-28
First Posted: 2012-11-30
Results First Posted:
Last Update Posted: 2017-11-13
Locations: GSK Investigational Site, Scottsdale, Arizona, 85259, United States|GSK Investigational Site, Memphis, Tennessee, 38120, United States|GSK Investigational Site, Nashville, Tennessee, 37203, United States|GSK Investigational Site, San Antonio, Texas, 78229, United States|GSK Investigational Site, Salt Lake City, Utah, 84112-5550, United States|GSK Investigational Site, Heidelberg, Victoria, 3084, Australia|GSK Investigational Site, Melbourne, Victoria, 3004, Australia|GSK Investigational Site, London, W1G 6AD, United Kingdom
Study Documents:

NCT Number: NCT00885612
Study Title: 10 Year Coronary Heart Disease (CHD) Risk Evaluation and Its Treatment Pattern Analysis in Postmenopausal Early Breast Cancer (EBC) Patients Taking Aromatase Inhibitors (AI)
Study URL: https://beta.clinicaltrials.gov/study/NCT00885612
Acronym:
Study Status: COMPLETED
Brief Summary: 10-year CHD risk evaluation and its treatment pattern analysis in postmenopausal early breast cancer patients taking aromatase inhibitors.
Study Results: NO
Conditions: Breast Cancer
Interventions:
Primary Outcome Measures: The primary objective of this study is to

define 10-year CHD risk according to Framingham risk score in postmenopausal early breast cancer patients who are taking aromatase inhibitors as an adjuvant treatment., 1 visit
Secondary Outcome Measures: To describe 10-year CHD risk comparing to the historical data of 10-year cancer-specific mortality in breast cancer, 1 Visit|To analyse CHD management patterns according to defined 10-year CHD risk categories, 1 Visit|To describe correlation between concommitant medication(Anthracycline, Trasuzumab) and CHD risk, 1 Visit
Other Outcome Measures:
Sponsor: AstraZeneca
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1114
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NIS-OKR-DUM-2009/1
Start Date: 2009-05
Primary Completion Date: 2010-03
Completion Date: 2010-03
First Posted: 2009-04-22
Results First Posted:
Last Update Posted: 2010-06-29
Locations: Research Site, Cheonan, Chungcheongnam-do, Korea, Republic of|Research Site, Chuncheon, Gangwon-do, Korea, Republic of|Research Site, Goyang-si, Gyeonggi-do, Korea, Republic of|Research Site, Seongnam-si, Gyeonggi-do, Korea, Republic of|Research Site, Pohang, Gyeongsangbuk-do, Korea, Republic of|Research Site, Masan-si, Gyeongsangnam-do, Korea, Republic of|Research Site, Anyang, Korea, Republic of|Research Site, Busan, Korea, Republic of|Research Site, Chunan, Korea, Republic of|Research Site, DaeGu, Korea, Republic of|Research Site, Daejeon, Korea, Republic of|Research Site, Daejon, Korea, Republic of|Research Site, GuangJu, Korea, Republic of|Research Site, Gwangju, Korea, Republic of|Research Site, Incheon, Korea, Republic of|Research Site, Inchon, Korea, Republic of|Research Site, Jeonju, Korea, Republic of|Research Site, Kangnung, Korea, Republic of|Research Site, Koyang, Korea, Republic of|Research Site, Kyunggi, Korea, Republic of|Research Site, Pusan, Korea, Republic of|Research Site, Seoul(Kangbuk), Korea, Republic of|Research Site, Seoul(Kangdong), Korea, Republic of|Research Site, Seoul(Kangnam), Korea, Republic of|Research Site, Seoul(Yeouido), Korea, Republic of|Research Site, Seoul, Korea, Republic of|Research Site, Suwon, Korea, Republic of|Research Site, Ulsan, Korea, Republic of
Study Documents:

NCT Number: NCT04636255
Study Title: Physical Capacity in Hodgkin Lymphoma Survivors

Study URL: https://beta.clinicaltrials.gov/study/NCT04636255
Acronym:
Study Status: RECRUITING
Brief Summary: The study aims to investigate if physical capacity obtained in the cardiopulmonary exercise test can predict cardiovascular alterations in Hodgkin Lymphoma (HL) Survivors. In addition, to study the effects of exercise training on physical capacity and cardiovascular responses in these patients.
Study Results: NO
Conditions: Hodgkin Lymphoma, Adult|Cardiovascular Diseases|Radiation Effect|Chemotherapy Effect
Interventions: PROCEDURE: Physical Characteristics|DIAGNOSTIC_TEST: Assessment of Heart rate variability|DIAGNOSTIC_TEST: Blood Pressure and Cardiac Autonomic Control|DIAGNOSTIC_TEST: Evaluation of Baroreflex Control|DIAGNOSTIC_TEST: Cardiac Function and Structure|DIAGNOSTIC_TEST: Assessment of Coronary Anatomy and Calcium Score|DIAGNOSTIC_TEST: Blood Assessments|DIAGNOSTIC_TEST: Physical Capacity|PROCEDURE: Physical Training
Primary Outcome Measures: Physical Capacity - Peak oxygen consumption (mL/kg/min), Oxygen consuption in crescent effort will be calculated by aggregation of volume (mL), body weight (Kg) and time (minutes)., 4 months
Secondary Outcome Measures: Heart Hate (beat/min), Post-exercise heart rate will be evaluated by the number of beats in time masurement (one minute)., 4 months|Cardiac Function - Ejection Fraction, Ejection Fraction (EF=ESV-EDV/EDV) combines end systolic (ESV) and diastolic volumes (EDV)(mL), 4 months
Other Outcome Measures:
Sponsor: University of Sao Paulo General Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: FACTORIAL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 432715154
Start Date: 2017-10-21
Primary Completion Date: 2022-10-21
Completion Date: 2023-10-21
First Posted: 2020-11-19
Results First Posted:
Last Update Posted: 2023-05-10
Locations: Luciana de Souza Santos, Sao Paulo, SP, 05403-900, Brazil
Study Documents:

NCT Number: NCT02309255
Study Title: The NOR-COR Study for Coronary Prevention

Study URL: https://beta.clinicaltrials.gov/study/NCT02309255
Acronym:
Study Status: COMPLETED
Brief Summary: The NOR-COR study is a cross-sectional, observational study designed to explore a large number of cardiovascular, inflammatory, genetic, behavioral, and psychosocial factors (including anxiety, depression, quality of life) in 1369 patients with established coronary heart disease (CHD) hospitalized in the Sections for Cardiology at the hospitals in Drammen (n=722) and Vestfold (n=647). Study data from an extensive questionnaire, clinical and laboratory data, and sputum/saliva for genetic analyses will be collected.

The main overall aim of the NOR-COR study is to develop new strategies to improve secondary prevention for underserved high risk patient-groups with CHD. The first study phase aims to collect information necessary to develop empirically based future secondary coronary prevention interventions. In a genetic sub-project markers associated with CHD and personality type will be explored.

The study will evaluate current secondary preventive programs and explore the mechanisms that link behavioral, psychosocial, inflammatory, and genetic factors to poor prognosis. The study will in short term provide new knowledge potentially useful for increasing participation in current cardiac rehabilitation/secondary preventive programs. For a longer perspective these associations may be useful for design of new intervention programs to selected high risk patient groups whom may be in need of programs with different content and/or of longer duration than those currently being applied.
Study Results: NO
Conditions: Secondary Coronary Prevention
Interventions: OTHER: no intervention
Primary Outcome Measures: Cardiovascular risk factors, lifestyle, and drug adherence, Within 2 years after study inclusion
Secondary Outcome Measures: Readmission with a coronary event, acute myocardial infarctrion and cardiovascular mortality, Within 5 years after study inclusion
Other Outcome Measures: The hospital anxiety and depression scale (HADS), Within 2 years after study inclusion
Sponsor: Vestre Viken Hospital Trust
Collaborators: The Hospital of Vestfold|Oslo University Hospital|Kalmar County Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 975
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NOR-COR REK ID 2013/1885

Start Date: 2014-02
Primary Completion Date: 2015-04
Completion Date: 2015-04
First Posted: 2014-12-05
Results First Posted:
Last Update Posted: 2015-06-15
Locations: Vestre Viken HF, Drammen Hospital and The Hospital of Vestfold, Drammen and Tønsberg, Buskerud and Vestfold, N-3004, Norway
Study Documents:

NCT Number: NCT01848912
Study Title: Temperature, Heart and Respiratory Rate Investigation Along With Variability Evaluation and Serum Biomarkers (THRRIVES)
Study URL: https://beta.clinicaltrials.gov/study/NCT01848912
Acronym: THRRIVES
Study Status: COMPLETED
Brief Summary: The purpose of this study is to find a way of detecting infection earlier in patients receiving bone marrow transplant. This is accomplished by continuous individualized monitoring of heart rate, respiratory rate and temperature variability in this patient population. The investigators are collecting data to determine whether or not subtle differences in heart rate, respiratory rate and temperature will help physicians to detect infection earlier in order to begin faster treatment before a patient's condition deteriorates. Blood tests will also be performed to check for certain biomarkers that may indicate infection
Study Results: NO
Conditions: Cancer
Interventions: DEVICE: Zephyr Biopatch Device
Primary Outcome Measures: Initiation or broadening of antibiotic for the purpose of treatment of infection, Patients are monitored for a period of up to 10 days or until their white blood cell count goes up, which could take an expected average of 20 days
Secondary Outcome Measures: Admission to ICU with organ failure or hospital, Patients are monitored for a period of up to 10 days or until their white blood cell count goes up, which could take an expected average of 20 days
Other Outcome Measures:
Sponsor: Ottawa Hospital Research Institute
Collaborators: The Ottawa Hospital Academic Medical Association
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 86
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 20120564-01H
Start Date: 2013-03
Primary Completion Date: 2022-05

Completion Date: 2022-05
First Posted: 2013-05-08
Results First Posted:
Last Update Posted: 2022-11-21
Locations: Bone Marrow Transplant Clinic,The Ottawa Hospital, General Campus, Ottawa, Ontario, Canada
Study Documents:

NCT Number: NCT02505412
Study Title: Subtle Myocardial Deformation Abnormalities in Asymptomatic Nf-1 Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02505412
Acronym:
Study Status: UNKNOWN
Brief Summary: Subtle myocardial deformation abnormalities in asymptomatic nf-1 patients: is cardiac screening needed?
Study Results: NO
Conditions: Neurofibromatosis Type 1
Interventions:
Primary Outcome Measures: myocardial deformation indices as measured in percentage (change of original length), up to 2 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Tel-Aviv Sourasky Medical Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 50
Funder Type: OTHER_GOV
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: TLV-0212-15
Start Date: 2015-10
Primary Completion Date: 2017-12
Completion Date: 2018-12
First Posted: 2015-07-22
Results First Posted:
Last Update Posted: 2015-07-22
Locations:
Study Documents:

NCT Number: NCT04508855
Study Title: Management of Atrial Fibrillation in Patients With Cancer (MAFIC Study)
Study URL: https://beta.clinicaltrials.gov/study/NCT04508855
Acronym: MAFIC
Study Status: RECRUITING
Brief Summary: The primary objective is to assess the safety and efficacy of switching from direct oral anticoagulants to low molecular

weight heparin in cancer patients during antineoplastic therapy
Study Results: NO
Conditions: Cancer|Atrial Fibrillation
Interventions: DRUG: Low molecular weight heparin
Primary Outcome Measures: Major bleeding, Death or a decrease in hemoglobin level of ≥ 2 g/dL over 24 hours or the need for transfusion of ≥ 2 units of packed red cells or clinically overt bleeding at critical site (eg, intracranial, retroperitoneal), 6 months|Clinical relevant bleeding, Bleeding that does not meet the criteria for major bleeding, however, it requires medical treatment or it affects the patient's daily activity, 6 months
Secondary Outcome Measures: Deep vein thrombosis or pulmonary embolism, t The first episode of symptomatic, documented deep vein thrombosis or pulmonary embolism, 6 months|Thromboembolic stroke or systemic embolism, The first episode of symptomatic, documented thromboembolic stroke or systemic embolism, 6 months
Other Outcome Measures:
Sponsor: AHEPA University Hospital
Collaborators: Theagenio Cancer Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 240
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: MAFIC_2020
Start Date: 2020-08-01
Primary Completion Date: 2023-08
Completion Date: 2023-12
First Posted: 2020-08-11
Results First Posted:
Last Update Posted: 2022-02-15
Locations: AHEPA University Hospital, Thessaloniki, 54636, Greece| Theagenio Cancer Hospital, Thessaloniki, Greece
Study Documents:

NCT Number: NCT02605512
Study Title: BreAst Cancer and Cardiotoxicity Induced by RAdioTherapy: the BACCARAT Study
Study URL: https://beta.clinicaltrials.gov/study/NCT02605512
Acronym: BACCARAT
Study Status: UNKNOWN
Brief Summary: Breast radiotherapy RT used until the 1990s was clearly responsible for increased mortality due to long term cardiac complications. Since the 2000s, improvements have appeared in dose distributions to organ at risks such as heart, but now, little is known on the risk of potential cardiac impairment in this population, in particular for chemotherapy naive patients. Based on the state that clinically detectable cardiotoxicity is generally preceded by

subclinical cardiac dysfunctions, the aim of the BACCARAT study (BreAst Cancer and Cardiotoxicity induced by RAdioTherapy) is to evaluate whether adjuvant 3DCRT induces cardiac toxicity that could be detected in the first two years after treatment based on a global approach with repeated analysis of subclinical functional and anatomical cardiac lesions in myocardial and coronary levels and circulating biomarkers.
Study Results: NO
Conditions: Breast Cancer|Cardiac Toxicity
Interventions: OTHER: Subclinical cardiac lesions and biomarkers
Primary Outcome Measures: Number of patients with decreased myocardial function assessed by echocardiography, Number of patients with a decrease in the mean strain or strain rate measured from the echocardiography of the order of 5% between the measurement before RT and 24 months after RT, 2 years after 3DCRT (baseline measures performed before radiotherapy)|Number of patients with increased coronary plaques assessed by CT coronary angiography, Number of patients with an increase of the average index of coronary plaques measured from the CT coronary angiography in the order of 15% between the measurements before RT and 24 months after RT, 2 years after 3DCRT (baseline measures performed before radiotherapy)
Secondary Outcome Measures: Decrease in the strain or strain rate, 6 months after 3DCRTand 2 years after 3DCRT (baseline measures performed before radiotherapy)|Modification in series of circulating biomarkers of cardiac lesions, Classical biomarkers of cardiac injury: C-reactive protein, Troponin I, B-type natriuretic peptide (NT-Pro BNP), beta2-Microglobulin, Galectin 3 / Inflammatory cytokines: Interleukin 6, Interleukin 8, Interleukin 18, TNF-α / Endothelial activation and dysfunction: sVCAM,-1 , s-ICAM-1, E-selectin, P-selectin , vWF, PAI-1, Fibrinogen , Thrombomodulin, TGF-β1 / Microparticles: CD14, CD31, CD41, CD3, CD235a / microRNAs : miR-1, miR-133, miR-208, miR-499, miR-126, miR-130, miR-145, miR-181, miR-150, miR-155, miR-223, miR-17, miR-18, miR-22, miR-34, miR-92, miR-140, miR-182, miR-199, miR-423, miR-590, 5 weeks after initiation of 3DCRT (corresponding to the end of 3DCRT sessions), 6 months after 3DCRTand 2 years after 3DCRT (baseline measures performed before radiotherapy)|Correlation between the absorbed radiation dose by the whole heart and different structures of the heart and measurements of strain and strain rate and indices of coronary plaques, 2 years
Other Outcome Measures:
Sponsor: Sophie JACOB
Collaborators: Institut de Radioprotection et de Surete Nucleaire|Clinique Pasteur|Institut National de la Santé Et de la Recherche Médicale, France
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL

Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING
Other IDs: IRSN_2015-A00990-49
Start Date: 2015-10
Primary Completion Date: 2019-09
Completion Date: 2020-09
First Posted: 2015-11-16
Results First Posted:
Last Update Posted: 2018-06-19
Locations: Clinique Pasteur, Toulouse, 31300, France
Study Documents:

NCT Number: NCT00162955
Study Title: Prevention of CHOP-induced Chronic Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT00162955
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to assess the protective effect of Valsartan on chronic cardiotoxicity induced by CHOP.
Study Results: NO
Conditions: Non-Hodgkin's Lymphoma
Interventions: DRUG: Valsartan
Primary Outcome Measures: Cardiac Event after 3rd and 6th course of CHOP(-R), Basically 14-21 (at a maximum 28) days after the start of 3rd and 6th course of CHOP(-R).
Secondary Outcome Measures: Changes of ECG, UCG and serum markers after 3 and 6 courses of CHOP (-R), 14-21 (at a maximum 28) days after the start of 3rd and 6th course of CHOP(-R).
Other Outcome Measures:
Sponsor: Osaka City University
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 150
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: OLSG-0401
Start Date: 2004-05
Primary Completion Date: 2010-09
Completion Date: 2010-09
First Posted: 2005-09-13
Results First Posted:
Last Update Posted: 2012-05-08
Locations: Graduate School of Medicine, Osaka City University, Osaka, 545-8585, Japan
Study Documents:

NCT Number: NCT05309655
Study Title: Cardiac Outcomes With Near-Complete Estrogen Deprivation
Study URL: https://beta.clinicaltrials.gov/study/NCT05309655
Acronym: CROWN
Study Status: RECRUITING
Brief Summary: The purpose of this research study is to understand what effect near complete estrogen deprivation (NCED) therapy has on the heart in breast cancer patients. Investigators want to understand if NCED changes how the heart works.
Study Results: NO
Conditions: Breast Cancer|Triple Negative Breast Cancer|Cardiovascular Complications
Interventions: DRUG: Adenosine Stress Cardiac Magnetic Resonance Imaging|DIAGNOSTIC_TEST: Electrocardiogram|DIAGNOSTIC_TEST: Computed Tomography Angiogram|OTHER: Laboratory Testing|BEHAVIORAL: Quality of Life Survey
Primary Outcome Measures: Change in Myocardial Blood Flow - 24 months, Change in myocardial blood flow will be measured by adenosine CMR imaging. Comparisons will be made using longitudinal mixed models to examine within- and between- group effects on outcomes measured. These mixed models will include fixed effects for group (NCED/TNBC), baseline assessment of the outcome of interest (i.e. MPR) to adjust for potential risk-factor profile differences between groups and the time point at which the measurements are made relative to the baseline assessment., At baseline and at 24 months
Secondary Outcome Measures: Change in Myocardial Blood Flow - 12 months, Change in myocardial blood flow will be measured by adenosine CMR imaging. Comparisons will be made using longitudinal mixed models to examine within- and between- group effects on outcomes measured. These mixed models will include fixed effects for group (NCED/TNBC), baseline assessment of the outcome of interest (i.e. MPR) to adjust for potential risk-factor profile differences between groups and the time point at which the measurements are made relative to the baseline assessment, At baseline and at 12 months|Change in Stiffness - Thoracic Pulse Wave Velocity, Stiffness will be assessed by thoracic pulse wave velocity (PWV) and distensibility using CMR imaging. Comparisons will be made using longitudinal mixed models to examine within- and between- group effects on outcomes measured. These mixed models will include fixed effects for group (NCED/TNBC), baseline assessment of the outcome of interest (i.e. MPR) to adjust for potential risk-factor profile differences between groups and the time point at which the measurements are made relative to the baseline assessment, At 12 months and at 24 months|Change in Myocardial Perfusion Reserves, Myocardial perfusion reserve will be measured with adenosine CMR imaging. Myocardial perfusion reserve is calculated as the percent change in myocardial blood flow between stress and rest perfusion imaging. Comparisons will be made using longitudinal mixed models to examine within- and between- group effects on outcomes measured. These mixed models will include fixed effects for group (NCED/TNBC), baseline assessment of the outcome of interest (i.e. MPR)

to adjust for potential risk-factor profile differences between groups and the time point at which the measurements are made relative to the baseline assessment, At 12 months and at 24 months|Number of Women at High Risk for Developing Deficits in Myocardial Blood Flow, The predictive models developed to identify premenopausal women treated with an aromatase inhibitor for high-risk hormone receptor-positive breast cancer at highest risk for developing deficits in myocardial blood flow will incorporate variables related to demographics, medical history, and additional clinical variables., At 24 months|Overall Survival, Disease outcomes will be monitored, including invasive-breast cancer free survival, at the annual visits throughout the study. With any change in anti-cancer therapy the specific reason for the change will be requested., Up to 5 years|Difference in Stress CMR Myocardial Blood Flow, Total coronary plaque burden from coronary computed tomography angiography will be measured to assess the difference in heart function, including cardiac volumes and mass and blood flow in both groups., At baseline and at 24 months
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators: National Cancer Institute (NCI)
Sex: FEMALE
Age: ADULT
Phases: EARLY_PHASE1
Enrollment: 90
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: IRB00083573|WFBCCC 98122|P30CA012197
Start Date: 2022-09-02
Primary Completion Date: 2024-12
Completion Date: 2027-12
First Posted: 2022-04-04
Results First Posted:
Last Update Posted: 2023-04-06
Locations: Duke Cancer Center, Durham, North Carolina, 27710, United States|Wake Forest Baptist Comprehensive Cancer Center, Winston-Salem, North Carolina, 27157, United States|Virginia Commonwealth University Massey Cancer Center, Richmond, Virginia, 23298, United States
Study Documents:

NCT Number: NCT02622412
Study Title: Evaluation of a Multi-professional Breathlessness Service for Patients With Breathlessness Due to Any Advanced Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT02622412
Acronym: BreathEase
Study Status: COMPLETED
Brief Summary: Breathlessness is a common and distressing symptom in patients with advanced diseases like cancer, chronic obstructive pulmonary disease (COPD), chronic heart failure (CHF) or lung

fibrosis, which broadly impacts on patients' quality of life and may result in high burden for carers.

This single-blinded randomized controlled fast track trial evaluates the effectiveness of a multi-professional breathlessness service in patients with advanced and chronic diseases. The intervention group will get immediate access to the breathlessness service whereas the control group will receive standard care and get access to the service after a waiting time of eight weeks. Primary endpoints are mastery of breathlessness and quality of life, measured with the CRQ (Chronic Respiratory Questionnaire) as well as the reduction of symptom burden of patients and burden of carers. The evaluation of the cost effectiveness of the breathlessness service from the perspective of the German health system is a further study aim.
Study Results: NO
Conditions: Breathlessness|COPD|Cancer|Chronic Heart Failure|Interstitial Lung Disease
Interventions: OTHER: Multi-professional breathlessness service (MBS)|OTHER: Delayed MBS Intervention
Primary Outcome Measures: Mastery of breathlessness (CRQ mastery subscale), Change from baseline in Mastery of breathlessness (at week 8) measured with the Chronic Respiratory Disease Questionnaire (CRQ) in a face-to-face interview. Mastery represents one of the four CRQ domains containing 4 items. Patients rate their experience on each item a 7-point scale ranging from 1 (maximum impairment) to 7 (no impairment). The subscale "Mastery" is calculated by averaging the scores of the 4 items belonging to this subscale., From Baseline to Follow-Up (0, 8, 16, 28 weeks)|Quality of Life (CRQ), Change from baseline in Quality of Life (at week 8) measured with the CRQ. The CRQ contains 20 items across four domains: dyspnea, fatigue, emotional function, and mastery. Quality of life is calculated by adding all responses to all 20 items. Patients rate their experience on each item a 7-point scale ranging from 1 (maximum impairment) to 7 (no impairment), From Baseline to Follow-Up (0, 8, 16, 28 weeks)|Symptom Burden (IPOS), Change from baseline in palliative care needs and specific symptoms (at week 8) assessed with the Integrated Palliative Care Outcome Scale (IPOS). The IPOS includes 10 symptoms and 7 questions on patients and carers emotional situation, spiritual concerns, and provision of information and support. The overall profile score is the sum of the scores from each of the 17 questions., From Baseline to Follow-Up (0, 8, 16, 28 weeks)|Carers' burden of disease (ZBI), Change from baseline in carers' burden (at week 8) assessed with the Zarit Burden Inventory (ZBI), measuring personal strain and role strain. The revised version contains 22 items. Each item is a statement which the carer is asked to endorse using a 5-point scale. Response options range from 0 (never) to 4 (nearly always)., From Baseline to End of Intervention (0, 8, 16 weeks)
Secondary Outcome Measures: Breathlessness severity (NRS), Change from baseline in breathlessness severity (at week 8) measured with numerical rating scales (NRS). The NRS will be used to assess

breathlessness over the last 24 hours on average,at rest and on exercise. Responses on a rating scale range from 1 (no breathlessness) to 10 (strongest imaginable breathlessness)., From Baseline to Follow-Up (0, 8, 16, 28 weeks)|Generic health-related quality of life (EQ-5D-5L), Change from baseline in patients' generic health-related quality of life measured with the EuroQoL Group 5-Dimension 5-Level Self Report Questionnaire (EQ-5D-5L). The EQ-5D-5L essentially consists of 2 pages - the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The visual analogue scale of the EQ-5D-5L questionnaire ranges from 0 to 100 (with 0 representing the worst health the patient can imagine and 100 representing the best health the patient can imagine). Value sets of the EuroQol Group by time trade-off (TTO) will be used for scoring algorithm.

The EQ-5D-5L is a standardized instrument applicable to a wide range of health conditions for use as a measure of health and is especially suited to cost effectiveness analyses., From Baseline to Follow-Up (0, 8, 16, 28 weeks)|Costs of health service utilization in Euros, Mean costs of intervention and control group (excluding study related costs) will be estimated. To calculate sum of costs in Euros per group to receive one aggregated outcome, firstly the following resource use data will be collected: Outpatient care, Medication, Medical aids, Inpatient care, Nursing home/hospice, Rehabilitation, Remedies (physiotherapy, massage, other), Formal care, Home help, Informal care, Work absenteeism, and early retirement. Secondly, resource use categories will be monetarily valued using unit cost and multiplied with the collected amount of resource use. Thirdly, mean costs in Euros per group will be calculated., From Baseline to Follow-Up (0, 8, 16, 28 weeks)|Patient survival measured in days, Survival is defined as time from randomization to death irrespective of the cause of death. Participants who will not die during study course will be censored at the time of last contact which is planned for week 28 after last patient in. Survival status will be assessed by phone for all participants., From randomization until death, up to end of study (24 months)
Other Outcome Measures:
Sponsor: Ludwig-Maximilians - University of Munich
Collaborators: University Hospital Munich|Helmholtz Zentrum München|University of Cambridge|King's College London
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 183
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|

Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: 01GY1331
Start Date: 2015-03-02
Primary Completion Date: 2019-02-01
Completion Date: 2019-04-30
First Posted: 2015-12-04
Results First Posted:
Last Update Posted: 2019-08-09
Locations: Hospital of the University of Munich, Department of Palliative Medicine, Munich, Bavaria, 81377, Germany
Study Documents:

NCT Number: NCT02665312
Study Title: Cardiotoxicity and Risk Factors in Patients With Colorectal Cancer Receiving Fluoropyrimidine
Study URL: https://beta.clinicaltrials.gov/study/NCT02665312
Acronym:
Study Status: UNKNOWN
Brief Summary: observational prospective study, designed for patients with colorectal cancer receiving for the first time 5-FU or capecitabine, with or without other chemotherapy combinations.
Study Results: NO
Conditions: Colorectal Cancer
Interventions:
Primary Outcome Measures: Assessment of the incidence of cardiovascular events during the first three cycles of therapy with capecitabine or 5-FU, 24 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Fondazione del Piemonte per l'Oncologia
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 200
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CheckPoint
Start Date: 2016-01
Primary Completion Date: 2018-01
Completion Date: 2019-01
First Posted: 2016-01-27
Results First Posted:
Last Update Posted: 2016-09-23
Locations: Ospedale San Lazzaro - ASL CN 2 Alba Bra, Alba, Cuneo, 12051, Italy|Fondazione del Piemonte per l' Oncologia - IRCCS Candiolo, Candiolo, Turin, 10060, Italy|AO Ordine Mauriziano di Torino, Turin, 101028, Italy|AOU Città della Salute e della Scienza di Torino - Presidio Molinette - Oncologia Medica 1, Turin, 10126, Italy|

AOU Città della Salute e della Scienza di Torino - Presidio Molinette - Oncologia Medica 2, Turin, 10126, Italy|Ospedale Cottolengo, Turin, 10152, Italy|Humanitas Gradenigo, Turin, 10153, Italy|Ospedale San Giovanni Bosco - ASL TO2, Turin, 10154, Italy
Study Documents:

NCT Number: NCT04541212
Study Title: Identification and Evaluation of Patients at Risk of Developing Cardiotoxicity After Receiving Chemotherapy for Breast Cancer, Lymphoma or Leukemia
Study URL: https://beta.clinicaltrials.gov/study/NCT04541212
Acronym: CarChem
Study Status: RECRUITING
Brief Summary: This is an observational study of the occurrence of cardiac toxicity in patients with breast cancer,lymphoma or leukemia receiving chemotherapy including an anthracycline. Patients will be identified at the oncology clinic and will be included in the study if all eligible criteria are met. The study will involve retrospective and prospective evaluations.

Safety will be assessed through reporting of serious adverse events (SAEs) related to study procedures.
Study Results: NO
Conditions: Breast Cancer|Lymphoma|Leukemia
Interventions: DIAGNOSTIC_TEST: Cardiac Imaging|OTHER: Data Collection
Primary Outcome Measures: Myocardial extracellular volume (ECV), Cohort A, Change from baseline to 3, 6, 12,and 24 months|Myocardial extracellular volume (ECV), Cohort B, Change from baseline to prior study entry, 12 and 24 months post study entry.
Secondary Outcome Measures: Left ventricular (LV) systolic function (global and regional), Cohort A, Change from baseline to 3, 6, 12,and 24 months.|Biomarker of myocardial injury (high-sensitivity troponin (hs-cTn)), Cohort A, Change from baseline to 3, 6, 12,and 24 months.|Biomarker of elevated LV fitting pressure (N-Terminal-pro-hormone B-type Natriuretic Peptide (NT-proBNP)), Cohort A, Change from baseline to 3, 6, 12,and 24 months.|Biomarker of inflammation (high-sensitivity C-reactive protein (hs-CRP)), Cohort A, Change from baseline to 3, 6, 12,and 24 months.|Clonal hematopoiesis associated gene mutations., Cohort A, Change from baseline to 24 months..|Telomere length measurement, Cohort A, Change from baseline to 24 months..|Left ventricular (LV) systolic function (global and regional), Cohort B, Change from study entry to 12 and 24 months.|Biomarker of myocardial injury (high-sensitivity troponin (hs-cTn)), Cohort B, Change from study entry to 12 and 24 months.|Biomarker of elevated LV fitting pressure (N-Terminal-pro-hormone B-type Natriuretic Peptide (NT-proBNP)), Cohort B, Change from study entry to 12 and 24 months.|Biomarker of inflammation (high-sensitivity C-reactive protein (hs-CRP)), Cohort B, Change from study entry to 12 and 24 months.|Clonal hematopoiesis associated gene mutations., Cohort B, Change from baseline to 24 months..|Telomere length measurement, Cohort B, Change

from baseline to 24 months..
Other Outcome Measures:
Sponsor: Montreal Heart Institute
Collaborators: AstraZeneca
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 300
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: MHICC-2018-003
Start Date: 2021-12-02
Primary Completion Date: 2026-01
Completion Date: 2026-01
First Posted: 2020-09-09
Results First Posted:
Last Update Posted: 2023-02-22
Locations: CIUSSS Ouest de l'ile de Montreal - St-Mary's Hospital, Montréal, Quebec, H3T 1M5, Canada|CIUSSS de l'Est-de-l'Île-de-Montréal - Hôpital Maisonneuve-Rosemont, Montréal, Quebec, Canada|Montreal Heart Institute, Montréal, Quebec, Canada
Study Documents:

NCT Number: NCT05504148
Study Title: Protection of Cardiovascular Function With Crocin in BrEast Cancer Patients Undergoing Radiotherapy and Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT05504148
Acronym: ProtECtion
Study Status: RECRUITING
Brief Summary: The potential cardiovascular toxicity of tumor treatment and its resulting cardiovascular events have gradually become an important health risk for tumor survivors. Prevention and early identification of cardiovascular toxicity has now become one of the bottlenecks in improving the prognosis of cancer patients. Compared to conventional echocardiographic indicators, new ultrasound technology based on speckle tracking imaging (STI) has shown superiority in the diagnosis, risk stratification and prognosis evaluation of cardiovascular diseases. Crocin, one of the main active components of saffron, has been found protective effect on cardiovascular toxicity in basic studies. This is a randomized, double-blind, placebo-controlled, single-center clinical study to observe the effect of crocin on cardiovascular function caused by breast cancer treatment.

One hundred and twenty breast cancer patients planning to undergo radiotherapy or chemotherapy will be included and randomly divided into a crocin group and a placebo group to observe the effect of total saffron tablets on cardiovascular function in patients with early breast cancer radiotherapy and chemotherapy. Participants will take

crocin or placebo (4 tablets/time, 3 times a day) during each cycle of chemotherapy for 8 days, started on the 1st day before radiotherapy/ chemotherapy. Follow-up was performed every 3 months after enrollment, and the follow-up period was 6 months.

Primary study endpoints include the differences between groups in the difference in LVEF and GLS measured by echocardiography at the end of the experiment compared to baseline. Secondary study endpoint include the differences in the incidence rates of serum troponin exceeding the upper limit of normal value and NT-proBNP higher than the normal age reference value, the frequency and duration of chest tightness, chest pain and palpitation, the degree of arrhythmia and ST-T changes displayed by dynamic electrocardiogram, the other echocardiographic parameters (the E/e', global circumferential strain, global radial strain, 3D-GAS, LV torsion, LV rotation/derotation velocity, SDI, RVFWS, and indexes of left ventricular diastolic function and right ventricular function) at the end of the experiment compared to baseline between the two groups.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: crocin|DRUG: Placebo
Primary Outcome Measures: The change of LVEF measured by echocardiography, The differences between the two groups in the difference of LVEF measured by Echocardiography at the end of the experiment compared to that at the baseline., At the end of 6-month follow-up compared to the baseline|The change of GLS measured by echocardiography, The differences between the two groups in the difference of GLS measured by Echocardiography at the end of the experiment compared to that at the baseline., At the end of 6-month follow-up compared to the baseline
Secondary Outcome Measures: The incidences of the increase of serum troponin and/or NT-proBNP, Differences in the incidence rates of serum troponin exceeding the upper limit of normal value and NT-proBNP higher than the normal age reference value between the two groups during follow-up., During 6 months of following up|The incidences of chest tightness, chest pain and palpitation, The differences in the incidence of chest tightness, chest pain and palpitation between the two groups, During 6 months of following up|The incidences of arrhythmia and ST-T changes, Differences between the two groups in the incidences of arrhythmia and ST-T changes displayed by dynamic electrocardiogram., During 6 months of following up|The differences of global circumferential strain, global radial strain, global area strain measured by echocardiography., Differences between groups in the difference in global circumferential strain, global radial strain, global area strain measured by echocardiography at the end of the experiment compared to baseline., At the end of 6-month follow-up compared to the baseline|The indexes of E, e', a', tricuspid regurgitation velocity measured by echocardiography., Differences between groups in the difference in the indexes of left ventricular diastolic function measured by echocardiography at the end of the

experiment compared to baseline., At the end of 6-month follow-up compared to the baseline|The indexe of E/e'measured by echocardiography., Differences between groups in the difference in the indexes of left ventricular diastolic function measured by echocardiography at the end of the experiment compared to baseline., At the end of 6-month follow-up compared to the baseline|The indexe of left atrial volume index (LAVI)measured by echocardiography., Differences between groups in the difference in the indexes of left ventricular diastolic function measured by echocardiography at the end of the experiment compared to baseline., At the end of 6-month follow-up compared to the baseline|The indexe of TAPSE measured by echocardiography., Differences between groups in the difference in the right ventricular function monitoring indicators measured by echocardiography at the end of the experiment compared to baseline., At the end of 6-month follow-up compared to the baseline|The indexe of RV fractional area change (FAC) measured by echocardiography., Differences between groups in the difference in the right ventricular function monitoring indicators measured by echocardiography at the end of the experiment compared to baseline., At the end of 6-month follow-up compared to the baseline|The indexe of right ventricular free wall global longitudinal strain (RVGLS) measured by echocardiography., Differences between groups in the difference in the right ventricular function monitoring indicators measured by echocardiography at the end of the experiment compared to baseline., At the end of 6-month follow-up compared to the baseline
Other Outcome Measures:
Sponsor: Qilu Hospital of Shandong University
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 6010121027
Start Date: 2021-03-29
Primary Completion Date: 2023-06-25
Completion Date: 2023-09-25
First Posted: 2022-08-17
Results First Posted:
Last Update Posted: 2022-09-22
Locations: Qilu Hospital of Shandong University, Jinan, Shandong, 250012, China
Study Documents: Study Protocol and Statistical Analysis Plan|Informed Consent Form

NCT Number: NCT00777751

Study Title: Radiation Therapy and Cardiac Enzymes
Study URL: https://beta.clinicaltrials.gov/study/NCT00777751
Acronym:
Study Status: COMPLETED
Brief Summary: The goal of this clinical research study is to learn if the radiation that you are receiving will result in an increase in certain proteins produced by the heart called cardiac biomarkers.
Study Results: NO
Conditions: Tumor
Interventions:
Primary Outcome Measures: Elevation in cardiac biomarkers by measuring cardiac troponins (troponin T and troponin I), BNP, and CK-MB., 4 Time Points: within 1 week prior to radiation therapy (RT), within 1-3 days of RT completion, and at 1 and 3 months after completion of RT.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 30
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2007-0489
Start Date: 2008-10-06
Primary Completion Date: 2016-11-21
Completion Date: 2016-11-21
First Posted: 2008-10-22
Results First Posted:
Last Update Posted: 2018-01-10
Locations: University of Texas MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT05258448
Study Title: COr Loco-regional Advanced Lung Cancer Treated With Chemo-radiotherapy (COLA)
Study URL: https://beta.clinicaltrials.gov/study/NCT05258448
Acronym: COLA
Study Status: RECRUITING
Brief Summary: Patients with loco-regional NSCLC planned for curative treatment with chemoradiotherapy will be invited to participate in a prospective study; besides routine treatment, the patients will be followed with an ECG and cardiac MR for at least two years after radiotherapy treatment.
Study Results: NO
Conditions: Cardiac Toxicity|Lung Cancer Stage III|Lung Cancer Stage II|Radiation Toxicity|Cardiac Disease

Interventions: OTHER: Chemoradiotherapy
Primary Outcome Measures: Overall survival, All cause mortality, 2 Years|Change in Left Ventricular Ejection Fraction, Change from baseline, evaluated by cardiac MR, Baseline, at 6, 12 and 24 months.| Number of participants with treatment related adverse events and cardiac disease after radiotherapy as assesed by CTCAE v4.0., Assesed by patient interview and review of medical record., 2 years.| Cardiovascular specific mortality, Assesed by patient interview and review of medical record, 2 years.
Secondary Outcome Measures: Late enhacment, Evaluated by cardiac MR., At Baseline, 6, 12 and 24 months.|LVEDV changes, Left ventricular enddiastolic change in cMR, 2 years|LVESV changes, Left ventricular endsystolic change in cMR, 2 years|LV mass in gram, Left ventricular mass in gram., 2 years
Other Outcome Measures:
Sponsor: Odense University Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: S-20160086
Start Date: 2015-08
Primary Completion Date: 2023-01
Completion Date: 2024-06
First Posted: 2022-02-28
Results First Posted:
Last Update Posted: 2022-02-28
Locations: Odense University Hospital, Odense C, 5000, Denmark
Study Documents:

NCT Number: NCT03375892
Study Title: The Use of Deep Inspiration Breath Hold and Prone Irradiation to Decrease Cardiac Radiation Exposure
Study URL: https://beta.clinicaltrials.gov/study/NCT03375892
Acronym:
Study Status: COMPLETED
Brief Summary: This study aims to discover more about radiation techniques for people treated for left-sided breast cancer that minimizes exposure to the heart, as noted by mean heart dose.
Study Results: NO
Conditions: Breast Cancer|Ductal Carcinoma in Situ|Invasive Breast Cancer
Interventions: OTHER: Deep Inspiration Breath Hold during Radiation| OTHER: Free breathing during radiation
Primary Outcome Measures: Changes in EKG parameters prior to, during or after radiation therapy., Changes in QRS wave form will be

categorized as 'present' or 'absent' based on the presentation (or lack) of a r' wave, or notched r or s wave on the EKG tracing. QRS-T angle will be measured in degrees., Baseline, 6 weeks, 6 months and 12 months
Secondary Outcome Measures: Change in mitochondrial energy production, as measured in leukocytes (peripheral blood mononuclear cells) from patients prior to and after undergoing radiation therapy., Mitochondrial energy production will be measured by determining oxygen consumption rate (pmol of O2 consumed per second per·10\^6 cells)., baseline, 6 weeks, and 6 and 12 months post-radiation therapy|Changes in left ventricular ejection fraction prior to, during or after radiation therapy., This will be measured as a percentage., Baseline and 12 months|Changes in left atrial volume prior to, during or after radiation therapy., This will be measured in millimeters., Baseline and 12 months|Left ventricular wall thickness prior to, during or after radiation therapy., This will be measured in millimeters., Baseline and 12 months|Arterial and aortic stiffness., This will be assessed by measuring the ascending aortic diameters 3 cm above the aortic valve at end-diastole and end-systole in the 2D parasternal view., Baseline and 12 months
Other Outcome Measures:
Sponsor: Medical College of Wisconsin
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 11
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: PRO00030436
Start Date: 2018-03-03
Primary Completion Date: 2021-03-21
Completion Date: 2021-03-21
First Posted: 2017-12-18
Results First Posted:
Last Update Posted: 2022-08-03
Locations: Froedtert Hospital and Medical College of Wisconsin, Milwaukee, Wisconsin, 53226, United States
Study Documents:

NCT Number: NCT03746392
Study Title: Project to Improve Communication About Serious Illness - Pilot Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03746392
Acronym: PICSI-P
Study Status: COMPLETED
Brief Summary: This two-year pilot study will test whether a one-page "Jumpstart Form" will affect goals-of-care discussions in the

hospital. This form will be provided to clinicians and will include patient-specific information about preferences for goals-of-care communication and for care, as well as tips to improve this communication. Jumpstart forms will also be provided to patients or, if they are unable to communicate, their surrogates/family members. The information on the form will be obtained from questionnaires. The form is tailored to help patients and surrogates talk with clinicians about goals of care. This study is based on a successful application of Jumpstart Form in the outpatient clinic setting.
Study Results: NO
Conditions: Malignant Neoplasm|Leukemia, Lymphocytic, Chronic, B-Cell|Lung Disease Chronic|Congestive Heart Failure|Liver Failures, Chronic|Renal Insufficiency, Chronic|Dementia|Diabetes Complications|Peripheral Vascular Disease|Frail Elderly
Interventions: BEHAVIORAL: Jumpstart Intervention
Primary Outcome Measures: Documentation of goals of care, Presence or absence of documentation of goals of care discussions in the patient's electronic health record during the current hospitalization, At hospital discharge, an average of 2 weeks
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Washington
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 150
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: STUDY00004821
Start Date: 2018-07-01
Primary Completion Date: 2020-06-30
Completion Date: 2020-06-30
First Posted: 2018-11-19
Results First Posted:
Last Update Posted: 2020-11-04
Locations: Harborview Medical Center, Seattle, Washington, 98104, United States|University of Washington Medical Center, Seattle, Washington, 98195, United States
Study Documents:

NCT Number: NCT01018719
Study Title: Evaluation of Radiation Induced Toxicity to the Heart by Multi-detector Computed Tomography (MDCT)
Study URL: https://beta.clinicaltrials.gov/study/NCT01018719
Acronym:
Study Status: UNKNOWN
Brief Summary: The current study is aimed to evaluate various imaging

methods, including multidetector computed tomography (MDCT) as potential surrogates to assess the degree of damage caused to the heart by radiation therapy to the breast, in breast cancer survivors many years before it becomes clinically apparent.
Study Results: NO
Conditions: Breast Cancer
Interventions: DEVICE: MDCT, ECG, Echocardiography
Primary Outcome Measures: Degree of damage to the coronary arteries as measured by MDCT, 5 to 15 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Western Galilee Hospital-Nahariya
Collaborators: Rambam Health Care Campus
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 100
Funder Type: OTHER_GOV
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: cardiotoxicity66809
Start Date: 2010-01
Primary Completion Date: 2011-12
Completion Date:
First Posted: 2009-11-25
Results First Posted:
Last Update Posted: 2009-11-25
Locations:
Study Documents:

NCT Number: NCT03978819
Study Title: ANI Parasympathetic Monitoring in Neurosurgery
Study URL: https://beta.clinicaltrials.gov/study/NCT03978819
Acronym: ANI
Study Status: COMPLETED
Brief Summary: Surgery of large cerebellopontine angle (CPA) tumors (\>2 x 2 cm diameter), with compression of the pons exposes the patient to inadvertent parasympathetic nerve stimulation (IPNS) leading to bradycardia and asystole.

The analgesia nociception index (ANI) monitor assesses the balance between analgesia and nociception through the detection of parasympathetic tone. ANI \>80 generally denotes excessive analgesia (EA). The main objective of this study was to determine whether ANI values for IPNS are different or the same as ANI values for EA. This study also aims at calculating the number of patients with IPNS and EA during surgery of large CPA tumours.
Study Results: NO
Conditions: Bradycardia
Interventions: DEVICE: ANI

Primary Outcome Measures: Differences in instantaneous ANI (ANIi) values during bradycardia versus ANIi values when Remifentanil effect size concentration >6ng/mL, ANI, HR and Remifentanil effect site concentration were continuously recorded with event markers on the ANI monitor at the onset of bradycardia (HR\<45 bpm) or Remifentanil effect site concentration\>6ng/mL, ANIi values recorded at Day 1 only during surgery (duration: 4-6 hours)|Differences in the area under the ROC curves between ANI values for IPNS and EA analgesia, ROC curves were built at different ANIi for IPNS or EA, ANIi values recorded at Day 1 only during surgery (duration: 4-6 hours)
Secondary Outcome Measures: Percentages of IPNS and EA cases, The percentages of IPNS or EA cases on the overall study population were calculated., Cases observed at Day 1 only during surgery (duration: 4-6 hours)
Other Outcome Measures:
Sponsor: Association de Developpement de la Neuroanesthesie Reanimation
Collaborators: University of Bordeaux
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: DC 2015/143
Start Date: 2015-11
Primary Completion Date: 2017-11
Completion Date: 2017-11
First Posted: 2019-06-07
Results First Posted:
Last Update Posted: 2019-06-07
Locations: CHU Bordeaux University Hospital, Bordeaux, 33076, France
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT01143519
Study Title: Study of the Effect of SNPs in p53 and p53 Response Elements on the Inflammatory Response to DNA Damage
Study URL: https://beta.clinicaltrials.gov/study/NCT01143519
Acronym:
Study Status: COMPLETED
Brief Summary: Background:

- Research has shown that certain proteins in cells may be linked to higher risks of developing inflammations, tumors, and other medical problems. By examining how the blood cells of healthy volunteers respond to environmental exposures, researchers hope to better understand the relationship of genes, environmental factors, and human diseases.

Objectives:

- To examine how specific genes and proteins in blood cells respond to environmental exposures.

Eligibility:

- Healthy volunteers between 18 and 45 years of age.

Design:

* The study will involve one visit of 45 to 60 minutes.
* Participants will be screened with a brief physical examination and finger stick to determine if they are eligible to donate blood for the study, and will complete a questionnaire about any medications or other drugs (e.g., cigarettes) they may be taking.
* Participants will provide a blood sample for research purposes.
Study Results: NO
Conditions: HIV-1 Seropositive|Inflammation|Cancer|Cardiomyopathy
Interventions:
Primary Outcome Measures: p53 target gene expression, The primary endpoint of this study is p53 target gene expression measured by RTPCR for the following five SNPs: p53 rs1042522, MDM2 rs2279744, FLT1 C-677T, TLR8 rs3761624 and RMM1 rs1465952., analysis on blood drawn at visit
Secondary Outcome Measures: p53 promoter occupancy, Measured by ChIP analysis for the following SNPs: FLT1 C-677T, TLR8 rs3761624 and RMM1 rs1465952., analysis on blood drawn at visit
Other Outcome Measures:
Sponsor: National Institute of Environmental Health Sciences (NIEHS)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 178
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 100134|10-E-0134
Start Date: 2012-05-21
Primary Completion Date:
Completion Date:
First Posted: 2010-06-14
Results First Posted:
Last Update Posted: 2023-07-17
Locations: NIEHS Clinical Research Unit (CRU), Research Triangle Park, North Carolina, United States
Study Documents:

NCT Number: NCT04413487

Study Title: Early Detection of Heart Problems in Cancer Patients Receiving Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04413487
Acronym:
Study Status: WITHDRAWN
Brief Summary: Subjects will include patients diagnosed with breast cancer or hematological cancer who are planned for chemotherapy treatment with anthracycline or trastuzumab; and who have one or more risk factors for cardiovascular disease. Subjects will received an extra echocardiogram to determine if heart problems can be detected earlier.
Study Results: NO
Conditions: Heart Failure
Interventions: OTHER: Extra echocardiogram
Primary Outcome Measures: Change in left ventricular ejection fraction (LVEF), a decrease in LVEF of ≥10 percentage points from baseline to a value of \< 50% OR a decrease of LVEF by ≥ 5 percentage points from baseline to LVEF \<50% for patients who have a baseline LVEF of 50-54%, through study completion, an average of 1 year
Secondary Outcome Measures: Survival status, alive or deceased, through study completion, an average of 1 year|Change in symptoms that may be indicative of heart failure, Presence of absence of symptoms, through study completion, an average of 1 year|Change in treatment that may be indicative of heart failure, Presence or absence of treatment for heart failure, through study completion, an average of 1 year|Change in strain echo that may be indicative of heart failure, Presence or absence of heart failure by imaging, through study completion, an average of 1 year
Other Outcome Measures:
Sponsor: The Guthrie Clinic
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 0
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 20
Start Date: 2020-03
Primary Completion Date: 2020-05-28
Completion Date: 2020-05-28
First Posted: 2020-06-04
Results First Posted:
Last Update Posted: 2020-06-04
Locations:
Study Documents:

NCT Number: NCT00215085
Study Title: Cardiac Tumors in Children

Study URL: https://beta.clinicaltrials.gov/study/NCT00215085
Acronym:
Study Status: TERMINATED
Brief Summary: The purpose of this study is to define the natural history of untreated cardiac tumors, study the pathology of primary cardiac tumors, review the surgical treatment and results of primary cardiac tumors and to determine the prognosis for these tumors.
Study Results: NO
Conditions: Congenital Heart Disease
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Children's Healthcare of Atlanta
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 70
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 05-091
Start Date: 2005-05
Primary Completion Date:
Completion Date: 2006-11
First Posted: 2005-09-22
Results First Posted:
Last Update Posted: 2012-03-16
Locations: Children's Healthcare of Atlanta, Atlanta, Georgia, 30322, United States
Study Documents:

NCT Number: NCT02471885
Study Title: Effect of Remote Ischaemic Conditioning in Oncology Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02471885
Acronym: ERIC-ONC
Study Status: UNKNOWN
Brief Summary: Cancer survival has improved steadily due to earlier detection and treatment. Despite the established efficacy of anthracycline chemotherapy, its damaging effects on the heart (cardiotoxicity) limits treatment and confers acute and long term adverse cardiovascular consequences. Protective strategies for the heart (cardioprotection) with iron binders (chelation), heart rate (beta blockade) and blood pressure (renin angiotensin inhibition) medications have demonstrated promise in adult cancer patients, but these treatments are typically prescribed only after significant changes in heart chamber size and pumping ability are detected by imaging investigations (myocardial dysfunction).

Furthermore, these conventional therapies are constrained by important side effects that affect bone marrow, blood pressure, and the kidneys.

Remote ischaemic conditioning (RIC) protects the heart by activating cell survival pathways through brief repeated inflations and deflations of a blood pressure cuff to limit blood flow temporarily (noninjurious ischaemia). These innate survival mechanisms prevent part of the cellular injury that occurs during the ischaemia reperfusion cascade during a heart attack (myocardial infarction). Ischaemia reperfusion injury also shares common biochemical pathways with anthracycline cardiotoxicity, and thus RIC may be a novel form of nonpharmacological cardioprotection that can be applied when undergoing anthracycline chemotherapy.

The investigators propose a pilot single centre randomised controlled trial to investigate the effect of RIC on reducing heart muscle damage (myocardial injury) in anthracycline-treated cancer patients. The investigators will assess subclinical myocardial injury using high-sensitivity blood tests (troponin T levels) and advanced imaging techniques, monitor heart rhythm disturbances (cardiac arrhythmia) and analyse metabolic changes in urine and blood during chemotherapy, at specified time points, and follow up to 5 years after completing chemotherapy treatment).
Study Results: NO
Conditions: Cardiotoxicity
Interventions: PROCEDURE: Remote Ischaemic Conditioning|OTHER: Placebo
Primary Outcome Measures: hs-Troponin T (hs-TnT) levels, Biomarker of myocardial injury using high-sensitivity Troponin-T for above time points as serial measurements., at baseline, at 3-24 hours after end of infusion of each chemotherapy cycle, then at initiation of chemotherapy infusion (cycles 2-6, occurring at intervals of 3-weeks), then at 1-, 3-, 6-, 12- months follow up
Secondary Outcome Measures: Major Adverse Clinical Cardiovascular Event (MACCE), Major Adverse Cardiovascular Event (myocardial infarction, clinical heart failure requiring admission, life-threatening arrhythmia atrioventricular (AV) block requiring pacemaker, cardiac or cancer death), 1-, 3-, 6-, 12- months follow up|Echocardiographic global longitudinal strain (GLS), Echocardiographic longitudinal function (GLS %), at baseline, then at 3- and 12- months follow up|Incidence of cardiac arrhythmia, two weeks ambulatory electrocardiographic (ECG) monitoring for atrial fibrillation, supraventricular tachycardia, ventricular tachycardia, atrioventricular block, at start of infusion of cycle 5 chemotherapy|Biomarker N-terminal pro-brain natriuretic peptide (NT-proBNP), for heart failure / raised left atrial pressure, at 3- months follow up|Micro ribonucleic acid (RNA) and mitochondrial de-oxyribonucleic acid (DNA) analysis, Comparison of changes in micro ribonucleic acid (miRNA) and mitochondrial deoxyribonucleic acid (mtDNA), markers of protein expression at baseline (before) and at 3-months' follow up

after completing chemotherapy regimen, at baseline and at 3-months follow up
Other Outcome Measures:
Sponsor: University College, London
Collaborators: University College London Hospitals
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 128
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 15/0276
Start Date: 2015-12-16
Primary Completion Date: 2020-12
Completion Date: 2021-12
First Posted: 2015-06-15
Results First Posted:
Last Update Posted: 2020-04-15
Locations: University College London Hospitals, London, WC1E 6BT, United Kingdom
Study Documents:

NCT Number: NCT01572883
Study Title: Effect of Concomitant Radiotherapy and Trastuzumab on Cardiotoxicity of Patients Treated for Early Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01572883
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine whether concomitant radiotherapy and trastuzumab (patients treated for early breast cancer) is really safe for the heart even years after treatment and if the investigators should use these two treatments concomitantly without additional harm.
Study Results: NO
Conditions: Breast Cancer
Interventions:
Primary Outcome Measures: difference in LVEF (Left Ventricular Ejection Fraction), we will compare LVEF (LVEF 1) measured before treatment with adjuvant Trastuzumab and concomitant Radiotherapy of breast/thoracic wall with LVEF (LVEF 2) measured at follow up (after adjuvant treatment) outpatient examination. We will then compare the difference in LVEF (LVEF 2-LVEF 1) measured in patients treated for left breast cancer with the difference in LVEF (LVEF 2-LVEF 1) measured in patients treated for right breast cancer, from one to six years from adjuvant radiotherapy for early breast cancer
Secondary Outcome Measures: occurrence of cardiovascular events over time in both groups (RT for left/right breast), occurrence of

cardiovascular events over time in both groups (irradiated left / right breast) will be showed by the method of Kaplan–Meier. Groups will be compared with the log rank test., from 6 months to five years after adjuvant therapy with trastuzumab
Other Outcome Measures:
Sponsor: Institute of Oncology Ljubljana
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 175
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: eHER2-TM
Start Date: 2011-12
Primary Completion Date: 2012-07
Completion Date: 2012-07
First Posted: 2012-04-06
Results First Posted:
Last Update Posted: 2014-10-16
Locations: Institut of oncology Ljubljana, Ljubljana, 1000, Slovenia
Study Documents:

NCT Number: NCT01018927
Study Title: Detecting Early Myocardial Infiltration w/Amyloid & Light Chain Deposition Disease in Multiple Myeloma Subjects
Study URL: https://beta.clinicaltrials.gov/study/NCT01018927
Acronym:
Study Status: TERMINATED
Brief Summary: The purpose of this study is to see if MRI techniques can be used for early evaluation of cardiac amyloidosis which is sometimes seen in individuals with multiple myeloma. Cardiac amyloidosis is a medical disorder that decreases heart function.
Study Results: NO
Conditions: Multiple Myeloma
Interventions: DEVICE: Administering three additional MRI images
Primary Outcome Measures: This study is to see if MRI techniques can be used for early evaluation of cardiac amyloidosis which is sometimes seen in individuals with multiple myeloma., The time frame is five additional minutes & three additional images during and MRI.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Arkansas
Collaborators: Siemens Molecular Imaging
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 44
Funder Type: OTHER

Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 110104
Start Date: 2009-06
Primary Completion Date: 2017-05-30
Completion Date: 2017-05-30
First Posted: 2009-11-25
Results First Posted:
Last Update Posted: 2017-05-31
Locations: University or Arkansas for Medical Sciences (UAMS), Little Rock, Arkansas, 72205, United States
Study Documents:

NCT Number: NCT04409379
Study Title: Association Between Telomere Length and Cardiac Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT04409379
Acronym:
Study Status: COMPLETED
Brief Summary: Compelling epidemiological evidence indicates that alterations of relative telomere length (RTL) are associated with cardiac dysfunction caused by chemotherapy in children with acute leukemia (AL).The aim of this study was to explore association between RTL content in peripheral blood cells could be used as a risk predictor for severity of cardiac damage.
Study Results: NO
Conditions: Cardiac Toxicity|Acute Leukemia|Childhood Cancer
Interventions: DIAGNOSTIC_TEST: Relative telomere length
Primary Outcome Measures: Relative telomere length, The ratio of RTL to hemoglobin contents was calculated for each sample from standard curves. After that, the ratio for each sample was normalized to a calibrator DNA in order to standardize between different runs, and then defined as the measurement of relative mtDNA contents.Relative expression of mtDNA were measured in young adults suffered from AL., From date of admission until the date of discharging from hospital, assessed up to 5 days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Air Force Military Medical University, China
Collaborators:
Sex: ALL
Age: CHILD
Phases:
Enrollment: 300
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: YL2019100602
Start Date: 2019-01-01
Primary Completion Date: 2020-05-01

Completion Date: 2020-05-01
First Posted: 2020-06-01
Results First Posted:
Last Update Posted: 2020-06-01
Locations: Xiao-Fan Zhu, Tianjin, Tianjin, 300000, China
Study Documents:

NCT Number: NCT05159479
Study Title: Defining Robust Predictors of Chemotherapy Related Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT05159479
Acronym:
Study Status: RECRUITING
Brief Summary: Cancer affects 1 in 2 people during their life. Major improvements in cancer treatment mean that many people are now living longer with cancer. But certain cancer drugs have the potential to damage the heart and blood vessels. One type of cancer therapy called fluoropyrimidines, is used in many cancers including bowel, breast, pancreatic and head and neck. This chemotherapy can cause chest pain, heart attacks and abnormal heart rhythms in approximately 10% of patients.

Adverse cardiac events lead to disruption of chemotherapy and can lead to adverse cancer outcomes. Some patients will require alternative treatment. Most cardiac events occur during the early cycles of treatment with fluoropyrimidines.

Currently, we do not know how to predict which patients are most likely to be affected. Patients deemed to be at a high cardiovascular risk are often denied this treatment which is first line for all gastrointestinal cancers. There is no hard evidence to support this approach and patients may be inappropriately denied treatment.

If we were able to confidently identify patients at the highest risk, then we could potentially reduce risk of toxicity by giving cardioprotective medications or we would be able to confidently identify those who should be given alternative chemotherapy.

In this study, we will prospectively perform a cardiovascular risk assessment in patients prior to initiation of chemotherapy using QRisk3. We will also perform baseline and serial electrocardiography and cardiac biomarkers with troponin T. We will follow up our patients for clinical cardiovascular events.
Study Results: NO
Conditions: Cardiotoxicity|Gastrointestinal Neoplasms
Interventions:
Primary Outcome Measures: Adjudicated Cardiovascular events during fluoropyrimidine chemotherapy, Defined as:

* Types 1-3 myocardial infarction with troponin \>99th percentile

upper limit,
* Incident myocardial ischaemia (chest pain with new inducible perfusion abnormality on perfusion cardiac MRI, --Myocarditis (diagnosed as per ESC Consensus statement
* Incident heart failure diagnosis (symptoms with NTproBNP \>400pg/ml or HF hospitalization),
* Incident arrhythmia (excluding isolated ectopy) or sudden cardiac death., 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University College, London
Collaborators: British Heart Foundation
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 600
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 140342
Start Date: 2021-10-13
Primary Completion Date: 2024-04-01
Completion Date: 2024-07-01
First Posted: 2021-12-16
Results First Posted:
Last Update Posted: 2021-12-16
Locations: St Bartholomews Hospital, London, EC1A 7BE, United Kingdom
Study Documents:

NCT Number: NCT01436604
Study Title: Early Detection of Cardiac Toxicity of Trastuzumab (Herceptin ®) in Patients Treated for Breast Carcinoma: Value of Magnetic Resonance Imaging
Study URL: https://beta.clinicaltrials.gov/study/NCT01436604
Acronym: MRTOX
Study Status: TERMINATED
Brief Summary: The main objective of this study is to compare the proportions of late enhancement in patients with Left ventricular (LV) dysfunction as Herceptin ® and in a control group consisting of patients who did not have LV dysfunction after 6 months under the same treatment.
Study Results: NO
Conditions: Cancer, Breast|LV Dysfunction
Interventions: OTHER: Cardiac MRI
Primary Outcome Measures: Proportions of late enhancement in patients with LV dysfunction as Herceptin ® and in a control group consisting of patients who did not have LV dysfunction after 6 months under the same treatment., A cardiac MRI is considered positive if demonstrated a late hyperintense from 15 to 20 minutes after injection of gadolinium chelate, whatever its size, topography subepicardial

(intramyocardial) and without vascular systematization.

The primary endpoint is the proportion of delayed enhancement in the LV dysfunction group and the control group., 2 years
Secondary Outcome Measures: Proportion of patients recovering at 6 months in the absence of late enhancement signal in MRI heart after injection of gadolinium and compare the results of biological assays, 2 years
Other Outcome Measures:
Sponsor: Centre Francois Baclesse
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 19
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: MRTOX
Start Date: 2012-02
Primary Completion Date: 2015-08
Completion Date: 2017-05
First Posted: 2011-09-19
Results First Posted:
Last Update Posted: 2017-07-28
Locations: Centre François Baclesse, Caen, 14076, France|Centre Georges-François Leclerc, Dijon, France|Clinique du Bois, Lille, France|CHU de NANCY, Nancy, 54511, France
Study Documents:

NCT Number: NCT01271127
Study Title: Screening for Coronary Artery Disease After Mediastinal Irradiation
Study URL: https://beta.clinicaltrials.gov/study/NCT01271127
Acronym: SCAR
Study Status: COMPLETED
Brief Summary: Survivors of Hodgkin Lymphoma (HL) are known to have an increased risk of developing late treatment sequelae such as cardiovascular events due to coronary artery disease. At present no active screening is performed in these patients since it is not known whether screening and subsequent treatment by means of revascularization is effective in reducing the risk of cardiovascular events in symptomatic individuals. In the trial the efficacy and therapeutic consequences of screening for coronary artery diasease by multi-slice CT (MSCT) among asymptomatic HL survivors will be evaluated.
Study Results: NO
Conditions: Radiation Therapy|Coronary Artery Disease|Hodgkin Lymphoma
Interventions: RADIATION: CT coronary angiography

Primary Outcome Measures: accurately identifying asymptomatic coronary artery disease, to determine whether Ct coronary angiography as a screening method acuurately identifies asymptomatic coronary artery disease in a high risk poulation (HL survivors after mediastinal irradiation), one year
Secondary Outcome Measures: prevalnce of cornary artery disease and frequency/type of subsequent intervention, to establish the prevelence of coronary abnormalities in HL survivors treated with mediastinal irradiation, and to determine the frequency and type of subsequent interventions, one year
Other Outcome Measures:
Sponsor: Leiden University Medical Center
Collaborators:
Sex: ALL
Age: ADULT
Phases: NA
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING
Other IDs: NL31278.058.10
Start Date: 2011-01
Primary Completion Date: 2013-06
Completion Date: 2013-06
First Posted: 2011-01-06
Results First Posted:
Last Update Posted: 2013-06-12
Locations: Leiden University Medical Center, Leiden, Zuid-Holland, 2300WB, Netherlands
Study Documents:

NCT Number: NCT03785704
Study Title: Clinical Study of Xinmailong Injection on Reducing Cardiovascular Toxicity in Adjuvant Chemotherapy in Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03785704
Acronym:
Study Status: RECRUITING
Brief Summary: Totally 60 subjects will be included in the study. The present study was aimed to observe and evaluate the effect of Xinmailong injection on reducing cardiovascular toxicity associated with adjuvant chemotherapy after breast cancer surgery. The primary endpoint was 6 months of cardiac safety. Secondary endpoints included 3 months of cardiac safety, adverse events (AE), severe adverse events (SAE), and DFS.
Study Results: NO
Conditions: Breast Neoplasms|Cardiac Event|Chemotherapeutic Toxicity
Interventions: DRUG: Xinmailong Injection
Primary Outcome Measures: The rate of no cardiac events during chemotherapy, Adverse events (AEs) and laboratory tests graded

according to the NCI CTCAE (version 4.0) .No cardiac events were defined until all relevant indicators (Electrocardiograph, Echcardiography and myocardial enzyme) were normal during chemotherapy., up to 12 months
Secondary Outcome Measures: Disease-free survival (DFS), The time between the start of a randomized clinical trial and the onset of disease recurrence or death from any cause, 5 years
Other Outcome Measures:
Sponsor: Peking Union Medical College
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: NCC1786
Start Date: 2019-01-01
Primary Completion Date: 2020-03-01
Completion Date: 2025-03-01
First Posted: 2018-12-24
Results First Posted:
Last Update Posted: 2020-01-22
Locations: National Cancer Center, Beijing, China
Study Documents:

NCT Number: NCT01280227
Study Title: Supporting Patient Provider Communication in Paediatric Care
Study URL: https://beta.clinicaltrials.gov/study/NCT01280227
Acronym: SiSom
Study Status: COMPLETED
Brief Summary: Children with Cancer or congenital heart disease (CHD) experience complex, physical, psychosocial and behavioural symptoms and problems due to the illness, treatment, and medical procedures. To help children cope with their problems and prevent psychological distress, the investigators developed SiSom, a support system to help children with cancer or CHD report their symptoms and problems in an age-adjusted manner on a touch-pad, portable computer.

This quasi-experimental study with 202 children age 7-12 with CHD or cancer will test the following hypotheses: When children use SiSom to report their symptoms and problems, and this information is provided to their clinicians in their outpatient consultations:

* Children and parents will experience less anxiety.
* Children and parents will be more satisfied with the outpatient visit.

* There will be greater congruence between children's reported symptoms and problems and those addressed by their clinicians as evidenced in documented patient care.

To better understand the mechanisms by which these effects may occur, the investigators will also explore:

* Differences between control and experimental groups in patient-provider communication in terms of instrumental and affective behaviour, participation, initiative and person addressed;
* The relationships among outcomes of patient-provider communication, congruence between patients' reported symptoms and those addressed by their clinicians and children's and parents' anxiety and satisfaction; and how these relationships differ between treatment and control conditions.

Finally, the investigators will investigate time requirements, ease of use and usefulness of SiSom by children and clinicians.

For analyses the investigators will use inferential statistics and qualitative analyses of the video-taped consultation sessions. This study will contribute to improving patient-centred care for a particularly vulnerable population, and to a better understanding of the triadic communication and interactions among child-parent and clinician.
Study Results: NO
Conditions: Cancer|Congenital Heart Disease
Interventions: BEHAVIORAL: SiSom
Primary Outcome Measures: Patient-provider communication, Single measure, video recording of medical consultation lasting approximately one hour
Secondary Outcome Measures: Patient-provider communication, Single measure, video recording of medical consultation lasting approximately one hour|Time requirements, ease of use, Single measure, after collection of all patient data|Congruence between children's reported symptoms and problems and those addressed by their clinicians as evidenced in documented patient care., Single measure, ten minutes post intervention|State anxiety, 10 minutes pre and 10 minutes post intervention
Other Outcome Measures:
Sponsor: Oslo University Hospital
Collaborators: The Research Council of Norway
Sex: ALL
Age: CHILD
Phases: NA
Enrollment: 144
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE

Other IDs: S-05288|175389/V50
Start Date: 2005-01
Primary Completion Date: 2010-10
Completion Date: 2016-07
First Posted: 2011-01-20
Results First Posted:
Last Update Posted: 2017-04-06
Locations: Rikshospitalet-Radiumhospitalet, Oslo, 0027, Norway
Study Documents:

NCT Number: NCT02199366
Study Title: Study of Cardiac MRI in Patients With Left-Sided Breast Cancer Receiving Radiation Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT02199366
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This is a pilot study to determine if there are changes in heart function following completion of radiation therapy for breast cancer as measured by cardiac magnetic resonance imaging (cardiac MRI) scans. Additional purposes of this study are to assess cardiac side effects from radiation treatment, evaluate cardiac MRI changes by radiation technique, and compare quality of life questionnaires.
Study Results: NO
Conditions: Breast Cancer
Interventions: PROCEDURE: Cardiac magnetic resonance (cardiac MRI)
Primary Outcome Measures: Proportion of participants with changes in cardiac function., A change in cardiac function may include shifts from baseline measures of LV mass, strain, ejection fraction, and late gadolinium enhancement., 1 year after completion of radiation therapy
Secondary Outcome Measures: Proportion of patients with serious cardiac side effects., Includes myocardial infarction, valve disorder, congestive heart failure, and angina., 1 year after completion of radiation therapy|Mean quality of life score., Comparison of baseline and post treatment quality of life questionnaires completed by participants., 1 year after radiation treatment
Other Outcome Measures:
Sponsor: University of Florida
Collaborators: Ocala Royal Dames
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 24
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UFPTI 1419-BR02|IRB201800163|UFJ 2014-116
Start Date: 2014-09
Primary Completion Date: 2021-07-07
Completion Date: 2025-04-22
First Posted: 2014-07-24

Results First Posted:
Last Update Posted: 2022-07-08
Locations: University of Florida Proton Therapy Institute, Jacksonville, Florida, 32206, United States
Study Documents:

NCT Number: NCT00436566
Study Title: Doxorubicin and Cyclophosphamide Followed By Trastuzumab, Paclitaxel, and Lapatinib in Treating Patients With Early-Stage HER2-Positive Breast Cancer That Has Been Removed By Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT00436566
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Drugs used in chemotherapy, such as doxorubicin, cyclophosphamide, and paclitaxel, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Monoclonal antibodies, such as trastuzumab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Lapatinib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Giving combination chemotherapy together with trastuzumab and lapatinib after surgery may kill any tumor cells that remain after surgery.

PURPOSE: This randomized phase II trial is studying the side effects and how well giving doxorubicin together with cyclophosphamide followed by trastuzumab, paclitaxel, and lapatinib works in treating patients with early-stage HER2-positive breast cancer that has been removed by surgery.
Study Results: YES
Conditions: Breast Cancer|Cardiac Toxicity
Interventions: BIOLOGICAL: trastuzumab|DRUG: cyclophosphamide|DRUG: doxorubicin hydrochloride|DRUG: lapatinib ditosylate|DRUG: paclitaxel|GENETIC: gene expression analysis|GENETIC: reverse transcriptase-polymerase chain reaction|OTHER: fluorophotometry|OTHER: laboratory biomarker analysis|OTHER: mass spectrometry|PROCEDURE: adjuvant therapy|PROCEDURE: quality-of-life assessment
Primary Outcome Measures: Number of Patients With Congestive Heart Failure (CHF) While on Active Treatment, 6 months
Secondary Outcome Measures: Adverse Event Profile as Measured by NCI CTCAE v 3.0, Measured by number of patients with at least one with grade 3+, Grade 4+, Hem, and Non-Hem AEs., 5 years|Cumulative Incidence (CI) of Cardiac Events, Evaluable patients included those completed the AC phase of their treatment regimen; with post AC cardiac evaluation indicates they are eligible to begin treatment with PTL; and those have begun their post-AC therapy.

Cardiac events: symptomatic congestive heart failure (CHF), cardiac death and other cardiac events (NCI Common Terminology Criteria for

Adverse Events (CTCAE) Grade \>=3), 5 years|Number of Patients Who Experience >= 10 Percent Drop in Left Ventricular Ejection Fraction (LVEF), Number of Patients Who Experience \>= 10 Percent Drop in Left Ventricular Ejection Fraction (LVEF) from baseline to any post-baseline time point., 5 years|Percentage of Participants With Disease-Free Survival (DFS), DFS was defined as the time from registration to the earliest date of documentation of any local, regional, or distant recurrence of breast cancer (BC); the development of a contralateral BC or second primary other than squamous or basal cell carcinoma of the skin, carcinoma in situ of the cervix, or lobular carcinoma in situ of the breast; or death from any cause without the documentation of one of these events. Participants were followed for a maximum of 5 years from randomization. The median OS with 95%CI was estimated using the Kaplan Meier method., 5 years|Percentage of Participants With Overall Survival (OS), OS was defined as the time from registration to death of any cause. Participants were followed for a maximum of 5 years from randomization. The median OS with 95%CI was estimated using the Kaplan Meier method., 5 years|Change in Overall LINEAR ANALOGUE SELF ASSESSMENT (LASA) and Change in Symptom Distress Scale (SDS) Overall QOL, LASA score is from 0-90 with 0 being the worst and 90 being the best. SDS score is from 13-65 with 65 being the worst and 13 being the best., 5 years|Proportion of Patients Experienced a Significant Decline in LINEAR ANALOGUE SELF ASSESSMENT (LASA) and a Overall Symptom Distress Scale (SDS) QOL Measurements, Overall Symptom Distress Scale (SDS) QOL Measurement and Overall LINEAR ANALOGUE SELF ASSESSMENT (LASA) QOL Measurement, 5 years|Incidence of Pulmonary Events, Pulmonary events to be included were grade 3 and higher pulmonary adverse events at least possibly related to study treatment, which occur at any time after post-AC treatment is begun, but prior to documentation of a breast cancer recurrence, contralateral breast cancer, secondary primary cancer, non-pulmonary death, or pulmonary death not related to study treatment., 5 years
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 122
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: |Primary Purpose: TREATMENT
Other IDs: CDR0000533793|P30CA015083|RC0639|06-004049
Start Date: 2007-03-16
Primary Completion Date: 2009-04
Completion Date: 2019-07-22
First Posted: 2007-02-19
Results First Posted: 2012-10-22
Last Update Posted: 2022-08-05

Locations: Mayo Clinic Cancer Research Consortium, Rochester, Minnesota, 55905, United States
Study Documents:

NCT Number: NCT01758419
Study Title: The Role of Myocardial SPECT in Evaluation of Irradiation-induced Changes.
Study URL: https://beta.clinicaltrials.gov/study/NCT01758419
Acronym:
Study Status: UNKNOWN
Brief Summary: Helical tomotherapy nowadays provides the most precise data on radiotherapy (RT) dose delivered to each region of the heart in left-sided breast cancer therapy, which allows greater sparing of the heart from doses associated with increased complications. However, heart disease shows a wide spectrum of pathologies, and multiple risk factors related. The damage of the myocytes may lead to not only myocardial perfusion defects, but also in functional deterioration, or even in biomarkers. In this study, we will monitor cardiovascular (CV) risk factors, metabolism, biomarkers, myocardial perfusion defect patterns, and cardiac functional parameters, in order to delineate of RT-related effects and clinical impacts.

Objective: The pilot study aims to investigate the correlation of post-tomotherapy cardiovascular effects with myocardial perfusion and cardiac functional studies.

Methods: The study plans to enroll female breast cancer patients who will undergo local RT after their surgery. Patients will receive global risk scoring assessment (Framingham Risk Score, FRS), blood sampling for basic biochemistry, inflammatory biomarker, and myocardial perfusion image (MPI) at the time points of before and after RT. The results of MPI will be analyzed in qualitative visual interpretation of perfusion patterns, and functional quantitative data for cardiac functional parameters as well. The patients will be regular followed-up in CV OPD. The association between baseline and follow-up MPI, biomarker and clinical presentation will be further investigated.
Study Results: NO
Conditions: Breast Cancer, Female
Interventions: RADIATION: Thallium-201 Myocardial Perfusion Study
Primary Outcome Measures: To investigate the correlation of post-RT cardiovascular effects with myocardial Tl-201 myocardial perfusion images, By literature reviewing, cardiovascular functional status in patients received helical tomography has not been fully investigated yet. And the post-therapeutic heart disease tends to show a wide spectrum of pathologies and multiple risk factors. We will monitor risk factors of underlying disease, family history, metabolism, biomarkers, myocardial perfusion defect patterns, and cardiac functional parameters, in order to delineation of RT-related effects and clinical prognosis., Dec, 2013 (after 12 months of baseline

study).
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Far Eastern Memorial Hospital
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 60
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: FEMH-IRB-101085-F
Start Date: 2012-12
Primary Completion Date: 2014-12
Completion Date: 2015-11
First Posted: 2013-01-01
Results First Posted:
Last Update Posted: 2014-05-08
Locations: Far Eastern Memorial Hospital, New Taipei City, 220, Taiwan
Study Documents:

NCT Number: NCT05784766
Study Title: Screening for Atrial Fibrillation in Patients With Cancer: A Pilot Randomized Controlled Clinical Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT05784766
Acronym: SARIC
Study Status: NOT_YET_RECRUITING
Brief Summary: Patients with cancer have a higher incidence of AF but despite the higher incidence of AF in the cancer population, there are no randomized controlled trials (RCTs) for AF screening in this population. RCTs of AF screening in the general population have shown that screening can effectively detect AF earlier, and helps to identify candidates for appropriate anticoagulation that may lead to improvement in clinical outcomes.
Study Results: NO
Conditions: Cancer
Interventions: DIAGNOSTIC_TEST: 30-second ECG using the Kardia Mobile| OTHER: routine care
Primary Outcome Measures: The Investigators will compare the incidence of newly diagnosed AF identified by screening versus usual care, To compare the incidence of newly diagnosed AF with point-of-care screening using a mobile, single-lead ECG versus usual care, in patients with a diagnosis of solid cancer. In this open-label, prospective pilot RCT, patients (n=480) with AF and solid cancer presenting for an outpatient visit will be randomized 1:1 to screening versus usual care. A 30-second screening ECG will be done using the Kardia Mobile device (AliveCor Inc, Cupertino, CA) paired with an iPad. The Investigators will compare the incidence of newly diagnosed AF identified by screening versus usual care., 6 MONTHS

Secondary Outcome Measures: To determine the effect of screening-detected AF on initiation of anticoagulation., To determine the effect of screening-detected AF on initiation of anticoagulation. Patients diagnosed with AF through screening will be referred to their primary care physician for initiation of anticoagulation based on their CHA2DS2VASc score.The Investigators will conduct chart review at the end of study to compare the proportion of patients appropriately initiated on anticoagulation between screening versus usual care., 6 MONTHS
Other Outcome Measures:
Sponsor: University of Oklahoma
Collaborators:
Sex: ALL
Age: OLDER_ADULT
Phases: NA
Enrollment: 480
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 15595
Start Date: 2023-07-01
Primary Completion Date: 2023-12-31
Completion Date: 2024-07-30
First Posted: 2023-03-27
Results First Posted:
Last Update Posted: 2023-03-27
Locations:
Study Documents:

NCT Number: NCT01480219
Study Title: Evaluation Of The Importance Of Risk-Factor Adjustment For Assessing The Relationship Between Voriconazole Utilization And The Development Of Non-Melanoma Skin Cancer Among Lung And Heart/Lung Transplant Patients, 2002-2009g
Study URL: https://beta.clinicaltrials.gov/study/NCT01480219
Acronym:
Study Status: COMPLETED
Brief Summary: The primary objective of the study is to assess the relationship (both crude and adjusted) between voriconazole utilization and the development of non-melanoma skin cancer among adult patients who received a lung or heart/lung transplant and were continuously enrolled in a large U.S. commercial health plan.
Study Results: YES
Conditions: Non-Melanoma Skin Carcinoma
Interventions: DRUG: voriconazole (Vfend)|OTHER: no voriconazole (Vfend)
Primary Outcome Measures: Number of Participants Who Developed Non-Melanoma Skin Cancer (NMSC), Baseline until non-melanoma skin cancer diagnosis, loss-to-follow-up due to death or termination of the health

plan or end of the study, assessed up to Year 8
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Pfizer
Collaborators: University of Southern California
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 467
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: A1501098
Start Date: 2011-08
Primary Completion Date: 2012-03
Completion Date: 2012-03
First Posted: 2011-11-28
Results First Posted: 2013-02-04
Last Update Posted: 2013-03-11
Locations:
Study Documents:

NCT Number: NCT02988219
Study Title: Cardiac Arrhythmias in Patients Undergoing Kidney Cancer Surgery Depending on the Anaesthesia Method
Study URL: https://beta.clinicaltrials.gov/study/NCT02988219
Acronym:
Study Status: COMPLETED
Brief Summary: This study evaluates the incidence of cardiac arrhythmias during the perioperative period in patients undergoing open kidney cancer surgery in the lateral position. All the participants will be randomly allocated to receive general (Group G) or combined epidural/general anaesthesia (Group G/E). The anaesthetic technique is standardized. The Holter monitor will be applied at the evening before the surgery, tracing continuously for a period of 24 hours (7PM-7PM)
Study Results: YES
Conditions: Arrhythmia, Cardiac|Kidney Cancer|Surgery|Anesthesia, Local
Interventions: DRUG: Bupivacaine-fentanyl|DEVICE: Holter ECG monitor|PROCEDURE: Open kidney cancer surgery|PROCEDURE: General anesthesia|PROCEDURE: Epidural Anaesthesia
Primary Outcome Measures: Incidence of Perioperative Cardiac Arrhythmias Evaluated by a Continuous ECG Holter Monitoring in the Perioperative Period, The investigator evaluates the incidence of cardiac arrhythmias, the type of arrhythmias and whether additional interventions were needed to treat them

Arrhythmias observed:

tachycardia \>100 bpm bradycardia \< 50 bpm pause (P-P interval \> 2 seconds) ventricular extrasystoles (VE) \> 1000/ 24 hours supraventricular extrasystoles (SVE) \>200/24 hours, 60 months
Secondary Outcome Measures: The Prevention of Cardiac Arrhythmias Occurence by Epidural Anesthesia Added to General Anesthesia Evaluated by a Number and Type of Arrhythmias Observed, The investigator evaluates the incidence of cardiac arrhythmias depending on anesthesia method by observing the number and type of arrhythmias and whether additional interventions were needed to treat them, 60 months
Other Outcome Measures:
Sponsor: Medical University of Warsaw
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: U/1/2010
Start Date: 2010-06
Primary Completion Date: 2014-12
Completion Date: 2016-12
First Posted: 2016-12-09
Results First Posted: 2017-01-16
Last Update Posted: 2017-05-30
Locations: I Department of Anaesthesiology and Intensive Care, Medical University of Warsaw, Warsaw, 02-005, Poland
Study Documents:

NCT Number: NCT03164148
Study Title: Heart Rate Variability (HRV) in Pituitary Adenoma
Study URL: https://beta.clinicaltrials.gov/study/NCT03164148
Acronym:
Study Status: UNKNOWN
Brief Summary: Several studies have been reported that heart rate is known to be associated with prognosis in chronic diseases and acute diseases. For example, a decrease in heart rate following myocardial infarction may lead to a higher mortality rate. It is also known to predict heart failure, diabetic neuropathy, and even depression.

The combined pituitary function test artificially induces hypoglycemia to observe the secretion of pituitary hormone. The degree of change in heart rate during hypoglycemia can predict the adequacy of the test, and heart rate can be changed according to the characteristic of the tumor. Also, the prognosis can be predicted based on this.

In our study, we used a licensed device approved by KFDA (Korea Food and Drug Administration) to measure heart rate variability in patients

with pituitary adenoma.
Study Results: NO
Conditions: Pituitary Adenoma
Interventions: DEVICE: T-REX TRI00A
Primary Outcome Measures: Changes in Heart rate variability according to the types of pituitary adenoma, 5 month of initial recruit
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Seoul St. Mary's Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: OTHER
Other IDs: KC17OESI0205
Start Date: 2017-05-17
Primary Completion Date: 2017-10-16
Completion Date: 2018-05-16
First Posted: 2017-05-23
Results First Posted:
Last Update Posted: 2017-05-23
Locations: Seoul St. Mary's hospital, Seoul, 06591, Korea, Republic of
Study Documents:

NCT Number: NCT04726319
Study Title: Family History App in Personalized Medicine
Study URL: https://beta.clinicaltrials.gov/study/NCT04726319
Acronym: FHAMe
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: A complete family history (FH) may identify persons at high risk for certain conditions. They can be offered genetic testing and life-saving screening and treatment. In practice, complete FH is rarely collected or entered into the electronic medical record (EMR). The Family History Screening Questionnaire is a survey patients complete to tell whether they are at increased risk of specific cancers, heart disease or diabetes. We will test a new way to record FH that includes an app to improve use of FH by family physicians and patients. The strategy includes education for patients and physicians about the importance of FH; patient completion of the FH questionnaire prior to appointments; and prompts in the EMR. We expect this to help family physicians and patients interpret FH and make the best decisions. We will assess the proportion of patients with new EMR FH information. We will explore if the strategy increases appropriate referrals for screening and genetic consultation for those at increased FH risk. We will also obtain patients' and physicians' feedback on this strategy. This new approach may improve FH

information exchange between patients and physicians, encourage shared decision-making and reduce cancer deaths and chronic disease burden.
Study Results: NO
Conditions: Cancer, Breast|Cancer, Ovarian|Cancer, Colorectal|Cancer, Prostate|Melanoma|Coronary Artery Disease|Diabetes Mellitus, Type 2
Interventions: OTHER: FHAMe Intervention
Primary Outcome Measures: Proportion of patients with new documentation of family history in EMR, The proportion of patients with new documentation of family history in the EMR within 30 days after the visit, compared to patients in control group practices, 30 days post visit|Positive family history documentation, The proportion of patients in the intervention arm with positive documented family history in the EMR, compared to patients in control group practices, 30 days post visit|Proportion of patients in each study arm with new documentation of family history in EMR, The proportion of patients with new documentation of family history in the EMR for each study arm as a whole, over the full 6-month period of the study, 6 months|Proportion of patients, for each consenting clinician, with new documentation of family history in EMR, The proportion of patients with new documentation of family history in the EMR for each consenting clinician, 6 months prior to the intervention and 6 months after, 1 year|Family history of breast/ovarian/colorectal/prostate cancer, Proportion of patients with documented family history of cancer in the EMR measured through the number of 1st degree relatives, 30 days post visit|Changes in risk-appropriate screening based on family history, Through the use of UTOPIAN data which is routinely collected and qualitative interviews with family physicians using semi-structured interview guides, we will explore whether the FH strategy enables risk-appropriate screening based on FH, and referral of patients at high FH risk to genetics, 30 days post visit
Secondary Outcome Measures: Recruitment rate, Rate of practice and participant recruitment during the intervention period, 6 months|Participation rate, Proportion of patients completing the questionnaire, and providers attending the webinar, reviewing family history, using clinical tools, and having family history discussions with patients, 6 months|Usage of family history information, Exploring how family history was obtained and used by patients and physicians through questionnaires and qualitative interviews, 30 days|Attitudes towards the FHAMe intervention, Exploring patient and team experiences and attitudes to the innovation through questionnaires and qualitative interviews, 30 days
Other Outcome Measures:
Sponsor: University of Toronto
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 627
Funder Type: OTHER
Study Type: INTERVENTIONAL

Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SCREENING
Other IDs: 20-0270-E
Start Date: 2021-09-20
Primary Completion Date: 2022-06-30
Completion Date: 2023-12
First Posted: 2021-01-27
Results First Posted:
Last Update Posted: 2022-08-15
Locations: Mount Sinai Hospital, Toronto, Ontario, M5G 1X5, Canada
Study Documents:

NCT Number: NCT02688166
Study Title: Cardiac MRI Biomarker Testing (GCC 1618)
Study URL: https://beta.clinicaltrials.gov/study/NCT02688166
Acronym:
Study Status: TERMINATED
Brief Summary: This research study can help understand how cardiac changes may occur with radiation therapy to the heart based off measurements obtained through biomarkers and cardiac imaging.

Researchers plan to perform cardiac imaging and biomarkers for any cardiac injury. Cardiac magnetic resonance imaging (CMR) provides the ability to quantitatively measure cardiac function and injury. The cardiac biomarkers that will be tested are effective in the diagnosis, risk-stratification, and monitoring of heart failure.
Study Results: NO
Conditions: Breast Cancer|Lung Cancer (Non-Small Cell)|Thoracic Cancer|Thymic Cancer|Mesothelioma
Interventions: OTHER: Complete Cardiac Magnetic Resonance Imaging (MRI)
Primary Outcome Measures: Evaluate for evidence of changes in cardiac function measured by cardiac MRI prior to and following external beam radiotherapy who are receiving moderate doses of radiation to the heart., Baseline and 2 years|Evidence of changes in cardiac function as measured by serum biomarkers following external beam radiotherapy who are receiving moderate doses of radiation to the heart., Baseline and 2 years
Secondary Outcome Measures: Correlate changes in cardiac function measured by cardiac MRI with radiotherapy dose volume histograms evaluating multiple components of the heart., Baseline and 2 years|Correlate changes in cardiac function measured by serum biomarkers with radiotherapy dose volume histograms evaluating multiple components of the heart., Baseline and 2 years
Other Outcome Measures:
Sponsor: University of Maryland, Baltimore
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:

Enrollment: 6
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: HP-00068503
Start Date: 2018-02-01
Primary Completion Date: 2022-09-09
Completion Date: 2022-09-09
First Posted: 2016-02-23
Results First Posted:
Last Update Posted: 2022-10-13
Locations: Ummc Msgccc, Baltimore, Maryland, 21201, United States
Study Documents:

NCT Number: NCT01082419
Study Title: Acoustic Radiation Force Impulse Imaging (ARFI) : a New Technique to Assess Liver Elasticity
Study URL: https://beta.clinicaltrials.gov/study/NCT01082419
Acronym: NARFI
Study Status: COMPLETED
Brief Summary: Liver stiffness measurement (LSM) by non invasive methods is increasingly used to estimate liver fibrosis in patients with chronic liver diseases. However, there is growing evidence that fibrosis is not the only determinant of liver stiffness. Indeed inflammation, cholestasis, congestion could also interfere with stiffness measurements. Acoustic radiation force impulse imaging (ARFI) is a new technology to perform real time LSM. Using a standard ultrasonographic probe, it offers elastography with a flexible metering box at variable depth, allowing the examination of specific area.
Study Results: NO
Conditions: Liver Fibrosis|Liver Cirrhosis|Viral Hepatitis|Liver Tumour|Cardiac Failure|Biliary Cholestasis.
Interventions: DEVICE: ARFI measurement|DEVICE: ARFI measurement|DEVICE: ARFI measurement
Primary Outcome Measures: The elasticity parameter will be for each patient the median of ten ARFI values (m/s) in the right liver., One or two 30 min visit according to the patient group
Secondary Outcome Measures: Inter and intra observer reproducibility, Three 30 min visits in healthy volunteer group.|Median (m/s) of ARFI values between before and after effective treatment for liver reversible disease, From patient admission until patient healing in groups F&G.
Other Outcome Measures:
Sponsor: University Hospital, Bordeaux
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 109

Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: CHUBX 2009/21
Start Date: 2010-04
Primary Completion Date: 2013-04
Completion Date: 2013-04
First Posted: 2010-03-08
Results First Posted:
Last Update Posted: 2014-11-07
Locations: University Hospital Bordeaux, Bordeaux, 33075, France
Study Documents:

NCT Number: NCT00782366
Study Title: Predictive Genetic Risk Assessment Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT00782366
Acronym: PGT
Study Status: COMPLETED
Brief Summary: This proof-of-principle clinical trial at Mayo Clinic studies how patients and their physicians understand and utilize predictive genetic risk assessment. A critical goal of this clinical trial is to understand how individual patients and their doctors perceive and respond to genetic risk information that is largely uncertain.
Study Results: NO
Conditions: Colon Cancer|Lung Cancer|Atrial Fibrillation|Diabetes Type 2|Obesity|Breast Cancer|Graves Disease|Osteoarthritis|Celiac Disease|Myocardial Infarction|Prostate Cancer
Interventions: GENETIC: SNP analysis
Primary Outcome Measures: Assess accessibility and feasibility, including positive and negative aspects of integrating predictive genomics at the clinic focusing on patients' and physicians' attitudes, March 2008-March 2009
Secondary Outcome Measures: Assess effects of predictive genomics on self-reported health behavior and on physician-patient interaction, March 2008-March 2009
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 26
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 07-007414
Start Date: 2008-03
Primary Completion Date: 2010-01

Completion Date: 2010-01
First Posted: 2008-10-31
Results First Posted:
Last Update Posted: 2011-04-27
Locations: Mayo Clinic, Rochester, Minnesota, 55905, United States
Study Documents:

NCT Number: NCT01724450
Study Title: Carvedilol Effect in Preventing Chemotherapy - Induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT01724450
Acronym: Ceccy
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate if carvedilol can prevent the cardiotoxicity after chemotherapy in breast cancer.
Study Results: NO
Conditions: Breast Cancer|Heart Failure|Cardiotoxicity
Interventions: DRUG: Carvedilol|DRUG: Placebo
Primary Outcome Measures: Prevention of systolic dysfunction in patients undergoing chemotherapy with anthracycline. Systolic dysfunction is characterized by a 10% drop in ejection fraction of left ventricle., 96 weeks
Secondary Outcome Measures: Prevention of myocardial injury measured by the levels of biomarkers (ultrasensitive troponin, BNP and miRNA-208) Effect of carvedilol in the prevention of diastolic dysfunction., 96 weeks
Other Outcome Measures:
Sponsor: University of Sao Paulo
Collaborators: Hospital A.C. Camargo|Instituto do Cancer do Estado de São Paulo
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: Ceccy Trial
Start Date: 2013-04
Primary Completion Date: 2017-06
Completion Date: 2017-06
First Posted: 2012-11-09
Results First Posted:
Last Update Posted: 2018-02-05
Locations: Heart Institute University of Sao Paulo, Sao Paulo, 05403-000, Brazil
Study Documents:

NCT Number: NCT04856267
Study Title: Exploration of Arrhythmia Burden in Cardiac Amyloidosis Using Implantable Loop Recorders
Study URL: https://beta.clinicaltrials.gov/study/NCT04856267
Acronym: EXACLIBUR
Study Status: RECRUITING
Brief Summary: The overall aim of this study is to improve our understanding of the effects of the build-up of amyloid deposits in the heart, in particular, our understanding of the risk of abnormal heart beats, or rhythms, associated with people with cardiac (heart) amyloidosis. Symptoms such as palpitations (fast, strong or irregular heart beat) and blackouts are common in people with cardiac amyloidosis, but there is not enough information on what causes this. At present, there is also not enough information on when they occur, how often they happen, and which patients are at risk of having serious, life-threatening types of abnormal heart rhythms.

Some of these abnormal heart rhythms can be treated with medicine; others need electronic devices (e.g. pacemakers) implanted or inserted in the heart to prevent serious harm. The information on when is the best time to implant these life-saving devices remains limited. In this study, a small device known as an implantable loop recorder (ILR) will be implanted under the skin on the chest wall to continuously monitor participants' heart rhythm.

This will help us answer some of the questions about what causes the abnormal heart rhythms, when they happen, and which patients are particularly likely to have them. Furthermore, it may help us to identify earlier, rather than later, those who are at risk of developing abnormal heart rhythms. This may lead to improvements in the care of people with cardiac amyloidosis in the future. Participants may not directly benefit from taking part in this study; however, there is a chance that the ILR may reveal heart rhythm abnormalities in some participants which might not be picked up otherwise, and so may lead to a change in their treatment.
Study Results: NO
Conditions: Arrythmia|Cardiac Amyloidosis|Systemic AL Amyloidosis|Sudden Cardiac Death
Interventions: DEVICE: LINQ device - implantable cardiac monitor - referred to in the application as "implantable loop recorder" or "ILR")
Primary Outcome Measures: Explore the characteristics (incidence and nature) of significant heart rhythm disturbances in subjects with cardiac amyloidosis by means of implantable cardiac monitor (ILR), Primary outcome measure is the presence of any clinically significant heart rhythm abnormality as revealed from the implantable cardiac monitor (ILR) over the course of the study, Through study completion, up to 2 years
Secondary Outcome Measures: Examine the correlation between the characteristics of cardiac arrhythmias, as revealed by implantable

cardiac monitor (ILR) with findings from other structural and functional assessment performed as standard of care (SOC), Secondary outcome measure is the correlation of heart rhythm disturbances identified from the implantable cardiac monitor (ILR), with other structural and functional variables obtained from other SOC tests such as, but not limited to, T1 mapping and ECV from CMR, serum biomarkers and the six-minute walk test (6MWT) distance, Through study completion, up to 2 years
Other Outcome Measures:
Sponsor: Marianna Fontana
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 20/NS/0038
Start Date: 2021-05-27
Primary Completion Date: 2023-05
Completion Date: 2023-05
First Posted: 2021-04-23
Results First Posted:
Last Update Posted: 2021-09-30
Locations: Royal Free London NHS Foundation Trust, London, NW3 2QG, United Kingdom
Study Documents:

NCT Number: NCT01510743
Study Title: Ultrasound Guided Central Vein Catheterization and Complications
Study URL: https://beta.clinicaltrials.gov/study/NCT01510743
Acronym:
Study Status: COMPLETED
Brief Summary: There has been no study comparing the complication rates between internal jugular vein catheterization and subclavian vein catheterization when they are performed using sonographic view. This prospective study would reveal the sort of complication and its rate.
Study Results: NO
Conditions: Brain Tumor
Interventions: PROCEDURE: Catheterization of subclavian vein|PROCEDURE: Catheterization of internal jugular vein
Primary Outcome Measures: complication, any one of arterial puncture, hematoma, pneumothorax, hemothorax, during central vein catheterization and operation day
Secondary Outcome Measures: Access time, from penetration of skin to aspiration of venous blood into the syringe, during central venous catheterization|Number of attempts, once/twice/three times, during

central venous catheterization|catheter tip placement, After reviewing the postoperative chest X ray film, we will check the position of the central venous catheter tip. The possible pisition of catheter tip is as follows:

(1) Superior vena cava and Rirht Atrium junction (2)Right internal jugular vein (3)Left Internal jugular vein (4)Right Axillary vein (5)Lt. Axillary vein, postoperative 1 day
Other Outcome Measures:
Sponsor: Seoul National University Bundang Hospital
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1484
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: B1112_069_003
Start Date: 2012-01-30
Primary Completion Date: 2018-04
Completion Date: 2018-04
First Posted: 2012-01-16
Results First Posted:
Last Update Posted: 2018-08-27
Locations: Seoul National University Bundang Hospital, Seongnam, Gyounggi, 463-707, Korea, Republic of
Study Documents:

NCT Number: NCT05635266
Study Title: A Single-Site Tissue Repository Providing Annotated Biospecimens for Approved Investigator-directed Biomedical Research Initiatives
Study URL: https://beta.clinicaltrials.gov/study/NCT05635266
Acronym:
Study Status: RECRUITING
Brief Summary: To collect, preserve, and/or distribute annotated biospecimens and associated medical data to institutionally approved, investigator-directed biomedical research to discover and develop new treatments, diagnostics, and preventative methods for specific and complex conditions.
Study Results: NO
Conditions: Age-Related Macular Degeneration|Allergies|Alpha-Gal Syndrome|Alzheimer Disease|Amyloidosis|Ankylosing Spondylitis|Arthritis|Alopecia Areata|Asthma|Atopic Dermatitis|Autism|Autoimmune Hepatitis|Behcet's Disease|Beta-Thalassemia|Cancer|Celiac Disease|Kidney Diseases|COPD|Crohn Disease|Cystic Fibrosis|Diabetes|Dravet Syndrome|DMD|Fibromyalgia|Graves Disease|Thyroid Diseases|Hepatitis|Hidradenitis Suppurativa|ITP|Leukemia|ALS|Lupus or SLE|Lymphoma|

Multiple Sclerosis|Myasthenia Gravis|Heart Diseases|Parkinson Disease|
Pemphigus Vulgaris|Cirrhosis|Psoriasis|Schizophrenia|Scleroderma|
Sickle Cell Disease|Stroke|Ulcerative Colitis|Vasculitis|Vitiligo
Interventions: DIAGNOSTIC_TEST: Specimen sample
Primary Outcome Measures: Biospecimen & Clinical Data Collection, To collect enough biospecimens and associated clinical data to allow researchers to come to statistically relevant scientific results, 10 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Sanguine Biosciences
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 20000
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SAN-BB-02
Start Date: 2021-10-26
Primary Completion Date: 2023-10
Completion Date: 2023-10
First Posted: 2022-12-02
Results First Posted:
Last Update Posted: 2022-12-02
Locations: Sanguine Biosciences, Waltham, Massachusetts, 02451, United States
Study Documents:

NCT Number: NCT03603366
Study Title: Study to Evaluate How Patients Regard the Benefits and Risks of Low-dose Aspirin for the Prevention of Heart and Blood Vessels Disease and for the Prevention of Cancer of the Colon and Rectum
Study URL: https://beta.clinicaltrials.gov/study/NCT03603366
Acronym:
Study Status: COMPLETED
Brief Summary: Research shows that low-dose Aspirin prevents diseases of heart and blood vessels as well as cancer of the colon and rectum and it is also associated with risk of bleeding. In this study, they want to learn how patients regard the benefits and risks of low-dose Aspirin for the prevention of these diseases. The researchers also want to learn how patients balance these risks and benefits.
Study Results: NO
Conditions: Cardiovascular Disease|Colorectal Cancer
Interventions: DRUG: Acetylsalicylic acid (Aspirin, BAYE4465)
Primary Outcome Measures: Perceive of low dose aspirin, Using qualitative interviews to assess how patients and physicians perceive the benefits and risks of low-dose aspirin for the prevention of

cardiovascular disease (CVD) and colorectal cancer (CRC), Up to 1 hour|Patients' benefit/risk trade-offs, Using quantitative surveys to elicit patients' benefit/risk trade-offs on key efficacy and safety outcomes of low-dose aspirin in CVD and CRC prevention, Up to 1 hour
Secondary Outcome Measures: Change in likelihood of AEs, Quantify the change in likelihood of adverse events (AEs) that patients are willing to accept in order to experience the benefits of low-dose aspirin for CRC and CVD prevention compared to CVD prevention alone, Up to 1 hour|Preferences of aspirin using in different subgroups, Assess how different subgroups of patients, such as those using low-dose aspirin and those eligible for but not using low-dose aspirin, differ in their preferences, Up to 1 hour
Other Outcome Measures:
Sponsor: Bayer
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1028
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 20211
Start Date: 2019-08-14
Primary Completion Date: 2019-10-14
Completion Date: 2019-10-14
First Posted: 2018-07-27
Results First Posted:
Last Update Posted: 2020-10-05
Locations: Many locations, Multiple Locations, Italy
Study Documents:

NCT Number: NCT01849614
Study Title: Assessment of Ability of Breath Hold for Left-sided Breast Cancer Radiation Therapy to Reduce Side Effects to Heart
Study URL: https://beta.clinicaltrials.gov/study/NCT01849614
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this research study is to demonstrate that Deep Inspiration Breath Hold (DIBH), the technique used at the University of North Carolina (UNC) for left-side breast cancer radiation therapy, can reduce side effects to the heart.
Study Results: NO
Conditions: Breast Cancer
Interventions: OTHER: Cardiac SPECT perfusion scan
Primary Outcome Measures: Changes in cardiac perfusion, Cardiac perfusion will be assessed using SPECT cardiac perfusion scans pre- and 6 months post-radiation. Any post-radiation summed-rest score (SRS) \> 0 will be counted as a perfusion defect in the calculation of the perfusion defect rate., 6-months post radiation

Secondary Outcome Measures: Wall-motion abnormalities, The incidence of wall-motion abnormalities will be assessed using SPECT in the same 12 segment scoring system used to quantify perfusion. Wall-motion abnormalities will be recorded as present or absent in each cardiac segment. When present, wall-motion abnormalities wil be classified as gypokinetic, akinetic, or dyskinetic. The extent of wall involvement (small or large portion) will be described as mild or severe., 6-months post-treatment
Other Outcome Measures:
Sponsor: UNC Lineberger Comprehensive Cancer Center
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 25
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: LCCC1239
Start Date: 2013-03
Primary Completion Date: 2016-03
Completion Date: 2016-03
First Posted: 2013-05-08
Results First Posted:
Last Update Posted: 2016-05-12
Locations: University of North Carolina at Chapel Hill, Department of Radiation Oncology, Chapel Hill, North Carolina, 27599, United States
Study Documents:

NCT Number: NCT03137537
Study Title: Ivabradine in the Management of Cardiac Autonomic Dysfunction Associated With Thoracic Radiation Therapy.
Study URL: https://beta.clinicaltrials.gov/study/NCT03137537
Acronym:
Study Status: TERMINATED
Brief Summary: This study will explore whether ivabradine lowers heart rate, and thus improves exercise capacity, in survivors of lymphoma who have an elevated resting heart rate as a side effect of prior radiation treatment.

The drugs involved in this study are:

* Ivabradine
* Placebo
Study Results: YES
Conditions: Lymphoma|Autonomic Imbalance|Cancer Survivorship
Interventions: DRUG: Ivabradine|DRUG: Placebo Oral Tablet
Primary Outcome Measures: To Investigate Whether Ivabradine Lowers Resting HR, Compared To Placebo, In Survivors Of Lymphoma, Calculate the change in resting HR (from Holter monitor data) from baseline to 6

weeks for each patient in the study. Then compare the median change with ivabradine to the median change with placebo., 6 weeks
Secondary Outcome Measures: To Evaluate Whether Ivabradine Improves Exercise Duration, Compared To Placebo, In Survivors Of Lymphoma, Calculate the change in exercise duration (from exercise treadmill stress tests) from baseline to 6 weeks for each patient in the study. Then compare the median change in exercise duration with ivabradine to the median change in exercise duration with placebo., 6 weeks
Other Outcome Measures: To Evaluate Whether Ivabradine Improves Additional Markers of Cardiac Sympatho-vagal Balance, Compared To Placebo, In Survivors Of Lymphoma, Calculate the change in cardiac autonomic function (from cardiac autonomic function testing) from baseline to 6 weeks in one half of the patients in the study (n=30), 6 weeks|To Evaluate Whether Ivabradine Improves Health Related Quality Of Life Compared To Placebo, In Survivors Of Lymphoma, Calculate the change in health related quality of life (from SF-36 quality of life surveys) from baseline to 6 weeks for each patient in the study (n=60), 6 weeks
Sponsor: Dana-Farber Cancer Institute
Collaborators: Amgen
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 23
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: TREATMENT
Other IDs: 17-022
Start Date: 2018-02-27
Primary Completion Date: 2020-11-18
Completion Date: 2020-11-18
First Posted: 2017-05-02
Results First Posted: 2022-01-19
Last Update Posted: 2022-02-10
Locations: Massachusetts General Hospital, Boston, Massachusetts, 02114, United States|Boston Children Hospital, Boston, Massachusetts, 02115, United States|Brigham and Women's Hospital, Boston, Massachusetts, 02115, United States
Study Documents: Study Protocol and Statistical Analysis Plan|Informed Consent Form

NCT Number: NCT05934214
Study Title: EXploring Immune-related Adverse Events of Immune checkpoinT Inhibitors Using VigiBase, the WHO Pharmacovigilance Database
Study URL: https://beta.clinicaltrials.gov/study/NCT05934214
Acronym: EXIT
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This is an observational, retrospective

pharmacovigilance study based on reports registered and transmitted in VigiBase®, the WHO's international database.

This study includes all reports identified as exposure to an ICI and suspect of inducing adverse drug reaction.

The aim of the study is to characterize immune-related adverse reactions associated with immune-checkpoint inhibitors, particularly their time-to-onset, co-occurence, factors associate with their over-report and fatality.
Study Results: NO
Conditions: Cancer|Immune-related Adverse Event|Immune Checkpoint Inhibitor-Related Myocarditis
Interventions: DRUG: Immune checkpoint inhibitor
Primary Outcome Measures: Factors associated with an increased rate of fatality among reports with an immune-related adverse event (irAE)., Reports with a fatal outcome will be compared to reports with no fatal outcome. Odds ratio will be calculated to compare covariates potentially associated with an increase risk of fatality, including irAE type, cancer type reported, patient's age, gender, comorbidities, type of ICI or ICI combination and other treatments., any report prior to january 2023
Secondary Outcome Measures: Factors associated with an increased reporting of main irAE types, Main irAEs are identified through MedDRA terms declared. For each irAE and each risk factors, an odds ratio will be calculated to assess a potential over-reporting. Factors evaluated will include but will not be limited to: cancer type, anticancer treatment type, socio-demographic variables (gender, age, country of reporting etc ...), year of reporting among others., any report prior to january 2023|Time to onset for each irAE type, any report prior to january 2023|Rate of relapse with treatment rechallenge, For each irAE, the rate (percentage) of irAE reccurence after treatment rechallenge., any report prior to january 2023
Other Outcome Measures:
Sponsor: Groupe Hospitalier Pitie-Salpetriere
Collaborators: Institut Curie
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 141630
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CIC1421-23-05
Start Date: 2023-01-01
Primary Completion Date: 2023-07-01
Completion Date: 2023-07-01
First Posted: 2023-07-06
Results First Posted:
Last Update Posted: 2023-07-06

Locations: AP-HP, Pitié-Salpêtrière Hospital, Department of Pharmacology, CIC-1421, Pharmacovigilance Unit, INSERM., Paris, 75013, France|CIC Paris-Est, Paris, 75013, France
Study Documents:

NCT Number: NCT05761314
Study Title: Solid Tumors in RASopathies
Study URL: https://beta.clinicaltrials.gov/study/NCT05761314
Acronym: 4218
Study Status: RECRUITING
Brief Summary: RASopathies are a group of syndromes, caused by variants of genes involved in the regulation of the Ras/MAP/ERK pathway. This intracellular transduction pathway profoundly affects embryogenic development, organogenesis, synaptic plasticity and neuronal growth.

RASopathies are characterized by multi-organ involvement, growth delay, premature aging and haemato-oncological manifestations.

Based on evidences provided by literature, cancer screening protocols are applied in some individuals affected by RASopathies, even though detailed information about prevalence and molecular pathogenesis of such tumors is still not clearly elucidate.
Study Results: NO
Conditions: RASopathy|Costello Syndrome|Cardio-Facio-Cutaneous Syndrome|Noonan Syndrome
Interventions: DIAGNOSTIC_TEST: Molecular characterization of solid tumor in RASopathies
Primary Outcome Measures: Prevalence of solid tumors in RASopathies, To detect prevalence of solid tumors in monocentric cohort of RASopathies, 5 years
Secondary Outcome Measures: Molecular characterization of solid tumors in RASopathies, NGS analysis on tumor tissue samples, 5 years
Other Outcome Measures:
Sponsor: Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 4218
Start Date: 2021-10-12
Primary Completion Date: 2023-10-30
Completion Date: 2026-10-12
First Posted: 2023-03-09
Results First Posted:

Last Update Posted: 2023-03-09
Locations: Department of Woman and Child Health and Public Health, Fondazione Policlinico A. Gemelli, IRCCS, Roma, 00168, Italy
Study Documents:

NCT Number: NCT02149914
Study Title: The Changes of Ryodoraku and HRV After PPI Treatment in GERD Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02149914
Acronym:
Study Status: UNKNOWN
Brief Summary: Gastroesophageal reflux disease(GERD) mainly related to the reflux of stomach content induced by the dysfunction of lower esophageal sphincter. Proton pump inhibitors (PPI) can effectively block gastric acid secretion but the drug reactions and the degree of improvement in symptoms are sometimes unpredictable. The aim of this study is to investigate the association between the clinical efficacy of PPI in patients with GERD and the personal physical status by Ryodoraku and ANSWatch.
Study Results: NO
Conditions: Non-erosive Reflux Disease|Barrett's Esophagus
Interventions: DEVICE: Ryodoraku|DEVICE: ANSWatch|DEVICE: UGI endoscopy|OTHER: GerdQ|DRUG: PPI
Primary Outcome Measures: gastroesophageal reflux disease questionnaire, To assess the severity of GERD, four weeks
Secondary Outcome Measures: Upper gastrointestinal endoscopy, To assess the grade of reflux esophagitis, four weeks
Other Outcome Measures:
Sponsor: Taichung Tzu Chi Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING
Other IDs: REC103-20
Start Date: 2014-05
Primary Completion Date: 2016-07
Completion Date: 2016-07
First Posted: 2014-05-29
Results First Posted:
Last Update Posted: 2014-11-20
Locations: Taichung Tzu Chi Hospital, Taichung City, 427, Taiwan
Study Documents:

NCT Number: NCT04939883
Study Title: Effects of Carvedilol on Cardiotoxicity in Cancer

Patients Submitted to Anthracycline Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04939883
Acronym: CardioTox
Study Status: RECRUITING
Brief Summary: Neoplasia is the main cause of general death in the Brazilian population. In 2016, they were responsible for approximately 211,343 (16%) deaths, followed by cardiovascular diseases (12.6%). Despite the high mortality rate of neoplasia, oncological treatment have advanced substantially in recent decades improving the prognosis of patients. However, growing evidence suggest that some oncological agents may induce significant toxicity that may play a major role in the quality of life, morbidity and mortality. The cardiovascular system is often negatively affected with cancer therapy, predisposing several patients to stop appropriate treatments or to have cardiovascular events related to the cardiotoxicity. The most typical manifestation of cardiotoxicity and related consequences (heart failure) are related to the use of anthracyclines. Anthracyclines are part of the chemotherapy regimen for solid tumors and hematological neoplasms in children and adults, and are associated with an increase in life expectancy. Carvedilol is an α and β-blocker that also has antioxidant properties. Preliminary studies have shown that carvedilol and its metabolites prevent lipid peroxidation, inhibit the formation and inactivate free radicals, in addition to preventing the depletion of endogenous antioxidants, such as vitamin E. These effects would potentially prevent anthracycline injury but definitive evidence is still needed. This is a multi-center, double-blind, randomized, placebo-controlled study that aims to establish the efficacy of carvedilol for the primary prevention of left ventricular systolic dysfunction in cancer patients obtained with anthracycline chemotherapy, in different schedules and doses.
Study Results: NO
Conditions: Cancer
Interventions: DRUG: Carvedilol|DRUG: Placebo
Primary Outcome Measures: Drop in ejection fraction within 12 months of starting treatment., Drop in ejection fraction\> 10% to values less than 50% of the left ventricle, 12 months|Cardiac events within 12 months of starting treatment., Cardiac events such as death, resuscitated cardiac arrest, myocardial infarction, heart failure and cardiac arrhythmias, 12 months
Secondary Outcome Measures: Drop in ejection fraction within 24 months., Drop in ejection fraction greater than 10% and values less than 55%, 24 months|Reduction in myocardial strain in 24 months from the start of treatment., Relative reduction of more than 15% in myocardial strain, 24 months|Diastolic dysfunction within 24 months, Development of diastolic dysfunction within 24 months, 24 months|Elevation of biomarkers during chemotherapy and up to 24 months of follow-up, Elevation of biomarkers (NT-pro BNP and troponin) during chemotherapy and up to 24 months of follow-up, 24 months|Quality of life (EuroQol-5D)., Quality of life measured by questionnaire in up to 24 months., 24 months|Cardiovascular complications in 24 months.,

Cardiovascular complications (death, resuscitated cardiac arrest, myocardial infarction, heart failure and cardiac arrhythmias) in 24 months., 24 months
Other Outcome Measures: Diagnosis of neoplasia within 24 months., Diagnosis of another neoplasia, 24 months|Progression of oncological disease within 24 months., Progression of oncological disease, 24 months|Tumor recurrence within 24 months., Tumor recurrence, 24 months.
Sponsor: Hospital Sirio-Libanes
Collaborators: Ministry of Health, Brazil
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 1018
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: AVAP-NG 989
Start Date: 2021-08-01
Primary Completion Date: 2023-12-30
Completion Date: 2024-12-30
First Posted: 2021-06-25
Results First Posted:
Last Update Posted: 2022-09-21
Locations: Hospital Sirio Libanes, São Paulo, Sao Paulo, 01308-050, Brazil
Study Documents:

NCT Number: NCT03760237
Study Title: Cardiovascular Function in Acute Leukemia
Study URL: https://beta.clinicaltrials.gov/study/NCT03760237
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: An observational, prospective study to describe the rates and predictors of cardiovascular events in patients with acute leukemia.
Study Results: NO
Conditions: Leukemia, Myeloid, Acute|Leukemia, Lymphoid, Acute|Cardiotoxicity
Interventions: OTHER: observation only
Primary Outcome Measures: Left Ventricular dysfunction, defined as a reduction in Left Ventricular Ejection Fraction of more than 10 percentage points from baseline and to less than 50%., 1 year
Secondary Outcome Measures: Incidence of Cardiovascular Events, 1 year|Incidence of Symptomatic Heart Failure, 1 year|Incidence of Cardiac Death and all mortality, 1 year
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine

Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 130
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC48418
Start Date: 2018-12-10
Primary Completion Date: 2023-12
Completion Date: 2023-12
First Posted: 2018-11-30
Results First Posted:
Last Update Posted: 2022-06-02
Locations: Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT00924937
Study Title: CORonary Diet Intervention With Olive Oil and Cardiovascular PREVention
Study URL: https://beta.clinicaltrials.gov/study/NCT00924937
Acronym: CORDIOPREV
Study Status: COMPLETED
Brief Summary: The purpose of this study is to compare the effects of the consumption of two different dietary patterns (low fat versus Mediterranean Diet) on the incidence of cardiovascular events of persons with coronary disease.
Study Results: NO
Conditions: Myocardial Infarction|Unstable Angina|Malignancy|Cognitive Decline|Diabetes Mellitus|Metabolic Syndrome
Interventions: BEHAVIORAL: Mediterranean Diet|BEHAVIORAL: Low Fat Diet
Primary Outcome Measures: Combined apparition of hard cardiovascular events (myocardial infarction, revascularization, ischemic stroke, documented peripheral artery disease or cardiovascular death) after a median follow-up of 7 years., Combined apparition of hard cardiovascular events (myocardial infarction, revascularization, ischemic stroke, documented peripheral artery disease or cardiovascular death) after a median follow-up of 7 years., Seven Years
Secondary Outcome Measures: Evolution of arteriosclerosis: Evaluation of arteriosclerosis at different vascular beds. Silent arteriosclerosis., Data from clinical and/or diagnostic tests will be analyzed, Seven Years|Concentration of LDL cholesterol., Concentration of LDL cholesterol in blood samples, Seven Years|Atherogenic ratio, and Total cholesterol/HDL and LDL/HDL., Comparison of Atherogenic ratio, and Total cholesterol/HDL and LDL/HDL during the study, Seven Years|Metabolic control of carbohydrates (assessed by glycemic and insulin responses to intravenous tolerance test to glucose, basal

glycemia and hba1c)., Study of the metabolism of carbohydrates during the trial, Seven Years|Blood pressure., Study of blood pressure in response to the study, Seven Years|Incidence of malignancy., Appearance of malignancy, Seven Years|Progression of Cognitive Decline., Cognitive decline will be evaluated by validated questionnaires, Seven Years|Extended composite of cardiovascular disease progression, Incidence of cardiac death, myocardial infarction, angina event, coronary revascularization or cardiac transplant, stroke, symptomatic heart failure, or any other clinical manifestation of cardiovascular event., Seven Years|Extended composite of heart events, Incidence of cardiac death , myocardial infarction , unstable angina , revascularization, heart failure, heart transplantation, cardiac arrest, Seven Years|Incidence of type 2 Diabetes Mellitus, Incidence of type 2 Diabetes Mellitus during the study, Up to Seven Years|Anthropometric changes. Metabolic disease, Clinical features of metabolic disease: Metabolic Syndrome, Metabolic Phenotypes of Obesity or other classifications based on anthropometric features will be assessed during the study, Up to Seven Years|Gut Microbiota, Changes in the percentage of different families of Microbiota will be analyzed during the study, and their impact on clinical events., Up to Seven Years|Arrhythmias, Study of relationship between existing or new Arrhythmias on clinical events, Up to Seven Years|Individual evaluation of all components of the primary outcome., Individual apparition of hard cardiovascular events:

* myocardial infarction
* revascularization
* ischemic stroke
* documented peripheral artery disease
* cardiovascular death, Up to Seven Years|Global Metabolomics, Global metabolomics in plasma, as well as techniques targeting specific sets of metabolites such as lipid-based lipid species, protein by proteomics, etc., Up to Seven Years|Specific metabolomics, Specific metabolomics in plasma fractions, specific bioparticles such as lipoproteins or specific cells, lipidomics, proteomics, targeted metabolomics, etc, Up to Seven Years|Gene Expression, Changes in Gene Expression using transcriptomic techniques such as gene expression microarrays, quantitative PCR, GeneChip, etc, Up to Seven Years| Inflammation and oxidative stress, Different physiological processes or metabolic pathways related to inflammation and oxidative stress will be studied, Up to Seven Years|AGEs, Metabolism of advanced glycation end products., Up to Seven Years|Mineral metabolism, Impact of mineral metabolism on atherosclerosis, Up to Seven Years| Echographic markers of cardiac function and clinical outcomes, Cardiac function studies by Echocardiography at baseline and during the study, Up to Seven Years|Microparticles, Study of endothelial microparticles (vesicles formed from endothelial cells membrane after injury). The quantification of the EPCs and EMPs will be performed by flow cytometry, Up to Seven Years|Subgroup analysis, 27. Differential impact on certain subgroups: Sex, age, anthropometry, genetics,

genomics, metabolism of immediate principles, cardiovascular risk factors, cancer, vascular function, Up to Seven Years
Other Outcome Measures: Endothelial function (Flow mediated dilation), Endothelium response to ischemia in the brachial artery. Area under the curve, flow peak and time to maximum flow will be performed, Up to Seven Years|genetics, genomics and epigenetics, Influence of genetic data in the development clinical outcomes, Up to seven years| postprandial lipaemia, Postprandial lipemia study based on oral fat tolerance test depending on clinical and genetic variables, Up to seven years|Study of other Clinical events, Clinical events not qualifying as primary endpoint nor in the secondary objectives 1 and 2, especially those associated with cardiovascular disease, Up to seven years|Subgroup Studies, Differential impact on certain subgroups: Sex, age, anthropometry, genetics, genomics, metabolism of immediate principles, cardiovascular risk factors, cancer, vascular function, Up to seven years|Further Studies, Additional secondary objectives will be carried out in light of current and/or future knowledge of ischemic heart disease risk factors, prognostic factors and pathophysiological pathways, and will include, but not be limited to, endothelial function, inflammation, cell biology, molecular biology, proteomics, genetics and epigenetics, Up to Seven Years
Sponsor: Hospital Universitario Reina Sofia de Cordoba
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1002
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: CORDIOPREV
Start Date: 2009-11
Primary Completion Date: 2018-07
Completion Date: 2021-05
First Posted: 2009-06-19
Results First Posted:
Last Update Posted: 2021-06-03
Locations: Reina Sofia University Hospital, Cordoba, 14001, Spain
Study Documents:

NCT Number: NCT00779285
Study Title: Safety Study of CAELYX in Patients With Metastatic Breast Cancer Previously Treated With Anthracyclines (Study P04057) (TERMINATED)
Study URL: https://beta.clinicaltrials.gov/study/NCT00779285
Acronym:
Study Status: TERMINATED
Brief Summary: The purpose of this study is to evaluate the cardiac safety of Caelyx in patients with metastatic breast cancer who have

previously received chemotherapy with anthracyclines.
Study Results: YES
Conditions: Breast Neoplasm
Interventions: DRUG: Pegylated Liposomal Doxorubicin
Primary Outcome Measures: Cardiac Events, A cardiac event was defined as a decrease in left ventricular ejection fraction (LVEF) of \>=20 points from baseline if the resting LVEF remained in the normal range, or a decrease of \>=10 points if the LVEF became abnormal (lower than the institutional lower limit of normal)., Every 4 weeks during 6 cycles.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Merck Sharp & Dohme LLC
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 1
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: P04057|EUDRACT NO. 2004-001177-25
Start Date: 2006-02
Primary Completion Date: 2006-08
Completion Date: 2006-08
First Posted: 2008-10-24
Results First Posted: 2010-02-11
Last Update Posted: 2015-07-14
Locations:
Study Documents:

NCT Number: NCT00655447
Study Title: Examining the Long-Term Risks of Oophorectomy
Study URL: https://beta.clinicaltrials.gov/study/NCT00655447
Acronym:
Study Status: COMPLETED
Brief Summary: At the time of hysterectomy for benign disease, the overall health benefits of preserving ovarian function in a large population of women have not been established.
Study Results: NO
Conditions: Coronary Heart Disease|Stroke|Breast Cancer|Ovarian Cancer|Cancer|Hip Fracture|Death
Interventions:
Primary Outcome Measures: mortality and morbidity due to the following conditions: coronary heart disease, stroke, breast cancer, ovarian cancer, other cancer, hip fracture and death from all causes., 28 years
Secondary Outcome Measures: The effect of postmenopausal hormone use on mortality and morbidity due to the following conditions: coronary

heart disease, stroke, breast cancer, ovarian cancer, other cancer, hip fracture and death from all causes., 28 years
Other Outcome Measures:
Sponsor: Parker, William H., M.D.
Collaborators: Ethicon, Inc.
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 32175
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PARW-OVCONS-0307
Start Date: 1980-01
Primary Completion Date: 2004-06
Completion Date: 2004-06
First Posted: 2008-04-09
Results First Posted:
Last Update Posted: 2008-04-09
Locations: Parker, Rosenman, Rodi Gynecology Group, Santa Monica, California, 90401, United States
Study Documents:

NCT Number: NCT02084147
Study Title: PET-MRI in Diagnosing Patients With Cancer, Cardiac Diseases, or Neurologic Diseases
Study URL: https://beta.clinicaltrials.gov/study/NCT02084147
Acronym:
Study Status: COMPLETED
Brief Summary: This randomized pilot clinical trial studies how well positron emission tomography (PET)-magnetic resonance imaging (MRI) works compared to standard-of-care PET-computed tomography (CT) in diagnosing patients with cancer, cardiac diseases, or neurologic diseases. PET-MRI combines two imaging methods that can be used to evaluate disease. PET-MRI is similar to standard-of-care PET-CT, but exposes the patient to less radiation. It is not yet known whether PET-MRI produces better image quality than PET-CT in diagnosing patients with cancer, cardiac disease, or neurologic disease.
Study Results: YES
Conditions: Cardiac Disease|Dementia|Inflammatory Disease|Fever of Unknown Origin|Vasculitis|Osteomyelitis|FDG Avid Cancers
Interventions: DEVICE: positron emission tomography|DEVICE: computed tomography|DEVICE: magnetic resonance imaging
Primary Outcome Measures: Overall Image Quality Scores, Overall image quality scores obtained from the two imaging modalities will be compared with the hypothesis that hybrid PET-MRI images is as good as PET-CT images or superior (not inferior) to the PET-CT images. Evaluation of overall image quality will be assessed using the following criteria: 1=excellent, 2=good, 3=acceptable, 4=poor, 5=not acceptable. A Wilcoxon (Mann-Whitney) rank-sum test with a 0.100

significance level will be used., Day 1|Lesion Based Standard Uptake Values (SUV), Lesion based SUV will be estimated and compared for PET-MR and PET-CT images in normal organs and compared. A two-sided two-sample t-test will be used to show significance of difference., Day 1|Area Under the Receiver Operating Characteristic Curve, A two-sided z-test will be used to detect the difference in the area under the curve showing the sensitivity, specificity, positive and negative predictive values as well as accuracy of diagnostic information., Day 1|Time Effort Associated With the PET-MRI Versus PET-CT With MRI, Statistical difference in time between PET-MRI versus sequential approach for PET-CT plus MRI. Workflow with shortest timely efforts and sufficient diagnostic information will be established as routine procedure., Day 1|Radiation Dose Reduction With PET-MRI, Dose measurements will be used to calculate effective radiation dose in each patient. Dose calculations of effective dose will be used to estimate dose savings in omitting the CT component of PET-CT. Statistical tests will use a 0.10 significance level and will be 2-sided, Day 1
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Case Comprehensive Cancer Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 72
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: CASE16Z12|NCI-2014-00376|CASE16Z12|P30CA043703
Start Date: 2013-03-07
Primary Completion Date: 2016-09-14
Completion Date: 2018-10-02
First Posted: 2014-03-11
Results First Posted: 2019-10-11
Last Update Posted: 2019-10-29
Locations: Case Comprehensive Cancer Center, Cleveland, Ohio, 44106-5065, United States
Study Documents:

NCT Number: NCT05594485
Study Title: Retrospective Study of Carebot AI CXR Performance in Preclinical Practice
Study URL: https://beta.clinicaltrials.gov/study/NCT05594485
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to describe the design, methodology and evaluation of the preclinical test of Carebot AI CXR software, and to provide evidence that the investigated medical device meets user requirements in accordance with its intended use. Carebot

AI CXR is defined as a recommendation system (classification "prediction") based on computer-aided detection. The software can be used in a preclinical deployment at a selected site before interpretation (prioritization, display of all results and heatmaps) or after interpretation (verification of findings) of CXR images, and in accordance with the manufacturer's recommendations. Given this, a retrospective study is performed to test the clinical effectiveness on existing CXRs.
Study Results: NO
Conditions: Artificial Intelligence|Lung Diseases|Pneumothorax|Pleural Effusion|Cardiomegaly|Lung Cancer|Pulmonary Edema|Consolidation|Pneumonia|Atelectasis|Hilar Calcification|Fracture Rib
Interventions: DEVICE: Carebot AI CXR
Primary Outcome Measures: Primary objective, Comparison of the accuracy of radiologist and Carebot AI CXR image assessment., 20-10-2022
Secondary Outcome Measures: Secondary objective, Comparison of the accuracy of radiologis with different experience vs. Carebot AI CXR. Weakness assessment of Carebot AI CXR., 20-10-2022
Other Outcome Measures:
Sponsor: Carebot s.r.o.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 127
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 00001
Start Date: 2022-08-15
Primary Completion Date: 2022-08-17
Completion Date: 2022-10-20
First Posted: 2022-10-26
Results First Posted:
Last Update Posted: 2023-07-13
Locations: Nemocnice Havířov, p. o., Havířov, 73601, Czechia
Study Documents:

NCT Number: NCT04037319
Study Title: Atrial Fibrillation After Surgery for Colorectal Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT04037319
Acronym: AFAR
Study Status: RECRUITING
Brief Summary: This study will report the incidence of atrial fibrillation after elective colorectal cancer resection in the over 65 age group. This will be used to validate a risk model for the development of post-operative atrial fibrillation.

Eligible patients will undergo electrocardiogram based screening for

atrial fibrillation, as well as brain natriuretic peptide tests prior to surgery. They will undergo 24 hour holter monitor prior to surgery, and at 30 and 90 days following surgery.

The primary outcome will be occurrence of atrial fibrillation within 90 days of surgery. Secondary outcomes include quality of life change, use of hospital services for atrial fibrillation, and complications of atrial fibrillation. This will be used to validate the pre-existing model for prediction of atrial fibrillation.
Study Results: NO
Conditions: Colorectal Cancer|Atrial Fibrillation New Onset
Interventions: DIAGNOSTIC_TEST: 24 Hour Holter Monitor
Primary Outcome Measures: Incidence of atrial fibrillation within 90 days of colorectal cancer surgery, defined as ≥30 seconds of atrial fibrillation identified on a 24-hour cardiac monitor OR absence of p waves and irregularly irregular rhythm on an electrocardiogram, 24-hour recordings will be undertaken at 30 \& 90 days post surgery, and electrocardiogram on the day of discharge from hospital., Within 90 days of colorectal cancer surgery
Secondary Outcome Measures: Quality of life change (EQ-5D-5L (Euroqol-five dimension-five level), Quality of life change as measured using EQ-5D-5L from baseline to 90 days post-surgery calculated as population adjusted health index based on total score. In the UK population this can range from -0.594 to 1.0. Higher values are associated with better quality of life scores. A positive change in quality of life index means improved quality of life., Within 90 days of colorectal cancer surgery|Occurrence of complications of atrial fibrillation, Includes stroke and embolic events, Within 90 days of colorectal cancer surgery|Number of events of use of health services for atrial fibrillation or sequelae of atrial fibrillation, Number of events where health services accessed (e.g. primary care, hospital) including for treatment of atrial fibrillation or consequences such as cardiac failure, thromboembolism, or stroke., Within 90 days of colorectal cancer surgery
Other Outcome Measures:
Sponsor: Sheffield Teaching Hospitals NHS Foundation Trust
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 720
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: STH20223
Start Date: 2020-01-16
Primary Completion Date: 2023-12-31
Completion Date: 2024-03-31
First Posted: 2019-07-30
Results First Posted:

Last Update Posted: 2021-10-08
Locations: Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, South Yorkshire, S5 7AU, United Kingdom
Study Documents:

NCT Number: NCT03984019
Study Title: Cardiac Changes After Stereotactic Radiotherapy for Early Stage NSCLC Cancer or Lung Metastasis
Study URL: https://beta.clinicaltrials.gov/study/NCT03984019
Acronym: HALO
Study Status: TERMINATED
Brief Summary: The investigators aim to optimize the radiation treatment of early stage lung cancer patients. Therefore, detailed understanding is needed of the type of toxicity and the location of these toxicities for patients who receive high fraction doses. These have not been measured in these patients before, therefore our primary research question is: is it possible to measure changes in cardiac condition after radiotherapy, with respect to cardiac arrhythmias, fibrosis, hemodynamic function change and pericarditis?
Study Results: NO
Conditions: Lung Cancer Stage I|Lung Cancer Stage II|Lung Metastases
Interventions: DIAGNOSTIC_TEST: Cardiac condition measurements
Primary Outcome Measures: Percentage of patients with a change in cardiac condition, Percentage of patients with at least 5% change in cardiac arrhythmia (outcome 2) and/or at least 5% change in fibrosis (outcome 3) and/or at least 5% change in hemodynamic function (outcome 4) and/or development of pericarditis post-treatment (outcome 5), 1 year|Percentage of change in cardiac arrhythmia, Percentage of change in ECG-derived QRS duration (s) between Pre- and Post-treatment values, 1 year|Percentage of change in fibrosis, Percentage of change in MRI-derived Extra Cellular Volume (cc) between Pre- and Post-treatment values, 1 year|Percentage of change in hemodynamic function, Percentage of change in MRI- and echocardiography-derived ejection fraction (%) between Pre- and Post-treatment values, 1 year|Binary change in pericarditis status, Presence of pericarditis signs on MRI post-treatment while absence of pericarditis signs pre-treatment: yes/no, 1 year
Secondary Outcome Measures: Local fibrosis, Is there a correlation between the presence of local fibrosis and dose to this region, 1 year|Morphology changes, Are changes in morphology visible on the MRI scans made during treatment, compared to the pre treatment MRIs, 1 year
Other Outcome Measures:
Sponsor: The Netherlands Cancer Institute
Collaborators: Dutch Cancer Society
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 10
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING
Other IDs: M19CCR
Start Date: 2021-01-13
Primary Completion Date: 2023-04-01
Completion Date: 2023-04-01
First Posted: 2019-06-12
Results First Posted:
Last Update Posted: 2023-05-24
Locations: Netherlands Cancer Institute, Amsterdam, 1066CX, Netherlands|Amsterdam UMC, location AMC, Amsterdam, 1105AZ, Netherlands|Leids Universitair Medisch Centrum (LUMC), Leiden, 2333ZA, Netherlands
Study Documents:

NCT Number: NCT04790266
Study Title: Early Detection of Cardiotoxicity From Systemic and Radiation Therapy in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04790266
Acronym: CARDIOTOX
Study Status: RECRUITING
Brief Summary: To assess the role of myocardial oedema on CMR (T2 mapping) after radiation therapy and cardiotoxic systemic therapy in predicting the incidence of cardiotoxicity, defined as by consensus guidelines* (decline of LVEF ≥10% points with a final LVEF \<53%) measured on CMR and ECHO over the time window of 12 months from the end of radiation therapy.
Study Results: NO
Conditions: Cardiotoxicity
Interventions: DIAGNOSTIC_TEST: Cardiac MRI
Primary Outcome Measures: CMR T2 mapping, To assess the role of myocardial oedema on CMR (T2 mapping) after radiation therapy and cardiotoxic systemic therapy in predicting the incidence of cardiotoxicity, defined as by consensus guidelines* (decline of LVEF ≥10% points with a final LVEF \<53%)., Time window of 12 months from the end of radiation therapy
Secondary Outcome Measures: GLS, To detect GLS decrease \>15% from baseline, measured on Echo over the time window of 12 months, Time window of 12 months from the end of radiation therapy|Myocardial edema, To assess the incidence of myocardial oedema on CMR (T2 mapping) after radiation therapy and cardiotoxic systemic therapy.

To assess the incidence of myocardial oedema on ECHO after radiation therapy and cardiotoxic systemic therapy., Time window of 12 months from the end of radiation therapy|Biomarkers (Troponine, pro-BNP, hs-CRP) correlate with LVEF, To see if the changes in Troponine (ng/L) will correlate with LVEF measurements, assessed by ECHO. To see if the changes in Troponine (ng/L) will correlate with LVEF measurements, assessed by CMR.

To see if the changes in pro-BNP (ng/L) will correlate with LVEF measurements, assessed by ECHO.

To see if the changes in pro-BNP (ng/L) will correlate with LVEF measurements, assessed by CMR.

To see if the changes in hs-CRP (mg/L) will correlate with LVEF measurements, assessed by ECHO.

To see if the changes in hs-CRP (mg/L) will correlate with LVEF measurements, assessed by CMR., Time window of 12 months from the end of radiation therapy|Biomarkers (Troponine, pro-BNP, hs-CRP) correlated with GLS, To see if the changes in Troponine (ng/L) will correlate with GLS measurements, assessed by ECHO.

To see if the changes in pro-BNP (ng/L) will correlate with GLS measurements, assessed by ECHO.

To see if the changes in hs-CRP (mg/L) will correlate with GLS measurements, assessed by ECHO., Time window of 12 months from the end of radiation therapy|Time to biomarkers (Troponine, pro-BNP, hs-CRP) increase, To compare the time to the Troponine (ng/L) positivity to the time to the decrease in GLS \>15% and/or decline of LVEF ≥10% points with a final LVEF \<53% measured on Echo.

To compare the time to the pro-BNP (ng/L) positivity to the time to the decrease in GLS \>15% and/or decline of LVEF ≥10% points with a final LVEF \<53% measured on Echo.

To compare the time to the hs-CRP (mg/L) positivity to the time to the decrease in GLS \>15% and/or decline of LVEF ≥10% points with a final LVEF \<53% measured on Echo., Time window of 12 months from the end of radiation therapy|Biomarkers (Troponine, pro-BNP, hs-CRP) predictors of cardiotoxicity, To see if the changes in Troponine (ng/L) will correlate with developement of cardiotoxicity, defined as by decline of LVEF ≥10% points with a final LVEF \<53%.

To see if the changes in pro-BNP (ng/L) will correlate with developement of cardiotoxicity, defined as by decline of LVEF ≥10% points with a final LVEF \<53%.

To see if the changes in hs-CRP (mg/L) will correlate with developement of cardiotoxicity, defined as by decline of LVEF ≥10% points with a final LVEF \<53%., Time window of 12 months from the end of radiation therapy|Major cardiovascular events, To detect major cardiovascular events (defined as acute myocardial infarction, hospitalization due to heart failure, atrial flutter/fibrillation, ventricular tachycardia) or death due cardiac problems during the follow up, follow-up|cardiac fibrosis, assess the role of fibrosis on

CMR (T1 mapping with evaluation of extracellular volume) after cardiotoxic radiation therapy and systemic therapy in predicting the incidence of cardiotoxicity, through study completion, an average of 1 year|acute asymptomatic pericarditis, incidence of acute asymptomatic pericarditis after radiation therapy, measured on CMR, through study completion, an average of 1 year|cardiac edema, investigate if the area of the edema on CRM correlates with RT dose distribution, through study completion, an average of 1 year
Other Outcome Measures:
Sponsor: Oncology Institute of Southern Switzerland
Collaborators: Cardiocentro Ticino|North Estonia Medical Centre|Fondazione IRCCS Policlinico San Matteo di Pavia
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 150
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2019-01395CE3508
Start Date: 2020-09-15
Primary Completion Date: 2024-12-31
Completion Date: 2024-12-31
First Posted: 2021-03-10
Results First Posted:
Last Update Posted: 2023-03-23
Locations: Oncology Institute of Italian Switzerland, Bellinzona, Ticino, 6500, Switzerland
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT05320406
Study Title: RElugolix VErsus LeUprolide Cardiac Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT05320406
Acronym: REVELUTION
Study Status: RECRUITING
Brief Summary: This phase IV clinical trial investigates the impact of prostate cancer treatment, specifically androgen deprivation therapy (ADT), on the heart and coronary vessels among men with localized, non-metastatic prostate cancer undergoing definitive radiation therapy and concomitant ADT. Recently, cardiovascular toxicity from hormone therapy that is routinely used for prostate cancer (e.g. leuprolide) has emerged as a concern, yet studies identifying who is at risk and the mechanism of cardiac damage are lacking. Additionally, a new hormone therapy drug, relugolix, has recently been Food and Drug Administration (FDA)-approved and may reduce toxicity to the heart. This trial intends to investigate the mechanism of cardiovascular toxicity from ADT, investigate the mechanism by which relugolix reduces cardiovascular toxicity, and identify predictive biomarkers to improve individualized risk-assessment for cardiovascular toxicity from ADT.

Study Results: NO
Conditions: Biochemically Recurrent Prostate Carcinoma|Localized Prostate Carcinoma|Stage I Prostate Cancer AJCC v8|Stage II Prostate Cancer AJCC v8|Stage IIA Prostate Cancer AJCC v8|Stage IIB Prostate Cancer AJCC v8|Stage IIC Prostate Cancer AJCC v8|Stage III Prostate Cancer AJCC v8|Stage IIIA Prostate Cancer AJCC v8|Stage IIIB Prostate Cancer AJCC v8|Stage IIIC Prostate Cancer AJCC v8
Interventions: RADIATION: Radiation therapy|DRUG: Leuprolide|DRUG: Relugolix
Primary Outcome Measures: Coronary plaque volume in major coronary arteries (i.e. left anterior descending, left circumflex, right major coronary arteries), Using cardiac computed tomography angiography (CCTA), coronary plaque volume will be determined by measuring extent of coronary vessel luminal stenosis on an ordinal scale 0-100% as defined by the Society of Cardiac Computed Tomography. Change in luminal stenosis from baseline to month 12 will be tested using paired tests (Wilcoxon signed rank test or McNemar test). The incidence of moderate-to-severe atherosclerosis (defined as \>50% luminal stenosis of a major coronary vessel) at month 12 will be compared between the three treatment groups using Fisher's exact test. Finally, the percent change of maximal stenosis from baseline to month 12 between the three treatment arms will be compared using Kruskal-Wallist test followed by pairwise Wilcoxon signed rank test (P-value adjusted for multiple testing using Holm-Bonferroni method). Multivariable adjustment will be utilized that control for anti-platelet/coagulation and statin use using general logistic regression., From baseline to 12 months post-treatment initiation|Incidence of high-risk coronary plaque features at month 12 after treatment initiation, Using CCTA, high-risk plaque features, categorized as positive remodeling, low attenuation plaque, and spotty calcium, will be measured at month 0 and month 12 for each treatment arm. Differences in incidence of high-risk plaque features amongst the three treatment arms will be compared using Fisher's exact test. Multivariable adjustment will be utilized that control for anti-platelet/coagulation and statin use using general logistic regression., From baseline to 12 months post-treatment initiation|Major adverse cardiovascular events, Incidence of myocardial infarction, need for coronary revascularization, and/or sudden cardiac death will be measured for up to 2 years following enrollment. Incidence curves will be estimated by the Kaplan-Meier method and compared between the three treatment arms using a two-sided log-rank test followed by pairwise comparisons with Bonferonni correction., From baseline to at least 2 years post-treatment initiation
Secondary Outcome Measures: Acute and late patient-reported morbidity, Adverse events will be assess using patient-reported outcomes (PRO) questionnaires including EPIC-26, IPSS, and SHIM scoring. Assessment will be collected before and at the end of radiotherapy treatment and in follow-up. For each symptom and each domain (i.e. frequency, severity, and interference), counts and frequencies will be provided for the worst score experienced by the patient by treatment arm. The proportion of patients with scores \>=1 and \>=3 will be compared

between groups using a chi-square test (or Fisher's exact test if cell frequencies are \<5)., Baseline and month 0, 3, 6, 12, 18, 24| Testosterone kinetics, Change in total and free testosterone levels will be measured at baseline and month 0, 3, 6, and 12 between treatment arms. Testosterone change over time will be summarized and plotted over time for each treatment arm. Testosterone levels over time will be assessed using mixed effects regression modeling., Baseline and month 0, 3, 6, 12
Other Outcome Measures:
Sponsor: Emory University
Collaborators: National Cancer Institute (NCI)
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 94
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: STUDY00003654|NCI-2022-00117|STUDY00003654|RAD5484-21|P30CA138292
Start Date: 2022-06-06
Primary Completion Date: 2024-04-29
Completion Date: 2025-04-29
First Posted: 2022-04-11
Results First Posted:
Last Update Posted: 2023-06-13
Locations: Emory Proton Therapy Center, Atlanta, Georgia, 30308, United States|Emory University Hospital Midtown, Atlanta, Georgia, 30308, United States|Emory University/Winship Cancer Institute, Atlanta, Georgia, 30322, United States|Emory Saint Joseph's Hospital, Atlanta, Georgia, 30342, United States
Study Documents:

NCT Number: NCT00333008
Study Title: A Dose Study of Doxil in a Dose Dense, 14 Day CDOP/Rituximab Regimen for Patients With Diffuse Large B-Cell Non-Hodgkin Lymphoma (NHL)> 60 Years or With Compromised Cardiac Status.
Study URL: https://beta.clinicaltrials.gov/study/NCT00333008
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to evaluate the feasibility and tolerability of delivering a full dose, on time schedule of dose-dense CDOP-R (cyclophosphamide, doxil, vincristine, prednisone, and rituximab) in NHL.
Study Results: NO
Conditions: Diffuse Large B Cell Lymphoma|Lymphoma, Non-Hodgkin
Interventions: DRUG: Doxil|DRUG: Cyclophosphamide|DRUG: Vincristine|DRUG: Prednisone|DRUG: Rituximab|DRUG: Pegfilgrastim
Primary Outcome Measures: Safety assessment: National Cancer Institute

(NCI) Common Terminology Criteria for Adverse Events (CTACAE) v3.0|
Efficacy: tumor evaluations every three (q 3) cycles
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: The Alvin and Lois Lapidus Cancer Institute
Collaborators: Ortho Biotech Products, L.P.
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 27
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: LY-012006
Start Date: 2006-05
Primary Completion Date:
Completion Date:
First Posted: 2006-06-02
Results First Posted:
Last Update Posted: 2006-09-26
Locations: Sinai Hospital of Baltimore, Baltimore, Maryland, 21215, United States|Northwest Hospital Center, Randallstown, Maryland, 21133, United States
Study Documents:

NCT Number: NCT03266809
Study Title: CARdiac Function Evaluation in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT03266809
Acronym: CARE-B
Study Status: COMPLETED
Brief Summary: This study will investigate the influence of systemic adjuvant/neoadjuvant therapy (SAT: chemotherapy +/- anti-HER2 antibodies (trastuzumab +/- pertuzumab) on heart function/rhythm and cardio-respiratory fitness in recently diagnosed breast cancer patients. In some patients, SAT damages the heart (so-called 'cardiotoxicity') and this can have a serious impact on the patient's quality of life and overall survival. It has also been suggested that anticancer therapies may lead to repolarization abnormalities, QT prolongation and autonomic dysfunction, clinically reflected by an increase in HR and a reduction in heart rate variability (HRV). There is a lack of information in the literature regarding the extent and time-course of changes in cardiac function, cardiac rhythm and cardio-respiratory performance ('fitness') in these patients. Moreover, the differential influences of specific treatment regimes (e.g. SAT or SAT plus radiotherapy) and different chemotherapy drugs on cardio-respiratory performance remain unclear. A better understanding of these issues is the primary aim of this study.
Study Results: NO
Conditions: Breast Cancer Female

Interventions:
Primary Outcome Measures: Cardiac Function (stroke volume or ejection fraction), Cardiac function during/following treatment in breast cancer patients., At completion of treatment, an average of 13 months|Cardiac Rhythm (heart rate variability), Cardiac rhythm during/following treatment in breast cancer patients., At completion of treatment, an average of 13 months
Secondary Outcome Measures: Physical activity level (accelerometer-based activity level 'counts'), Physical activity level during/following treatment in breast cancer patients., At completion of treatment, an average of 13 months|Cardiorespiratory function (rate of respiratory oxygen uptake), Cardiorespiratory function during/following treatment in breast cancer patients., At completion of treatment, an average of 13 months|Body mass composition (from DEXA scan), Body fat mass and fat-free mass, and bone mineral density, At completion of treatment, an average of 13 months
Other Outcome Measures:
Sponsor: Swansea University
Collaborators: Abertawe Bro Morgannwg University Health Board
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 17
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 188676
Start Date: 2017-08-01
Primary Completion Date: 2019-09-28
Completion Date: 2020-04-01
First Posted: 2017-08-30
Results First Posted:
Last Update Posted: 2022-12-01
Locations: Singleton Hospital, Swansea, Wales, SA2 8PP, United Kingdom
Study Documents:

NCT Number: NCT01152606
Study Title: A Study of Cardiac Safety in Patients With HER2 Positive Early Breast Cancer Treated With Herceptin
Study URL: https://beta.clinicaltrials.gov/study/NCT01152606
Acronym:
Study Status: COMPLETED
Brief Summary: This is a single cohort observational safety study. All patients will be treated and monitored according to the local clinical practice. No additional procedures/patient visits in comparison with the usual clinical practice are planned for the study. Data will be collected from centre's medical records for up to 5 years or death.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: trastuzumab [Herceptin]

Primary Outcome Measures: Incidence of symptomatic congestive heart failure\n(CHF) using New York Heart Association class II, III and IV, and cardiac death, On treatment and up to 5 years follow-up
Secondary Outcome Measures: Time to onset and the time to recovery of symptomatic congestive heart failure, On treatment and up to 5 years follow-up|Incidence of asymptomatic cardiac failure and other significant cardiac conditions, On treatment and up to 5 years follow-up
Other Outcome Measures:
Sponsor: Hoffmann-La Roche
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 3942
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: BO20652
Start Date: 2007-08-30
Primary Completion Date: 2016-05-31
Completion Date: 2016-05-31
First Posted: 2010-06-29
Results First Posted:
Last Update Posted: 2018-01-25
Locations: Lkh-Univ. Klinikum Graz; Klinik Für Gynäkologie, Graz, 8036, Austria|LKH-UNIV. KLINIKUM GRAZ; Klinische Abteilung für Onkologie, Graz, 8036, Austria|Lhk Klagenfurt; Abt. Für Gynäkologie, Klagenfurt, 9026, Austria|LKH Hochsteiermark; Abt. für Innere Medizin, Leoben, 8700, Austria|Ordensklinikum Linz Barmherzige Schwestern; Abt. fur Innere Medizin 1, Linz, 4010, Austria|Lhk Feldkirch; Interne Medizin Abt., Rankweil, 6830, Austria|Lkh Salzburg - Univ. Klinikum Salzburg; Iii. Medizinische Abt., Salzburg, 5020, Austria|A. Ö. Krankenhaus Der Barmherzigen Brüder; Abt. Für Chirurgie, St Veit An Der Glan, 9300, Austria|A.Ö. Lhk; Ii. Medizinische Abt. Mit Schwerpunkt Gaströnter. & Onkologie, Steyr, 4400, Austria|Lhk Vöcklabruck; Ii. Interne Abt., Vöcklabruck, 4840, Austria|Klinikum Kreuzschwestern Wels; Iv. Interne Abt., Wels, 4600, Austria| Krankenanstalt Rudolfstiftung; I. Med. Abt., Wien, 1030, Austria| Medizinische Universität Wien; Univ.Klinik für Frauenheilkunde - Klinik für Gynäkologie, Wien, 1090, Austria|Medizinische Universität Wien; Univ.Klinik für Innere Medizin I, Wien, 1090, Austria| Wilhelminenspital; I. Medizinische Abt., Wien, 1160, Austria|ZNA Middelheim, Antwerpen, 2020, Belgium|CH EpiCURA Site Louis Caty, Baudour, 7331, Belgium|AZ KLINA, Brasschaat, 2930, Belgium|AZ Sint Jan, Brugge, 8000, Belgium|HIS (Etterbeek Ixelles), Bruxelles, 1050, Belgium|Hospital Erasme; Neurologie, Bruxelles, 1070, Belgium| Cliniques Universitaires St-Luc, Bruxelles, 1200, Belgium|UZ Antwerpen, Edegem, 2650, Belgium|AZ Groeninge (Kennedylaan), Kortrijk, 8500, Belgium|CHU Sart-Tilman, Liège, 4000, Belgium|Clinique Ste-

Elisabeth, Namur, 5000, Belgium|Clinique St Pierre asbl, Ottignies, 1340, Belgium|AZ Delta (Campus Wilgenstraat), Roeselare, 8800, Belgium|AZ Nikolaas (Sint Niklaas), Sint Niklaas, 9100, Belgium|AZ Turnhout Sint Elisabeth, Turnhout, 2300, Belgium|Sint Augustinus Wilrijk, Wilrijk, 2610, Belgium|Studienzentrum Aschaffenburg, Aschaffenburg, 63739, Germany|Internist; Praxis Für Haemotologie & Onkologie, Bad Soden, 65812, Germany|Brustzentrum Bassum, Bassum, 27211, Germany|Onkologische Schwerpunktpraxis Kurfürstendamm, Berlin, 10707, Germany|Praxis Dr. Schoenegg, Berlin, 10719, Germany|DRK Kliniken Berlin Köpenick, Frauenklinik, Berlin, 12559, Germany|Praxis Dr Geuther, Berlin, 14195, Germany|Onkologische Schwerpunktpraxis Bielefeld; Haemotologie & Internistische onkologie, Bielefeld, 33604, Germany|Medizinisches Versorgungszentrum Bonn, Bonn, 53111, Germany|Universitätsklinikum Bonn; Zentrum für Geburtshilfe und Frauenheilkunde, Bonn, 53127, Germany|Med. Versorgungszentrum Filiale Donauwörth Onkologisches Zentrum, Donauwörth, 86609, Germany|Onkologisches Zentrum; Oncology, Donauwörth, 86609, Germany|St. Johannes Hospital, Dortmund, 44137, Germany|Praxis im Elbcenter 1 in Dresden-Pieschen; Dr. med. Thomas Goehler & Dipl.-Med. Steffen Doerfel, Dresden, 01127, Germany|BAG Freiberg-Richter, Jacobasch, Illmer, Wolf, Dresden, 01307, Germany|Universitätsklinikum "Carl Gustav Carus"; Frauenheilkunde und Geburtshilfe, Dresden, 01307, Germany|Universitätsklinikum Düsseldorf; Frauenklinik, Düsseldorf, 40225, Germany|Kreisklinik Ebersberg; Abteilung für Gynäkologie & Geburtshilfe, Ebersberg, 85560, Germany|Universitätsklinikum Erlangen; Frauenklinik, Erlangen, 91054, Germany|St Antonius Hospital; Frauenklinik, Eschweiler, 52249, Germany|Uniklinik Essen; Gynäkologie, Essen, 45122, Germany|Hämatologisch-Onkologische Gemeinschaftspraxis am Bethanien-Krankenhaus, Frankfurt am Main, 60389, Germany|Praxis für Interdisziplinäre Onkologie und Hämatologie GbR, Freiburg, 79110, Germany|Klinikum Fulda gAG; Frauenklinik, Fulda, 36043, Germany|Klinikum St. Georg GmbH; Franziskus-Hospital Harderberg; Klinik für Gynaekologie und Geburtshilfe, Georgsmarienhütte, 49124, Germany|Wilhelm-Anton-Hospital Klinik f.Hämatologie und internistische Onkologie, Goch, 47574, Germany|Martin-Luther-Universität Halle-Wittenberg, Halle, 06097, Germany|Universitätsklinikum Hamburg-Eppendorf; Frauenklinik, Hamburg, 20246, Germany|Kooperatives Mammazentrum Hamburg Krankenhaus Jerusalem, Hamburg, 20357, Germany|Praxis Harburger Ring, Hamburg, 21073, Germany|Iorc-Innovation Onkologie& Research& Consulting Gmbh; Praxis Lerchenfeld Hamburg, Hamburg, 22081, Germany|Dres. Sigrun Müller-Hagen Mathias Bertram und Ulrich Stein, Hamburg, 22457, Germany|SANA Klinikum Hameln-Pyrmont; Frauenklinik / Brustzentrum, Hameln, 31785, Germany|Diakovere Henriettenstift, Frauenklinik, Hannover, 30559, Germany|Medizinische Hochschule Zentrum Frauenheilkunde Abt.Gynäkologische Onkologie, Hannover, 30625, Germany|Stiftung Kathol. Krankenhaus Marienhospital Herne Klinik Mitte Frauenklinik, Herne, 44625, Germany|Universitaetsklinikum des Saarlandes; Klinik f. Frauenheilkunden und Geburtshilfe, Homburg/Saar, 66424, Germany|Universitätsklinikum Jena; Klinik und Poliklinik für Frauenheilkunde und Fortpflanzungsmedizin,

Jena, 07747, Germany|Westpfalz-Klinikum GmbH; Klinik für Frauenheilkunde und Geburtshilfe, Kaiserslautern, 67655, Germany| Gemeinschaftspraxis Dr. Siehl & Dr. Soeling, Kassel, 34119, Germany| Systemedic Frauenarzte Pruener Gang, Kiel, 24103, Germany| Gemeinschaftspraxis Für Haematologie/Onkologie, Köln, 50677, Germany| Uniklinik Köln; Klinik Für Frauenheilkunde, Köln, 50931, Germany| Asklepios Klinik; Abt. Gynäkologie, Langen, 63225, Germany|Klinik Lippe Lemgo; Medizinische Klinik II/Haematoonkologie, Lemgo, 32657, Germany|Universitätsklinikum Schleswig-Holstein / Campus Lübeck; Klinik für Frauenheilkunde und Geburtshilfe, Lübeck, 23538, Germany| Onkologische Gemeinschaftspraxis, Magdeburg, 39104, Germany| Universitätsmedizin Mainz; Klinik u. Poliklinik f. Geburtshilfe u. Frauenheilkunde, Mainz, 55131, Germany|Universitätsklinikum Marburg; Gynäkologie, Marburg, 35043, Germany|Ev. Krankenhaus, Mülheim, 45468, Germany|Gemeinschaftspraxis für Hämatologie und Onkologie, Münster, 48149, Germany|Praxis Für Haematologie & Onkologie Dr. B. Otremba, Oldenburg, 26121, Germany|Praxis Frau Dr. Schwarz, Oranienburg, 16515, Germany|Klinikum Passau; 2. Medizinische Klinik; Onkologie und Hämatologie, Passau, 94032, Germany|Krankenhaus Rheinfelden; Frauenklinik, Rheinfelden, 79618, Germany|Agaplesion Diakonieklinikum Rotenburg, Rotenburg-wuemme, 27356, Germany|Caritas Klinik St. Theresia -Frauenklinik Brustzentrum, Saarbruecken, 66113, Germany| Praxis Dr. Wagner, Saarbruecken, 66113, Germany|Klinik Saarbrücken Ggmbh; Brustzentrum, Saarbruecken, 66119, Germany|DRK Krankenhaus Saarlouis; Kooperatives Brustzentrum, Saarlouis, 66740, Germany| Marienkrankenhaus Abt. Gynäkologie und Geburtshilfe, Saint Wendel, 66606, Germany|MVZ für Hämatologie, Onkologie, Strahlentherapie und Palliativmedizin -; Klinik Dr. Hancken, Stade, 21680, Germany| Johanniter-Krankenhaus, Stendal, 39576, Germany|Klinik Der Hansestadt Stralsund Gmbh; Frauenklinik, Stralsund, 18435, Germany|Klinikum Traunstein, Traunstein, 83278, Germany|Klinikum Mutterhaus der Borromaeerinnen gGmbH; Haematologie/Onkologie, Trier, 54290, Germany| Katharinen-Hospital gGmbH, Unna, 59423, Germany|Kliniken Nordoberpfalz; Klinikum Weiden; Brustzentrum, Weiden, 92637, Germany| Gemeinschaftspraxis Hämatologie / Onkologie, Wiesbaden, 65191, Germany|Semmelweis Egyetem Onkologiai Központ, Budapest, 1083, Hungary|Municipal Hospital of Uzsoki Utca; Centre of Oncoradiology, Budapest, 1145, Hungary|Josa Andras Korhaz; Dept of Oncoradiology, Nyíregyháza, 4400, Hungary|Vas Megyei Markusovszky Korhaz ; Pulmonology, Szombathely, 9700, Hungary|Policlinico Ospedaliero Ss Annunziata; U.O. Di Clinica Oncologica, Chieti, Abruzzo, 66100, Italy| Ospedale San Carlo; Day Hospital Oncologia Medica, Potenza, Basilicata, 85100, Italy|Ospedale Oncologico Regionale; U.O. Oncologia Medica Ed Ematologia, Rionero in Vulture, Basilicata, 85028, Italy|Az. Osp. Pugliese; Dh Oncologico, Catanzaro, Calabria, 88100, Italy|Az. Osp. Mariano Santo; Centro Oncologico, Cosenza, Calabria, 87100, Italy|Azienda Ospedaliera S.G. Moscati; Division of Medical Oncology, Avellino, Campania, 83100, Italy|Az. Osp. Cardarelli; Divisione Di Oncologia, Napoli, Campania, 80131, Italy|Ist. Uni Federico Ii; Divisione Di Oncologia Medica - Dpt. Di Medicina Interna, Napoli,

Campania, 80131, Italy|Istituto Tumori Fondazione Pascale; Endocrinologia Oncologica, Napoli, Campania, 80131, Italy|Ospedale S. Gennaro; Oncologia Medica, Napoli, Campania, 80136, Italy|Az. Osp. S. Orsola Malpighi; Istituto Di Oncologia Seragnoli, Bologna, Emilia-Romagna, 40138, Italy|Opspedale Morgagni - Pierantoni; Dept. Di Oncologia Medica, Meldola, Emilia-Romagna, 47014, Italy|Ospedale Provinciale Santa Maria delle Croci, Ravenna, Emilia-Romagna, 48100, Italy|Irccs Centro Di Riferimento Oncologico (CRO); Dipartimento Di Oncologia Medica, Aviano, Friuli-Venezia Giulia, 33081, Italy|Centro Soc. Oncologico, Azienda Sanitaria Universitaria Integrata Trieste; CENTRO ONCOLOGICO, Trieste, Friuli-Venezia Giulia, 34100, Italy| Ospedale S. Maria Goretti; Divisione Di Oncologia Medica, Latina, Lazio, 04100, Italy|Ospedale San Giacomo in Augusta; Reparto Oncologia, Roma, Lazio, 00100, Italy|Policlinico Universitario Campus Biomedico; Uoc Oncologia Medica, Roma, Lazio, 00128, Italy|Azienda Complesso Ospedaliero S. Filippo Neri; Divisione Di Oncologia Medica, Roma, Lazio, 00135, Italy|Istituto Regina Elena; Oncologia Medica A, Roma, Lazio, 00168, Italy|Policlinico Militare Di Roma; Reparto Di Oncologia, Roma, Lazio, 00184, Italy|IRCCS Istituto Nazionale Per La Ricerca Sul Cancro (IST); Oncologia Medica A, Genova, Liguria, 16132, Italy|Ospedale S. Andrea Est Felettino; Oncologia Medica, La Spezia, Liguria, 19100, Italy|Asst Papa Giovanni XXIII; Oncologia Medica, Bergamo, Lombardia, 24128, Italy|Az. Osp. Spedali Civili; Divisione Di Oncologia - Iii Medicina, Brescia, Lombardia, 25123, Italy|Ospedale Di Casalpusterlengo; Day Hospital Oncologico, Casalpusterlengo, Lombardia, 20071, Italy|Ospedale Valduce; Dept. Di Oncologia Medica, Como, Lombardia, 22100, Italy|ASST DI LECCO; Oncologia Medica, Lecco, Lombardia, 23900, Italy|ASST OVEST MILANESE; Oncologia Medica, Legnano, Lombardia, 20025, Italy|Az. Osp. Carlo Poma; Divisione Di Oncologia Medica, Mantova, Lombardia, 46100, Italy|Istituto Europeo Di Oncologia, Milano, Lombardia, 20141, Italy|Asst Santi Paolo E Carlo; Unita Operativa Di Oncologia Medica, Milano, Lombardia, 20142, Italy| Fondazione Salvatore Maugeri; Divisione Di Oncologia Medica, Pavia, Lombardia, 27100, Italy|Fondazione Salvatore Maugeri; Servizio Di Prevenzione Oncologica, Pavia, Lombardia, 27100, Italy|Irccs Policlinico S. Matteo - Uni Pavia; Clinica Medica I Div. Med. Int. Onc. Medica E Gastroent., Pavia, Lombardia, 27100, Italy|Ospedale Di Circolo; Centro Di Senologia, Varese, Lombardia, 21100, Italy|Ospedale S. Croce Di Fano; Servizio Oncologia, Fano, Marche, 61032, Italy| Fondazione Del Piemonte Per L'oncologia Ircc Di Candiolo; Dipartimento Oncologico, Candiolo, Piemonte, 10060, Italy|Ospedale Degli Infermi Di Biella; Reparto Oncologia Medica, Ponderano (BI), Piemonte, 13875, Italy|A.O. Città della Salute e della Scienza - Presidio Molinette; divisione oncologia medica, Torino, Piemonte, 10126, Italy|Ospedale Sant'Anna - Uni Di Torino; Unita Di Oncologia Ginecologica, Torino, Piemonte, 10126, Italy|Ospedale Vito Fazzi; Div. Oncoematologia, Lecce, Puglia, 73100, Italy|IRCCS Ospedale Casa Sollievo Della Sofferenza; Oncologia, San Giovanni Rotondo, Puglia, 71013, Italy| A.O.U. Cagliari-P.O. Monserrato;U.O. Oncologia, Cagliari, Sardegna, 09100, Italy|Azienda Ospedaliero Universitaria Di Sassari;Oncologia,

Sassari, Sardegna, 07100, Italy|Centro Catanese Di Oncologia; Oncologia Medica, Catania, Sicilia, 95126, Italy|Az. Osp. M. Ascoli G. Di Cristina; Oncologia Medica, Palermo, Sicilia, 90127, Italy|La Maddalena Casa Di Cura Di Alta Specialita; Oncologia Chirurgica, Palermo, Sicilia, 90146, Italy|Az. Osp. ; Divisione Di Oncologia, Ragusa, Sicilia, 97100, Italy|USL 8 Ospedale San Donato; Oncology Endocrinology, Arezzo, Toscana, 52100, Italy|Ospedale Santa Maria Annunziata; Oncologia, Bagno a Ripoli, Toscana, 50012, Italy|Azienda Ospedaliero-Universitaria Careggi;S.C. Oncologia Medica 1, Firenze, Toscana, 50139, Italy|Ospedale Campo Di Marte; Dipartimento Oncologico, Lucca, Toscana, 55100, Italy|Azienda Usl 7; Dept. Oncologico, Poggibonsi, Toscana, 53036, Italy|Ospedale Santa Chiara; Oncologia Medica, Trento, Trentino-Alto Adige, 38100, Italy| Arcispedale S.Anna; Oncologia Medica, Cona (Ferrara), Veneto, 44124, Italy|Polo Ospedaliero Santorso, Santorso, Veneto, 36014, Italy| Ospedale Civile S. Bortolo; Divisione Di Oncologia, Vicenza, Veneto, 36100, Italy|Regionalne Centrum Onkologi; Oddzial Chorob Wewnetrznych I Onkologii, Bydgoszcz, 85-796, Poland|Oddzial Chemioterapii Szpitala Klinicznego Nr 1 w Poznaniu, Poznan, 60-569, Poland|Hospital General de Mataro; Servicio de Oncologia, Mataro, Barcelona, 08304, Spain| Corporacio Sanitaria Parc Tauli; Servicio de Oncologia, Sabadell, Barcelona, 08208, Spain|Hospital Universitario de Canarias;servicio de Oncologia, La Laguna, Tenerife, 38320, Spain|Complejo Hospitalario de Jaen-Hospital Universitario Medico Quirurgico; Servicio de Oncologia, Jaen, 23007, Spain|Hospital Regional Universitario Carlos Haya, Malaga, 29010, Spain|Hospital de Navarra; Servicio de Oncologia, Navarra, 31008, Spain|Hospital Universitario Virgen del Rocio; Servicio de Oncologia, Sevilla, 41013, Spain|Complejo Hospitalario de Toledo- H. Virgen de la Salud; Servicio de Oncologia, Toledo, 45004, Spain|Hospital Universitario Miguel Servet; Servicio Oncologia, Zaragoza, 50009, Spain|Gävle sjukhus onkologkliniken, Gaevle, 80187, Sweden|Lanssjukhuset Ryhov; Onkologkliniken, Jonkoping, 55185, Sweden| Länssjukhuset Kalmar; Oncology, Kalmar, 39185, Sweden|Centralsjukhuset Karlstad, Onkologkliniken, Karlstad, 65185, Sweden|Uni Hospital Linkoeping; Dept. of Oncology, Linköping, 58185, Sweden|Skånes University Hospital, Skånes Department of Onclology, Lund, 22185, Sweden|Karolinska Hospital; Oncology - Radiumhemmet, Stockholm, 17176, Sweden|Länssjukhuset Sundsvall, Onkologkliniken, Sundsvall, 85186, Sweden|Norrlands Universitetssjukhus, Umeå, Cancercentrum; Dept of Oncology, Umea, 90185, Sweden|Aberdeen Royal Infirmary; Medical Oncology Dept, Aberdeen, AB25 2ZN, United Kingdom|Belfast City Hospital; Dept of Oncology, Belfast, BT9 7AB, United Kingdom|Velindre Cancer Centre; Oncology Dept, Cardiff, CF14 2TL, United Kingdom| Broomfield Hospital; Oncology, Chelmsford, CM1 7ET, United Kingdom| Ninewells Hospital; Dept of Radiotherapy & Oncology, Dundee, DD1 9SY, United Kingdom|Royal Devon & Exeter Hospital; Oncology Centre, Exeter, EX2 5DW, United Kingdom|Glasgow Western Infirmary; Dept of Radiotherapy, Glasgow, G11 6NT, United Kingdom|Huddersfield Royal Infirmary, Huddersfield, HD3 3EA, United Kingdom|Queen Elizabeth Hospital, Kings Lynn, PE30 4ET, United Kingdom|St Thomas Hospital;

Medicine Div., London, SE1 7EH, United Kingdom|St George'S Hospital; Oncology Research Office /Oncology Opd, London, SW17 ORE, United Kingdom|Charing Cross Hospital; Medical Oncology., London, W6 8RF, United Kingdom|Christie Hospital; Breast Cancer Research Office, Manchester, M20 4QL, United Kingdom|James Cook Uni Hospital, Middlesborough, TS4 3BW, United Kingdom|Newcastle General Hospital, Newcastle Upon Tyne, NE4 6BE, United Kingdom|Royal Preston Hosptial, Preston, PR2 9HT, United Kingdom|Oldchurch Hospital, Romford, RM7 0BE, United Kingdom|Salisbury District General Hospital; Medical Oncology Dept, Salisbury, SP2 8BJ, United Kingdom|Royal Shrewsbury Hospitals Nhs Trust; Oncology, Shrewsbury, SY3 8XQ, United Kingdom|Southampton General Hospital; Medical Oncology, Southampton, SO16 6YD, United Kingdom|Worthing Hospital; Sussex Oncology Centre, Worthing Breast Unit, Worthing, B11 2DH, United Kingdom|Yeovil District Hospital; Macmillan Cancer Unit, Yeovil, BA21 4AT, United Kingdom|Airedale General Hospital; Oncology, York, BD20 6TD, United Kingdom
Study Documents:

NCT Number: NCT02236806
Study Title: Cardiotoxicity Prevention in Breast Cancer Patients Treated With Anthracyclines and/or Trastuzumab
Study URL: https://beta.clinicaltrials.gov/study/NCT02236806
Acronym: SAFE
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The aim of the study is to analyze the protective impact on the cardiac damage of beta blockers and ACE inhibitors for breast cancer patients treated with anthracyclines-based chemotherapy with or without trastuzumab.
Study Results: NO
Conditions: Breast Cancer|Cardiotoxicity
Interventions: DRUG: Bisoprolol|DRUG: Ramipril|DRUG: Placebo
Primary Outcome Measures: Left ventricular ejection fraction (LVEF), Change in LVEF (3-dimensional and 2-dimensional) at time-frame, at months 6,9,12,24|Global longitudinal strain (GLS), Change in GLS at time-frame, at months 6,9,12,24
Secondary Outcome Measures: Indexed left ventricular end diastolic volume (EDVI), Change in EDVI at time-frame, at months 6,9,12,24| Indexed left ventricular end systolic volume (ESVI), Change in ESVI at time-frame, at months 6,9,12,24
Other Outcome Measures:
Sponsor: Azienda Ospedaliero-Universitaria Careggi
Collaborators: University of Florence
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 262
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, CARE_PROVIDER)|Primary Purpose:

PREVENTION
Other IDs: SAFE2014
Start Date: 2015-07
Primary Completion Date: 2022-06
Completion Date: 2022-06
First Posted: 2014-09-11
Results First Posted:
Last Update Posted: 2022-02-01
Locations: Azienda Ospedaliero-Universitaria Careggi, Florence University, Florence, 50141, Italy
Study Documents:

NCT Number: NCT02550808
Study Title: Metabolic Changes in Patients With Chronic Cardiopulmonary Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT02550808
Acronym:
Study Status: UNKNOWN
Brief Summary: This study aims to evaluate prevalence of sarcopenia and cachexia in patients with chronic cardiopulmonary disease. The investigators will also investigate metabolic disorders like glucose metabolism, presence of metabolic syndrome, body composition and histological changes in skeletal muscle and body fat. Finally, patients will be followed for clinical endpoints.
Study Results: NO
Conditions: Heart Failure|Chronic Obstructive Pulmonary Disease|Malignancy|Chronic Kidney Disease
Interventions:
Primary Outcome Measures: Insulin resistance (HOMA-IR), HOMA-IR as calculated by formula using insulin and blood glucose, Baseline
Secondary Outcome Measures: Muscle strength (Handgrip test), Handgrip test, Baseline|Change in exercise capacity (6 minute walk test), Determined by incremental exercise test, 6 minute walk test, baseline and after 5 weeks|Neurohormonal activation (NT-proBNP concentration), NT-proBNP concentration, Baseline|Change in apoptosis in skeletal muscle (number of apoptotic cells per square mm), histological evaluation: number of apoptotic cells per square mm, Baseline and after 5 weeks|Change in insulin resistance (HOMA-IR), HOMA-IR as calculated by formula using insulin and blood glucose, Baseline and after 5 weeks
Other Outcome Measures:
Sponsor: General and Teaching Hospital Celje
Collaborators: University of Ljubljana|General Hospital Murska Sobota|Maastricht University
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 400
Funder Type: OTHER
Study Type: OBSERVATIONAL

Study Design: Observational Model: |Time Perspective: p
Other IDs: ML-MTB-001
Start Date: 2012-03
Primary Completion Date: 2016-07
Completion Date: 2017-12
First Posted: 2015-09-16
Results First Posted:
Last Update Posted: 2015-09-16
Locations: General Hospital Celje, Celje, SI-3000, Slovenia
Study Documents:

NCT Number: NCT05690009
Study Title: Real Clinical Practice Register of AlbUminuRia Detection in Patients With Previously undiAgnosed Chronic Kidney Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT05690009
Acronym: AURA
Study Status: RECRUITING
Brief Summary: Real clinical practice register of Albuminuria detection in patients with previously undiagnosed chronic kidney disease
Study Results: NO
Conditions: Chronic Kidney Diseases|Hypertension|Chronic Heart Failure|Ischemic Heart Disease|Atrial Fibrillation|PreDiabetes|Chronic Obstructive Pulmonary Disease|Cancer|Urolithiasis|COVID-19
Interventions:
Primary Outcome Measures: Prevalence of AU and its severity., Day 1
Secondary Outcome Measures: Number of comorbidities per patient with AU., Day 1|Frequency of prescribing renoprotective drugs., Day 1|Calculation of eGFR according to CKD-EPI formula 2021 in different phenotypes from the study population., Day 1|Prevalence of probable CKD in the study sample based on the clinical and laboratory data obtained during the screening., Day 1
Other Outcome Measures:
Sponsor: Eurasian Association of Therapists
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 12000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: AURA
Start Date: 2023-02-27
Primary Completion Date: 2023-12-31
Completion Date: 2023-12-31
First Posted: 2023-01-19
Results First Posted:
Last Update Posted: 2023-05-16
Locations: Eurasian Association of Therapists, Moscow, Russian

Federation
Study Documents:

NCT Number: NCT01370109
Study Title: Cardiovascular Effects of Sunitinib Therapy (CREST)
Study URL: https://beta.clinicaltrials.gov/study/NCT01370109
Acronym:
Study Status: COMPLETED
Brief Summary: Tyrosine kinase inhibitors such as sunitinib are used in the treatment of renal cell carcinoma and have significant off-target effects with cardiac toxicity and resultant ventricular cardiac dysfunction being a major concern. However, the mechanisms of these effects in humans remains poorly defined, as are the clinical methods to risk stratify and identify patients who will ultimately suffer from cardiac dysfunction. The goal of this multi-center study is to characterize the cardiovascular measures of cardiac function; 2) comprehensive measures of arterial function and left ventricular afterload; 3) biomarkers reflective of the pathophysiologic alterations. Through this work, the investigators will translate our basic understanding of sunitinib cardiotoxicity to humans and identify early predictors of sunitinib cardiotoxicity.
Study Results: NO
Conditions: Renal Cell Carcinoma 4
Interventions:
Primary Outcome Measures: Change from Baseline in Systolic Blood Pressure, 6 Months
Secondary Outcome Measures: Number of Participants with adverse events, Number of subjects with adverse events specifically, incident of hypertension and Cardiac dysfunction, 2 years
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 98
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 34810
Start Date: 2011-04
Primary Completion Date: 2017-12-31
Completion Date: 2017-12-31
First Posted: 2011-06-09
Results First Posted:
Last Update Posted: 2018-10-02
Locations: Abramson Cancer Center, University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT05676606
Study Title: Cardiotoxicity Monitoring With Single-lead Electrocardiogram
Study URL: https://beta.clinicaltrials.gov/study/NCT05676606
Acronym:
Study Status: RECRUITING
Brief Summary: This research is a multi-center prospective cohort interventional study aimed to determinate the capabilities of remote 1-minute single-lead electrocardiogram monitoring for cardiotoxicity detection, during two- three weeks (depending on the scheme of polychemotherapy) after the first cycle of polychemotherapy in patients with the first diagnosed cancer.
Study Results: NO
Conditions: Cardiotoxicity
Interventions: DEVICE: Remote 1-minute single-lead electrocardiogram (ECG) monitoring in cancer patients after the first polychemotherapy cycle.
Primary Outcome Measures: Severe asymptomatic cancer-therapy related cardiac dysfunction, Left ventricular ejection fraction reduction (LVEF) to \< 40% ., Up to one month after the first cycle of chemotherapy treatment|Moderate asymptomatic cancer-therapy related cardiac dysfunction, LVEF reduction by ≥10 percentage points to an LVEF of 40-49% or new LVEF reduction by \< 10 percentage points to an LVEF of 40-49% and either new relative decline in GLS by \>15% from baseline or new rise in cardiac biomarkers;, Up to one month after the first cycle of chemotherapy treatment|Mild asymptomatic cancer-therapy related cardiac dysfunction, LVEF ≥ 50% and new relative decline in GLS by \>15% from baseline and/or new rise in cardiac biomarkers., Up to one month after the first cycle of chemotherapy treatment| Chemotherapy-induced atrial fibrillation\ flutter., Rhythm with no discernible repeating P waves and irregular RR intervals is diagnosed on an standard 12-lead ECG or a single-lead ECG tracing of ≥ 30 s recording, Up to one month after the first cycle of chemotherapy treatment|Chemotherapy- induced atrioventricular block I-III degrees, ∗ First-degree atrioventricular block, on ECG, this is defined by a PR interval greater than 200 mc
∗ Second-degree atrioventricular block; not all P-waves are followed byQRS complexes.

Second-degree atrioventricular blockMobitz type I- this manifest on the ECG as gradual increase of PR interval before a block of QRS complexes occurs.

Second-degree atrioventricular blockMobitz type II-the block of QRS complexes occurs without gradual increase of PR interval.

• Third degree atrioventricular block- on the ECG P-waves have no relation to the QRS complexes., Up to one month after the first cycle of chemotherapy treatment|Chemotherapy-induced QTc interval prolongation:, QTc\> 500 ms and\\or QTc\> 60 ms deviation from

baseline., Up to one month after the first cycle of chemotherapy treatment|Chemotherapy-induced arterial hypertension:, Steady increase in systolic arterial blood pressure ≥140 mmHg and/or diastolic ≥90 mmHg in period after chemotherapy., Up to one month after the first cycle of chemotherapy treatment|Chemotherapy-induced arterial hypotension., Steady decrease in systolic arterial blood pressure ≤ 100 mmHg and/or diastolic ≤ 90 mmHg., Up to one month after the first cycle of chemotherapy treatment.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: I.M. Sechenov First Moscow State Medical University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 128
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: FZ 01
Start Date: 2020-12-10
Primary Completion Date: 2023-06-30
Completion Date: 2023-06-30
First Posted: 2023-01-09
Results First Posted:
Last Update Posted: 2023-01-10
Locations: I.M. Sechenov First Moscow State Medical University (Sechenov University), Moscow, 119991, Russian Federation
Study Documents:

NCT Number: NCT04092309
Study Title: Effect of Angiotensin Converting Enzyme and Sacubitril Valsartan in Patients After Bone Marrow Transplantation
Study URL: https://beta.clinicaltrials.gov/study/NCT04092309
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of the present study is to investigate the effect of ACE inhibitors and the sacubitril-valsartan complex in bone marrow transplant patients by assessing cardiovascular and endothelial parameters in order to search for a potent protective role.
Study Results: NO
Conditions: Hematopoietic Stem Cell Transplantation|Cardiotoxicity
Interventions: DRUG: ACE inhibitor, Sacubitril-Valsartan
Primary Outcome Measures: Effect of treatment in Left Ventricular Function, Left Ventricular Function is assessed by calculating Ejection fraction by 3D echocardiography., 2 years|Effect of treatment in left ventricular function, Left Ventricular function is assessed by Global Longitudinal Strain by speckle tracking echocardiography, 2 years|Effect of treatment in arterial stiffness, Arterial Stiffness is

evaluated by Pulse Wave Velocity, 2 years|Effect of treatment in glycocalyx thickness, Glycocalyx thickness is assessed by measuring perfused boundary region (PBR) of the sublingual arterial microvessels (range 5-25 µm, 2 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Athens
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 90
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: ACE_SAVA_3Decho_BMT
Start Date: 2019-09-20
Primary Completion Date: 2020-09-01
Completion Date: 2021-09-01
First Posted: 2019-09-17
Results First Posted:
Last Update Posted: 2020-04-03
Locations: "Attikon" University General Hospital, Athens, Attiki, 12462, Greece
Study Documents:

NCT Number: NCT00575406
Study Title: Multicentre Study to Determine the Cardiotoxicity of R-CHOP Compared to R-COMP in Patients With Diffuse Large B-Cell Lymphoma
Study URL: https://beta.clinicaltrials.gov/study/NCT00575406
Acronym: NHL-14
Study Status: COMPLETED
Brief Summary: Diffuse large B-cell lymphoma is the most prevalent subgroup within malignant lymphoma. Clinical benefit has been shown for the treatment with cyclophosphamide, doxorubicin, vincristin and prednisolone (CHOP regimen); this could be further improved recently by the addition of rituximab (R-CHOP), a monoclonal antibody.

Improved response and overall survival rates make it necessary to evaluate late toxicities of the therapy regimens. Cardiotoxicity is a known risk factor of specific chemotherapies, with 7% patients being affected if doxorubicin cumulative doses are under 550mg/sqm. Retrospective data analyses indicate that this incidence of cardiotoxicity may be higher under combination chemotherapy. Liposomal doxorubicin has been shown to have lower cardiotoxic effects and at the same time equivalent or higher efficacy compared to conventional doxorubicin.

The aim of this study is to evaluate alternative regimens for the

treatment of diffuse large B-cell lymphoma, substituting liposomal doxorubicin (R-COMP) for conventional doxorubicin (R-CHOP).
Study Results: NO
Conditions: Diffuse Large B-Cell Lymphoma
Interventions: DRUG: Rituximab|DRUG: Cyclophosphamide|DRUG: Doxorubicin|DRUG: liposomal Doxorubicin|DRUG: Vincristin|DRUG: Prednisolone
Primary Outcome Measures: Reduction of cardiotoxicity in the R-COMP arm versus R-CHOP, Study duration
Secondary Outcome Measures: Significance of serial NT-proBNP measurements for determination of anthracycline-dependent cardiotoxicity, Study Duration|Feasibility of evaluation with Haematopoietic Cell Transplantation Comorbidity Index (HCT-CI), Study duration|Rate of Complete Responses, At end of treatment|Difference in Overall Survival at 3 and 5 yrs, 5 years|Difference in Event-free Survival at 3 and 5 yrs, 5 years|Difference in Progression-free Survival at 3 and 5 yrs, 5 years|Difference in cause-specific death, 5 years
Other Outcome Measures:
Sponsor: Arbeitsgemeinschaft medikamentoese Tumortherapie
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 94
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: NHL-14|EudraCT 2007-004970-24
Start Date: 2007-12
Primary Completion Date: 2012-01
Completion Date: 2012-01
First Posted: 2007-12-18
Results First Posted:
Last Update Posted: 2013-08-30
Locations: Landeskrankenhaus Feldkirch, Feldkirch, A-6806, Austria|Universitaetsklinik Innsbruck/ Klinik für Innere Medizin, Innsbruck, A-6020, Austria|A.ö. Landeskrankenhaus Leoben, Leoben, A-8700, Austria|Krankenhaus d. Barmherzigen Schwestern Linz, Linz, A-4010, Austria|Krankenhaus der Elisabethinen Linz, Linz, A-4010, Austria|Krankenhaus der Stadt Linz, Linz, A-4020, Austria|Universitaetsklinik f. Innere Medizin III, Salzburg, A-5020, Austria|AKH Wien / Haematologie u. Haemostaseologie, Vienna, A-1090, Austria|Hanusch Krankenhaus, Vienna, A-1140, Austria|Klinikum Kreuzschwestern Wels GmbH, Wels, A-4600, Austria
Study Documents:

NCT Number: NCT03269708
Study Title: Improving Cardiac Secondary Prevention

Study URL: https://beta.clinicaltrials.gov/study/NCT03269708
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to determine whether providing individuals with personalized information on cellular aging, including telomere dynamics, will stimulate them to adhere to cardiac prevention strategies and improve exercise capacity.
Study Results: NO
Conditions: Myocardial Infarction|Secondary Prevention
Interventions: BEHAVIORAL: Education regarding telomere length
Primary Outcome Measures: Exercise capacity based on cardiopulmonary exercise testing, Online VO2 maximum, after 6-month cardiac rehabilitation program
Secondary Outcome Measures: Adherence to supervised exercise sessions, Proportion of prescribed supervised on-site exercise sessions attended, 6 months|Activity assessment, Garmin recording, 6 months
Other Outcome Measures:
Sponsor: Western University, Canada
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 109209
Start Date: 2019-03
Primary Completion Date: 2020-09
Completion Date: 2020-09
First Posted: 2017-09-01
Results First Posted:
Last Update Posted: 2018-10-26
Locations: London Health Sciences Centre, Western University, London, Ontario, N6A 5A5, Canada
Study Documents:

NCT Number: NCT00673608
Study Title: Magnetic Resonance Imaging (MRI) Assessments of the Heart and Liver Iron Load in Patients With Transfusion Induced Iron Overload
Study URL: https://beta.clinicaltrials.gov/study/NCT00673608
Acronym:
Study Status: COMPLETED
Brief Summary: This study will evaluate the change in cardiac iron load over a 53 week period measured by MRI in 2 cohorts of patients
Study Results: NO
Conditions: Hemoglobinopathies|Myelodysplastic Syndromes|Other Inherited or Acquired Anaemia|MPD Syndrome|Diamond-Blackfan Anemia|

Other Rare Anaemias|Transfusional Iron Overload
Interventions: DRUG: deferasirox
Primary Outcome Measures: Change in cardiac iron load and cardiac ejection fraction by MRI recorded at baseline and after 53 weeks., 12 months
Secondary Outcome Measures: Change in ventricular ejection fraction values, ventricular volumes and masses from baseline values after 53 weeks., 12 months|Change in cardiac T2* from baseline to 53 weeks in the MDS and other anaemias subgroup, compared to the thalassaemia subgroup., 12 months|Changes in serum ferritin from baseline values to 53 weeks., 12 months|Changes in Liver Iron Content (LIC) by MRI from baseline values to 53 weeks, 12 months|The relationship between the dosing regimen of Exjade® and changes in cardiac T2* and LIC R2 MRI, 12 months|Changes in markers of iron load levels between baseline and 53 weeks., 12 months|The safety and tolerability of deferasirox therapy from baseline to 53 weeks, 12 months
Other Outcome Measures:
Sponsor: Novartis
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 118
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CICL670AAU01
Start Date: 2007-11
Primary Completion Date: 2011-09
Completion Date: 2011-09
First Posted: 2008-05-07
Results First Posted:
Last Update Posted: 2017-02-23
Locations: Novarts Investigative Site, Adelaide, Australia|Novarts Investigative Site, Brisbane, Australia|Novarts Investigative Site, Melbourne, Australia|Novarts Investigative Site, Sydney, Australia
Study Documents:

NCT Number: NCT05595109
Study Title: Role of Silymarin in Chemotherapy Toxicity and Cognition Improvement in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05595109
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: Aim of the work This study aims to evaluate the possible beneficial role of silymarin in attenuating both doxorubicin related cardiac and hepatic toxicities and paclitaxel associated peripheral neuropathy and improving cognitive impairment in patients with breast cancer.

This study will be a randomized placebo controlled parallel study. The study will be performed in accordance with the ethical standards of Helsinki declaration in 1964 and its later amendments.

Group one: (Placebo group; n=28) which will receive four cycles of AC regimen (doxorubicin and cyclophosphamide; each cycle was given every 21 day) followed by 12 cycles of paclitaxel (each cycle was given in a weekly basis) plus placebo tablets once daily.

Group two: (Silymarin group; n=28) which will receive the same regimen plus silymarin 140mg once daily
Study Results: NO
Conditions: Breast Cancer|Peripheral Neuropathy|Cardiac Toxicities|Hepatic Toxicity|Cognitive Impairment
Interventions: DRUG: Silymarin|DRUG: Placebo
Primary Outcome Measures: change in ejection fraction, Doxorubicin related cardiotoxicity will be assessed through :Echocardiography at baseline, Before starting the first chemotherapy cycle (baseline), after the last AC cycle (for assessment of N-terminal prohormone of brain naturetic peptide "NT-proBNP") and after the last doxorubicin/cyclophosphamide (AC) cycle., 6 months|change in percentage of patients with peripheral sensory neuropathy, change in percentage of patients with peripheral sensory neuropathy grade ≥ 2 with the variation of both 12-item neurotoxicity questionnaire (Ntx-12) total score and pain rating scale score., 6 months
Secondary Outcome Measures: changes in serum levels of the measured biological markers., N-terminal prohormone of brain naturetic peptide "NT-proBNP") liver panel myeloperoxidase (MPO) neurofilament light chain (NFL) nuclear factor- Kabba B p65 (NF-κB p65) or TNF-alpha, 6 months
Other Outcome Measures:
Sponsor: Tanta University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 56
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 35945/10/22
Start Date: 2022-10-28
Primary Completion Date: 2023-04-28
Completion Date: 2024-10-28
First Posted: 2022-10-26
Results First Posted:
Last Update Posted: 2022-10-26
Locations: Tanta university, Tanta, 35945/10/2022, Egypt

Study Documents:

NCT Number: NCT05575791
Study Title: Evaluation of Preoperative Acceptance of Proactive Palliative Care Intervention
Study URL: https://beta.clinicaltrials.gov/study/NCT05575791
Acronym: iCare
Study Status: RECRUITING
Brief Summary: Advances in medicine have led to an increased life expectancy even with complex disease courses of malignant diseases.

This leads to frequent critical situations for patients and high risk surgical interventions. The majority of patients and their practitioners are not prepared for the consequences of a complex and possibly fatal course.

Palliative medicine makes it possible to anticipate the further course of the disease. As a result, palliative medicine has become increasingly important. The beginning of palliative medical interventions has extended from accompaniment limited to the dying phase to earlier phases of the disease.

An early integration of palliative medicine showed a positive effect on the quality of life, the degree of depression and survival in patients suffering from cancer, for example. Furthermore, patients were more able to accept a change in therapy goal at the end of life. Similar results were shown for patients with a non-malignant severe disease such as COPD or heart failure.

What needs further investigating is how to adequately screen and identify the patient populations who could benefit from early palliative care, so that they are prepared for potentially critical and life-threatening situations.

The investigator's objective is therefore whether the Anesthesiology Outpatient Clinic is a suitable screening location for initiating early integrated palliative care for patients with a serious, life-shortening illness and a high perioperative risk.
Study Results: NO
Conditions: Cancer|Heart Failure|Chronic Obstructive Pulmonary Disease|Postoperative Complications
Interventions:
Primary Outcome Measures: Acceptance of the preoperative palliative counseling offer, Percentage of patients who accept the palliative counseling offer in relation to the total number of patients identified in the screening of the anesthesia outpatient clinic, through study completion, an average of 1 year
Secondary Outcome Measures: Advance planning documents, Percentage of patients who, as a result of the palliative medical consultation offer, create or want to create a living will or power of attorney,

through study completion, an average of 1 year|Postoperative palliative counseling, Percentage of patients who would like further palliative medical advice postoperatively, through study completion, an average of 1 year|Acceptance of the preoperative palliative counseling offer depending on the underlying disease, Percentage of patients with and without a malignant disease who accept the counseling offer, through study completion, an average of 1 year|Therapy target decision-making situations, Percentage of patients in whom a decision to limit therapy occurs in the postoperative course, through study completion, an average of 1 year|Gender difference, Percentage of female patients who accept the counseling offer in relation to male patients, through study completion, an average of 1 year|Therapy goal decisions postoperatively, Percentage of patients who do not accept the offer of counseling and who have difficult therapy goal decisions postoperatively, through study completion, an average of 1 year
Other Outcome Measures:
Sponsor: Charite University, Berlin, Germany
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: EA1/292/20
Start Date: 2022-12-01
Primary Completion Date: 2023-11-30
Completion Date: 2023-11-30
First Posted: 2022-10-12
Results First Posted:
Last Update Posted: 2023-02-14
Locations: Department of Anesthesia and operative intensive Care, Campus Benjamin Franklin, Charité - University Hospital Berlin, Berlin-Steglitz, Berlin, 12203, Germany
Study Documents:

NCT Number: NCT04294108
Study Title: Why in Hospital After VATS Lobectomy
Study URL: https://beta.clinicaltrials.gov/study/NCT04294108
Acronym:
Study Status: COMPLETED
Brief Summary: The study aims to identify specific or potential reasons that prolong the length of hospital stay after video-assisted thoracoscopic surgery lobectomy.

The hypothesis is that patients who are still in hospital after video-assisted thoracoscopic surgery lobectomy are associated with prolonged air leak, infection, pneumonia, atrial fibrillation or other

complications or social factors.
Study Results: NO
Conditions: Carcinoma, Non-Small-Cell Lung|Pain, Postoperative|Postoperative Nausea and Vomiting|Infection|Air Leakage|Atrial Fibrillation
Interventions: OTHER: Prolong in-hospital stay
Primary Outcome Measures: Length of postoperative hospital stay, Through study completion, an average of 2 days
Secondary Outcome Measures: Number and frequency of postoperative complications, Up to 30 days|Numeric rating scale for postoperative pain in hospitalization, Patients are scored using a numeric rating scale ranging from 0 (no pain) to 10 (excruciating pain) per day., Through study completion, an average of 2 days|Drainage duration, The criteria of drain removal is that air leak was consistently below 20 ml/min for at least 12 hours and fluid production was non-bloody and non-chylous without an upper volume limit., Duration from postoperative chest tube placement to potential removal, an average of 2 days
Other Outcome Measures:
Sponsor: Rigshospitalet, Denmark
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 160
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: H-20014489
Start Date: 2020-04-20
Primary Completion Date: 2020-12-18
Completion Date: 2021-09-18
First Posted: 2020-03-03
Results First Posted:
Last Update Posted: 2021-11-03
Locations: Rigshospitalet, Copenhagen, 2100, Denmark
Study Documents:

NCT Number: NCT00590291
Study Title: Molecular Determinants of Coronaruy Artery Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT00590291
Acronym: GeneQuest
Study Status: TERMINATED
Brief Summary: The purpose of this study is to discover genes that may cause Coronary Artery Disease (CAD) or Arteriovenous Malformation (AVM).
Study Results: NO
Conditions: Coronary Artery Disease|Arteriovenous Malformations|Myocardial Infarction
Interventions:

Primary Outcome Measures: Coronary Artery Disease, 2009|Arteriovenous Malformation, 2009
Secondary Outcome Measures: Myocardial Infarction, 2009
Other Outcome Measures:
Sponsor: John Barnard
Collaborators: National Heart, Lung, and Blood Institute (NHLBI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1461
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: GeneQuest|IRB4333|1R01HL121358
Start Date: 1995-01
Primary Completion Date: 2021-04-01
Completion Date: 2021-04-01
First Posted: 2008-01-10
Results First Posted:
Last Update Posted: 2021-05-17
Locations: Cleveland Clinic, Cleveland, Ohio, 44195, United States
Study Documents:

NCT Number: NCT05507879
Study Title: Characterization of TRPC6 to Predict and Prevent Chemotherapy Related Cardiac Toxicity and Heart Failure in Patients With Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05507879
Acronym:
Study Status: RECRUITING
Brief Summary: This study examines TRPC6 in predicting and preventing chemotherapy related cardiac toxicity and heart failure in patients with breast cancer. Cardiac toxicity, changes in heart function is a well-recognized complication of certain cancer related therapies. Understanding these changes may allow early intervention against therapy-related cardiac toxicity and also identify novel therapeutic targets to protect patient long-term cardiac health. Studying samples of blood from patients with breast cancer in the laboratory may help doctors learn more about changes that occur in deoxyribonucleic acid (DNA), identify biomarkers related to cardiac toxicity, and prevent the development of therapy-induced cardiac toxicity in patients receiving chemotherapy.
Study Results: NO
Conditions: Breast Carcinoma|Cardiotoxicity
Interventions: PROCEDURE: Biospecimen Collection|OTHER: Electronic Medical Record
Primary Outcome Measures: Significance ofTRPC6 coding sequencing, Will compare the prevalence of rare missense variants in our cases against the null hypothesis to assess the significance of TRPC6 coding sequencing data in patients with dox-induced heart failure (HF). Will

use an exploratory analysis to estimate the prevalence, 95% confidence intervals and p-values depending on the number of patients with rare variants in the data set and due to the rarity (i.e. high degree of conservation in the TRPC6 coding sequence).Other methods include biospecimen collection and the TRPC6 coding sequence. Data collected will be stored in a database and studied by the PI., Up to study completion, up to four years to completion.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 300
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 22-001501|NCI-2022-05690|P30CA015083
Start Date: 2022-08-18
Primary Completion Date: 2026-09-01
Completion Date: 2027-09-01
First Posted: 2022-08-19
Results First Posted:
Last Update Posted: 2023-01-12
Locations: Mayo Clinic in Florida, Jacksonville, Florida, 32224-9980, United States
Study Documents:

NCT Number: NCT04810091
Study Title: Telotristat Ethyl for the Treatment of Carcinoid Heart Disease in Patients With Metastatic Neuroendocrine Tumor
Study URL: https://beta.clinicaltrials.gov/study/NCT04810091
Acronym:
Study Status: RECRUITING
Brief Summary: This phase III trial compares the effect of telotristat ethyl and the current standard of care somatostatin analog therapy or somatostatin analog therapy alone in treating patients with neuroendocrine tumor that has spread to other places in the body (metastatic). Telotristat ethyl and somatostatin analog therapy may help to control carcinoid syndrome and carcinoid heart disease.
Study Results: NO
Conditions: Locally Advanced Neuroendocrine Neoplasm|Metastatic Neuroendocrine Neoplasm
Interventions: DRUG: Placebo Administration|OTHER: Questionnaire Administration|DRUG: Telotristat Ethyl
Primary Outcome Measures: Percent change in N-terminal pro B-type natriuretic peptide (NT-proBNP), Baseline to 6 months
Secondary Outcome Measures: Change in 6-minute walk test (6MWT), Baseline to 3 and 6 months|Change in Carcinoid Valvular Heart Disease

(CVHD) score, Baseline to 3 and 6 months|Change (significant change or non-significant change) in global longitudinal myocardial strain assessment of the left and right ventricle, Baseline to 3 and 6 months|Change in tricuspid annular plane systolic excursion (normal vs. abnormal), Baseline to 3 and 6 months|Change in plasma 5-HIAA levels, Baseline to 3 and 6 months|Change in high sensitivity troponin T, Baseline to 3 and 6 months|Change in quality of life questionnaire, Baseline to 3 and 6 months|Incidence of adverse events, Up to 6 months
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: TREATMENT
Other IDs: 2019-1205|NCI-2021-00852|2019-1205
Start Date: 2021-05-18
Primary Completion Date: 2023-08-31
Completion Date: 2023-08-31
First Posted: 2021-03-22
Results First Posted:
Last Update Posted: 2023-02-08
Locations: M D Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT02249520
Study Title: Calibration of MR and PET-MR Imaging Protocols at RIC
Study URL: https://beta.clinicaltrials.gov/study/NCT02249520
Acronym:
Study Status: RECRUITING
Brief Summary: This is a protocol to facilitate on-site calibration of the technical aspects of the Siemens Biograph mMR (molecular MR) Positron Emission Tomography-Magnetic Resonance (PET-MR) scanner and the 3T Siemens Vida MR scanner at the Cedars-Sinai Medical Center (CSMC) Biomedical Imaging Research Institute (BIRI) Research Imaging Core after scanner installation. The mMR is a FDA-approved standard clinical device (non-experimental) and will be used in accordance with clearance and approval from the FDA. The Vida is a state-of-the-art FDA approved scanner and will be clinically licensed within a short time.
Study Results: NO
Conditions: Cancer|Coronary Artery Disease
Interventions: OTHER: PET-MR imaging on Biograph mMR scanner|OTHER: MR-only imaging on Biograph mMR scanner|OTHER: MR imaging on the Siemens Vida 3T MR scanner

Primary Outcome Measures: composite of measures of organ uptake, maximum target-to-background ratio and maximum standard uptake value as standard with FDG PET for maximum image quality for all standard protocols., The mMR is a FDA-approved standard clinical device (non-experimental) and will be used in accordance with clearance and approval from the FDA. Results obtained from these tests will not be analyzed towards the end point of any study and will solely be used to finalize and calibrate the technical performance of the new scanner. All scans will be visually assessed for technique calibration., one day
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Cedars-Sinai Medical Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 35521
Start Date: 2014-09
Primary Completion Date: 2040-12
Completion Date: 2040-12
First Posted: 2014-09-25
Results First Posted:
Last Update Posted: 2022-03-08
Locations: Cedars-Sinai Medical Center, Los Angeles, California, 90048, United States
Study Documents:

NCT Number: NCT03243604
Study Title: cARdiotoxicity Profile of aBIraTeRone in prostAte Cancer : a pharmacoviGilancE Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03243604
Acronym: ARBITRAGE
Study Status: COMPLETED
Brief Summary: Abiraterone associated with prednisone is used in prostate cancer. Abiraterone is a selective small-molecule inhibiting cytochrome P450 17A1 (CYP17A1), a key enzyme in androgen synthesis.

CYP17A inhibition is also responsible for mineral corticosteroid related adverse events as hypokaliemia, fluid retention, and hypertension. Primary hyperaldosteronism is associated with cardiovascular toxicities such as atrial fibrillation and cardiac failure. Other androgen-deprivation therapies are not associated with increased mineral corticosteroid level.

This study investigates reports of cardiovascular toxicities for treatment including L02 (sex hormones used in treatment of neoplastic diseases), and G03 (sex hormones) used in prostate cancer in the French pharmacovigilance database and in the EudraCT database.
Study Results: NO
Conditions: Arrhythmias, Cardiac|Atrial Fibrillation and Flutter|Tachycardia, Supraventricular|Cardiac Failure
Interventions: DRUG: L02 (sex hormones used in treatment of neoplastic diseases) and G03 (sex hormones)
Primary Outcome Measures: Analysis of disproportionality of reports for cardiotoxicity associated with abiraterone as compared to enzalutamide by performing a case- non-case study, Analysis of disproportionality of reports for cardiotoxicity associated with abiraterone as compared to enzalutamide by performing a case- non-case study, 2 months
Secondary Outcome Measures: Compare the reporting of suspected drug-induced supraventricular arrhythmias with abiraterone as compared to enzalutamide by performing a disproportionality analysis, Compare the reporting of suspected drug-induced supraventricular arrhythmias with abiraterone as compared to enzalutamide by performing a disproportionality analysis, 2 months|Compare the reporting of drug-induced cardiac failure with abiraterone as compared to enzalutamide by performing a disproportionality analysis, Compare the reporting of drug-induced cardiac failure with abiraterone as compared to enzalutamide by performing a disproportionality analysis, 2 months|Compare the reporting of drug-induced cardiac failure and/or supraventricular arrhythmias with abiraterone as compared to other androgen-deprivation therapies by performing a disproportionality analysis, Compare the reporting of drug-induced cardiac failure and/or supraventricular arrhythmias with abiraterone as compared to other androgen-deprivation therapies by performing a disproportionality analysis, 2 months|Description of other mineralocorticoid related adverse events (hypokaliemia, fluid retention, and hypertension) when the cardio toxicity occurs, Description of other mineralocorticoid related adverse events (hypokaliemia, fluid retention, and hypertension) when the cardio toxicity occurs, 2 months|Description of the population of patients having a cardio-vascular adverse event, Description of the population of patients having a cardio-vascular adverse event, 2 months|Description of the duration of treatment when the toxicity happens (role of cumulative dose), Description of the duration of treatment when the toxicity happens (role of cumulative dose), 2 months|Description of the drug-drug interactions associated with adverse events, Description of the drug-drug interactions associated with adverse events, 2 months|Causality assessment of reported cardiovascular events according to the WHO-UMC system, Causality assessment of reported cardiovascular events according to the WHO-UMC system, 2 months
Other Outcome Measures:
Sponsor: Groupe Hospitalier Pitie-Salpetriere
Collaborators:

Sex: MALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1717
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CIC1421-17-08
Start Date: 2017-05-16
Primary Completion Date: 2017-07-13
Completion Date: 2017-07-13
First Posted: 2017-08-09
Results First Posted:
Last Update Posted: 2018-10-18
Locations: Centre Régional de Pharmaco-vigilance - Paris, Pitié-Salpétrière, Paris, Ile De France, 75013, France
Study Documents:

NCT Number: NCT05726604
Study Title: 4D CT Scan Versus 3D CT Scan Concerning Cardiac Dosimetry Assesment for Left Sided Breast Cancers Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT05726604
Acronym: RD3D4
Study Status: RECRUITING
Brief Summary: To establish if the cardiac radiation dose assesment is well aproximated with routine 3D CT scan compared to 4D CT experimental scan with respiratory gating (breath motion monitoring). The study population relates to left side breast cancers female patients that require a radiation therapy treatment.
Study Results: NO
Conditions: Breast Cancer|Radiation-Induced Vascular Disease|Left Anterior Descending Coronary Artery Stenosis|Radiotherapy Side Effect|Cardiac Ischemia|Left Sided Breast Cancer|LAD (Left Anterior Descending) Coronary Artery Stenosis
Interventions: OTHER: Respiratory gating
Primary Outcome Measures: 3D LAD mean dose vs 4D LAD mean dose, To determine if the mean LAD (left anterior descending artery) dose significantly changes statistically between an usual 3D CT scan versus a 4D CT with breathing motion monitoring (10 breathing phases are monitored).

Based on stastical test with 95% confidence intervals, to evaluate if there is a significant difference between 4D CT LAD mean dose and 3D CT LAD mean dose., 1 week
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Central Hospital Saint Quentin
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT

Phases: NA
Enrollment: 15
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: CROSSOVER|Masking: NONE|Primary Purpose: OTHER
Other IDs: 2022-A02337-36
Start Date: 2023-03-02
Primary Completion Date: 2023-06-05
Completion Date: 2023-06-15
First Posted: 2023-02-14
Results First Posted:
Last Update Posted: 2023-06-09
Locations: Saint Quentin Hospital, Saint-Quentin, Hauts-de-france, 02100, France
Study Documents:

NCT Number: NCT03221127
Study Title: Kuopio Ischaemic Heart Disease Risk Factor Study (Nutrition Component)
Study URL: https://beta.clinicaltrials.gov/study/NCT03221127
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: To determine associations between dietary factors and risk of major chronic diseases and their risk factors
Study Results: NO
Conditions: Cardiovascular Diseases|Diabetes|Metabolic Syndrome|Cancer|Inflammatory Disease|Atherosclerosis|Cognitive Decline|Liver Diseases|Death|Pain, Chronic|Depression|Infection|Chronic Disease
Interventions:
Primary Outcome Measures: Cardiovascular disease, Incidence of cardiovascular disease, Annually between March 1984 and December 2052|Carotid atherosclerosis, Progression of common carotid artery - intima-media thickness (CCA-IMT), From baseline to 4-y, 11-y and 20-y examinations|Death, Incidence of death, Annually between March 1984 and December 2052
Secondary Outcome Measures: Type 2 diabetes, Incidence of type 2 diabetes, Annually between March 1984 and December 2052|Dementia, Incidence of dementia, Annually between March 1984 and December 2052|Cancer, Incidence of cancer, Annually between March 1984 and December 2052|Infectious disease, Incidence of hospitalization due infectious disease, Annually between March 1984 and December 2052
Other Outcome Measures:
Sponsor: University of Eastern Finland
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 2682
Funder Type: OTHER

Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: KIHD Nutrition
Start Date: 1984-03-01
Primary Completion Date: 2052-12-31
Completion Date: 2052-12-31
First Posted: 2017-07-18
Results First Posted:
Last Update Posted: 2019-04-18
Locations:
Study Documents:

NCT Number: NCT03286127
Study Title: Palliative Outcome Evaluation Muenster I
Study URL: https://beta.clinicaltrials.gov/study/NCT03286127
Acronym: POEM I
Study Status: UNKNOWN
Brief Summary: For patients with an advanced disease and their families an excellent and compassionate care is essential. However, in hospitals optimal end-of-life care is not yet fully realized and patient's needs are often not met. Palliative care is able to increase patients' quality of life and to carefully meet their and their families' needs.

To improve the awareness of unmet needs patient-reported outcome measurement has been the pivot of latest palliative care research. Besides the improvement of care outcome measurement allows the evaluation of the quality of palliative care and comparisons on a national and international level.

The aim of the present study is to evaluate the quality of palliative care in different settings (palliative care unit, inpatient and outpatient consultation teams) using the Integrated Palliative Care Outcome Scale (IPOS). The IPOS has been lately developed as improved follow-up version of the Palliative Care Outcome Scale (POS) integrating most important questions and simultaneously being brief and comprehensive. The study is planned as a multi-centric observational study. Primary endpoint is the reduction of symptom burden of patients.

The clinical study hypothesis bases on the assumption that palliative care can change the symptom burden, measured by a change in the IPOS overall profile score, and that there might be a difference in the size of the effect depending on the caring setting.
Study Results: NO
Conditions: Cancer|Chronic Heart Failure|COPD Exacerbation|Palliative Care
Interventions: OTHER: specialized palliative care
Primary Outcome Measures: symptom burden (IPOS), Change from baseline in palliative care needs and specific symptoms (at day 7) assessed

with the Integrated Palliative Care Outcome Scale (IPOS). The IPOS includes 10 symptoms and 7 questions on patients and carers emotional situation, spiritual concerns, and provision of information and support. The overall profile score is the sum of the scores from each of the 17 questions., From Baseline to End of Follow-Up (0, 1 week)
Secondary Outcome Measures: Generic health-related quality of life (EQ-5D-5L), Change from baseline in patients' generic health-related quality of life measured with the EuroQoL Group 5-Dimension 5-Level Self Report Questionnaire (EQ-5D-5L). The EQ-5D-5L essentially consists of 2 pages - the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The visual analogue scale of the EQ-5D-5L questionnaire ranges from 0 to 100 (with 0 representing the worst health the patient can imagine and 100 representing the best health the patient can imagine)., From Baseline to End of Follow-Up (0, 1 week)
Other Outcome Measures:
Sponsor: University Hospital Muenster
Collaborators: St. Franziskus Hospital|Raphaelsklinik Münster|Josephs Hospital Warendorf|Palliativnetz Muenster gGmbH
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 347
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UKM_POEM I
Start Date: 2017-09-11
Primary Completion Date: 2019-10
Completion Date: 2019-12
First Posted: 2017-09-18
Results First Posted:
Last Update Posted: 2018-10-09
Locations: Hospital St. Raphael Muenster, Muenster, North Rhine-Westphalia, 48143, Germany|Hospital St. Franziskus Muenster, Muenster, North Rhine-Westphalia, 48145, Germany|University Hospital Muenster, Muenster, North Rhine-Westphalia, 48149, Germany|Palliativnetz Muenster, Muenster, North Rhine-Westphalia, 48161, Germany|Hospital St. Josef Warendorf, Warendorf, North Rhine-Westphalia, 48231, Germany
Study Documents:

NCT Number: NCT05584163
Study Title: Pilot Study to Evaluate the Prevention and Safety of Doxorubicin-induced Cardiomyopathy Using Extracorporeal Shock Waves
Study URL: https://beta.clinicaltrials.gov/study/NCT05584163
Acronym:
Study Status: RECRUITING

Brief Summary: Until now, patients receiving doxorubicin chemotherapy should use only the cumulative dose related to known cardiotoxicity, or if cardiotoxicity occurs below the known cumulative dose, use of doxorubicin as chemotherapy should be stopped. In this study, in patients with normal heart function receiving doxorubicin chemotherapy, extracorporeal shock wave therapy was performed 3 times a week during chemotherapy, and 1 cycle of extracorporeal shock wave therapy was performed (every 6 weeks) every 2 cycles of chemotherapy. Echocardiography should be performed at baseline and every 4 cycles of chemotherapy, and follow-up 3 months after chemotherapy is completed to compare the incidence of cardiomyopathy caused by chemotherapy between the two groups.
Study Results: NO
Conditions: Breast Cancer
Interventions: DEVICE: Extracorporeal shock waves
Primary Outcome Measures: Chemotherapy induced cardiomyopathy, Primary efficacy endpoint: Cardiomyopathy is defined as the LV longitudinal strain value, an echocardiographic index, and the incidence rate of cardiomyopathy between the experimental group and the control group is compared. The definition of cardiomyopathy in LV longitudinal strain is as follows

- When the strain value of the longitudinal axis of the left ventricle (LV global longitudinal strain) decreases to less than -17.5% or reduction of \>15% compared to the baseline value., 3months, 6months
Secondary Outcome Measures: Chemotherapy induced cardiomyopathy 2, Secondary efficacy endpoint: To compare the rate of cardiomyopathy between the experimental group and the control group in breast cancer patients receiving doxorubicin-containing chemotherapy with baseline normal heart function. The definition of cardiomyopathy is as follows.

* A decrease of more than 10% in absolute left ventricular ejection fraction (LVEF) or
* A decrease of less than 50% from the normal range of left ventricular ejection fraction (\>55%), 3months, 6months
Other Outcome Measures:
Sponsor: Ewha Womans University Mokdong Hospital
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 72
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 2020-12-044-012
Start Date: 2020-10-01
Primary Completion Date: 2023-06

Completion Date: 2023-06
First Posted: 2022-10-18
Results First Posted:
Last Update Posted: 2023-06-02
Locations: Kiwhan Kim, Seoul, Yangcheon Gu, 03168, Korea, Republic of
Study Documents:

NCT Number: NCT03934905
Study Title: Protective Effects of the Nutritional Supplement Sulforaphane on Doxorubicin-Associated Cardiac Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT03934905
Acronym:
Study Status: RECRUITING
Brief Summary: Cardiomyopathy is a major complication of doxorubicin (DOX) chemotherapy, and 10-21% of breast cancer patients receiving DOX experience compromised cardiac function. Recent advancements have increased cancer survivorship but it remains clinically challenging to mitigate the cardiotoxic side effects. Although there are several strategies used to reduce the occurrence and severity of DOX-induced cardiotoxicity, they are not particularly effective. Hence, there is an urgent need to develop new strategies that prevent the cardiotoxic effects of DOX but maintain its potency as a cancer therapy. Because the cellular events responsible for the antitumor activity of DOX and DOX-induced cardiotoxicity are distinctly different, it may be possible to develop therapies that selectively mitigate DOX-induced cardiotoxicity. Thus, the investigators propose to test an adjuvant therapy that combines the phytochemical sulforaphane (SFN) with DOX to attenuate DOX-induced cardiomyopathy. SFN activates the transcription factor Nrf2 and induces defense mechanisms in normal cells. Furthermore, SFN inhibits carcinogenesis and metastases and enhances cancer cell sensitivity to DOX, seemingly through Nrf2-independent mechanisms. SFN has also been tested in several clinical trials, although never together with DOX. Our early animal studies suggest that by activating Nrf2, SFN selectively protects the mouse and rat from DOX cardiotoxicity, enhances survival and enhances the effects of DOX on cancer growth in a rat breast cancer model. The investigators suspect that SFN affects DOX metabolism in cancer cells to enhance tumor regression, or it may synergistically activate other key antitumor mechanisms. Hence, SFN may improve the clinical outcome of cancer therapy by (1) attenuating DOX cardiotoxicity and (2) enhancing the effects of cancer treatment on the tumor. Our hypothesis is that SFN protects the heart from DOX-mediated cardiac injury without altering the antitumor efficacy of DOX. In Aim 1, the investigators will conduct an early-phase clinical trial to determine if SFN is safe to administer to breast cancer patients undergoing DOX chemotherapy. In Aim 2, the investigators will determine if SFN decreases DOX-induced inflammatory responses and enhances Nrf2- and SIRT1-target gene expression in breast cancer patients. Notably, transcript and protein signatures in peripheral blood mononuclear cells (PBMCs) can predict cardiac function in patients undergoing DOX chemotherapy for

breast cancer. The investigators will also determine if SFN/DOX treatment activates Nrf2- and SIRT1-dependent gene expression, alters the levels of biomarkers for presymptomatic DOX-cardiotoxicity and mitigates the generation of cardiotoxic metabolites in PBMCs and plasma. These studies will facilitate the development of SFN co-treatment as a strategy to enhance the efficacy and safety of DOX cancer therapy.
Study Results: NO
Conditions: Anthracycline Related Cardiotoxicity in Breast Cancer
Interventions: DRUG: sulforaphane|DRUG: Placebo Oral Tablet
Primary Outcome Measures: Change in cardiac function after DOX therapy with or without sulforaphane through diagnostic studies, 2D Echo will be used to measure cardiac function amongst patients on DOX therapy who are exposed to sulforaphane or placebo., At baseline and 1 year from baseline assessment.
Secondary Outcome Measures: Elevation of troponin levels as a surrogate evidence of DOX related cardiotoxicity will be checked at baseline, prior to each DOX therapy and then at 1 year from baseline assessment (Each cycle is 14 days)., Troponin will be used to assess for cardiotoxicity amongst patients on DOX therapy who are exposed to sulforaphane or placebo., At baseline, prior to each cycle of DOX, at completion of 4th cycle of DOX therapy and 1 year from baseline assessment.|Tumor size in patients on DOX therapy with or without sulforaphane treatment will be assessed at baseline, at completion of DOX chemotherapy (4 cycles planned with each cycle being 14 days) and at 1 year from baseline assessment., We will use PET imaging for comparison of change in tumor size for patients on DOX therapy with or without sulforaphane., 2 days before first DOX treatment, 2 days after completion of 4th cycle of DOX therapy and 1 year from first DOX treatment
Other Outcome Measures:
Sponsor: Texas Tech University Health Sciences Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1|PHASE2
Enrollment: 70
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: L19-065
Start Date: 2022-06-01
Primary Completion Date: 2025-11-01
Completion Date: 2026-06-01
First Posted: 2019-05-02
Results First Posted:
Last Update Posted: 2022-07-19
Locations: Texas Tech University Health Sciences Center, Lubbock,

Texas, 79430, United States
Study Documents: Study Protocol and Statistical Analysis Plan|Informed Consent Form

NCT Number: NCT01135849
Study Title: B-Receptor Signaling in Cardiomyopathy
Study URL: https://beta.clinicaltrials.gov/study/NCT01135849
Acronym:
Study Status: COMPLETED
Brief Summary: We hope to determine the importance of different genes (including B receptors) in anthracycline-induced cardiomyopathy. This has important benefits to patients exposed to anthracyclines, as this could help determine whether certain individuals have increased susceptibility to cardiac injury.
Study Results: NO
Conditions: Carcinomas|Amyloidosis|Anal Cancer|Anemia|Cholangiocarcinoma of the Extrahepatic Bile Duct|Transitional Cell Carcinoma of Bladder|Bone Marrow Transplant Failure|Bone Cancer|Cancer of Brain and Nervous System|Breast Cancer|Carcinoma of the Large Intestine|Endocrine Cancer|Esophageal Cancer|Eye Cancer|Gall Bladder Cancer|Gastric (Stomach) Cancer|Gastrooesophageal Cancer|Gastrointestinal Stromal Tumor (GIST)|Gynecologic Cancers|Head and Neck Cancers|Hepatobiliary Neoplasm|Kidney (Renal Cell) Cancer|Leukemia|Lung Cancer|Hodgkin Disease|Lymphoma, Non-Hodgkin|Mesothelioma|Multiple Myeloma|Myelodysplastic Syndromes (MDS)|Neuroendocrine Tumors|Myeloproliferative Disorders|Pancreatic Cancer|Prostate Cancer|Skin Cancer|Soft Tissue Sarcoma|Testicular Cancer|Thymus Cancer|Thyroid Cancer
Interventions:
Primary Outcome Measures: Development of cardiomyopathy, Decrease in fractional shortening below normal (\<28%), Within 5 years after receiving anthracyclines.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Daniel Bernstein
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 99
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PEDSVAR0038|SU-11172008-1345
Start Date: 2008-11
Primary Completion Date: 2010-10
Completion Date: 2010-10
First Posted: 2010-06-03
Results First Posted:
Last Update Posted: 2015-11-17

Locations: Stanford University School of Medicine, Stanford, California, 94305, United States
Study Documents:

NCT Number: NCT04199663
Study Title: Socioeconomic Status, Secondary Prevention Activities and Recurrence After a Myocardial Infarction
Study URL: https://beta.clinicaltrials.gov/study/NCT04199663
Acronym:
Study Status: COMPLETED
Brief Summary: This is a nationwide cohort study on real-world patients (n≈30,000) surviving a first myocardial infarction (MI) 2006-2013 and alive to attend a routine 1-year follow-up. Associations between Socioeconomic Status (SES) and secondary preventive actions (SPAs) throughout the first year is studied and assessed as possible mechanisms underlying the increased risk of a first recurrent hard cardiocvascular (CV) outcome, recurrent atherosclerotic cardiovascular disease (rASCVD), in patients with low Socioeconomic Status during long-term follow-up (2006-2018).
Study Results: NO
Conditions: Socioeconomic Status|Secondary Prevention|Myocardial Infarction|Cardiovascular Disease|Stroke
Interventions:
Primary Outcome Measures: first recurrent atherosclerotic cardiovascular disease event (rASCVD), composite outcome including non-fatal MI (I210-I214, I219, I220, I221, I228 or I229) or coronary heart disease death (CHD) (I210-I214, I219, I220, I221, I228, I229, I461 or I469) or fatal or non-fatal ischemic stroke (I630-I635, I638 or I639) according to the International Classification of Diseases 10th edition (ICD-10), from date of 1-year visit post-MI (baseline) until date of outcome, censoring or study end (2018)
Secondary Outcome Measures:
Other Outcome Measures: Goal: physical training program, participated in organized physical training program after the initial care, at 1-year revisit|Goal: LDL-C goal, attained LDL-C level below treatment target, at 1-year revisit|Goal: Blood pressure goal, attained blood pressure levels below treatment target, at 1-year revisit|Goal: smoking cessation, Patients being current smokers at their initial care who successfully quit smoking., at 1-year revisit|Goal: physical activity, reported \>30 minutes of physical activity ≥5 times a week, at 1-year revisit|Goal: statin treatment, on statin treatment 1 year after the index MI, at 1-year revisit|Goal: Renin-angiotensin-aldosteron system (RAAS)-inhibition, Patients with congestive heart failure, diabetes or hypertension at the index Mi on treatment with angiotensin converting enzyme inhibitor or angiotensin receptor blocker., at 1-year revisit|Goal: HbA1c goal, Patients with diabetes with attained HbA1c treatment target, at 1-year revisit|SPA: cardiac rehabilitation program, participation in structured program after the index MI, during 1st year after initial care|SPA: diet course, participation in course after the index MI, during 1st year after

initial care|SPA: statin intensity increase, statin intensity increase decided at routine revisits (Dosages categorized into high (Rosuvastatin 20–40 mg or Atorvastatin 40–80 mg), moderate (Rosuvastatin 5–10 mg, Atorvastatin 10–20 mg, or Simvastatin 20–40 mg) and low (Simvastatin 10 mg)), 2 months or 1 year after initial care|SPA: high intensity statins, on high intensity statin treatment (Rosuvastatin 20–40 mg or Atorvastatin 40–80 mg), at 1-year revisit|SPA: LDL-C reduction, LDL-C reduction between routine revisits, 2 months and 1 year after initial care|SPA: lipid monitoring, Blood lipid panel measured, 2 months or 1 year after initial care|SPA: type of follow-up, decided follow-up by office revisit or by phone, 2 month revisit|SPA: reperfusion, type of reperfusion treatment chosen in STEMI and NSTEMI, initial care|SPA: revascularized, achieved complete revascularization in STEMI and NSTEMI, initial care|SPA: staged procedure, Decision on continued invasive procedures at a later stage, initial care|SPA: smoking cessation counseling, received through cessation program or counseling, 2 months or 1 year after initial care|SPA: HbA1c monitoring, Patients with diabetes at initial care having their HbA1c measured at least twice, during initial care, at 2 months and 1 year after initial care|SPA: Anti-stress program, Patients reporting anxiety or sadness participating in anti-stress program, 1 year after initial care|SPA: counter-metabolic syndrome actions, Patients with the metabolic syndrome participating in physical training and diet course or in cardiac rehabilitation program, 2 months or 1 year after initial care
Sponsor: Karolinska Institutet
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 30191
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 3
Start Date: 2006-01-01
Primary Completion Date: 2018-12-31
Completion Date:
First Posted: 2019-12-16
Results First Posted:
Last Update Posted: 2020-02-20
Locations:
Study Documents:

NCT Number: NCT04150120
Study Title: eHealth as an Aid for Facilitating and Supporting Self-management in Families With Long-term Childhood Illness
Study URL: https://beta.clinicaltrials.gov/study/NCT04150120
Acronym: eChildHealth
Study Status: ENROLLING_BY_INVITATION

Brief Summary: The overall aim is twofold: 1) to stretch the borderline regarding the present knowledge of clinical and economic cost-effectiveness of eHealth as an aid for facilitating and supporting self-management in families with long-term childhood illness, and 2) to develop a sustainable multidisciplinary research environment for advancing, evaluating, and implementing models of eHealth to promote self-management for children and their families.

A number of clinical studies are planned for, covering different parts of paediatric healthcare. The concept of child-centred care is essential. Experienced researchers from care science, medicine, economics, technology, and social science will collaborate around common issues. Expertise on IT technology will analyse the preconditions for using IT; economic evaluations will be performed alongside clinical studies; and cultural and implementation perspectives will be used to analyse the challenges that arise from the changes in relations among children, family and professionals, which may occur as a result of the introduction of eHealth.

Child health is not only important in itself. Investments in child health may also generate significant future gains, such as improved educational and labour market performance. Six complex, long-term and costly challenges in paediatric healthcare are planned for, involving eHealth technology such as interactive video consultation, pictures, on-line monitoring, and textual communication. The research follows an international framework for developing and evaluating complex interventions in healthcare. End-users (families) and relevant care providers (professionals in health and social care) will participate throughout the research process. The overall aim is certainly to analyse eHealth as an aid for facilitating and supporting self-management. However, the plan also includes the research issue whether eHealth at the same time improves the allocation of scarce health care- and societal resources.
Study Results: NO
Conditions: Preterm Birth|Pediatric Cancer|Hirschsprung Disease|Congenital Malformation|Congenital Heart Disease|Nutrition Disorder, Child
Interventions: DEVICE: e-health device with application
Primary Outcome Measures: The PedsQL Healthcare Satisfaction Generic Module, The PedsQL Healthcare Satisfaction Generic Module is composed of 24 items comprising 6 dimensions. Item scaling: 5-point Likert scale: 0 (Never) to 4 (Always) and Not Applicable. Higher scores indicate higher satisfaction. The scale includes the variables: information, family inclusion, communication, technical skills, emotional needs, and overall satisfaction., After their participation in the study has ended, on average after 2-4 weeks.|Cost-utility ratios, Health economic variables, After their participation in the study has ended, on average after 2-4 weeks.
Secondary Outcome Measures: The child's general and specific health status, This questionnaire contains information about the health of

each child both at the time when the study begins and when the study ends. It asks for information on the weight of the child, the diagnosis, the treatment, specific needs when released from hospital, general health status when released from hospital, general health status at end of study. The answers are either given as multiple choice or as free text., Before the study begins and after their participation in the study has ended, on average after 2-4 weeks.|The PedsQL 2.0 Family Impact Module, The PedsQL 2.0 Family Impact Module is composed of 36 items comprising 8 dimensions. Item scaling: 5-point Likert scale: 5-point Likert scale from 0 (Never) to 4 (Almost always). Higher scores indicate better functioning., After their participation in the study has ended, on average after 2-4 weeks.|The Parental Stress (Parental - Persistent Role Problems), The Parental Stress (Parental - Persistent Role Problems) is composed of 9 items. Item scaling: 5-point Likert scale: 5-point Likert scale from 0 (Does not happen) to 4 (Happens always). Lower scores indicate less stress., After their participation in the study has ended, on average after 2-4 weeks.|Adverse events that occurs during the study period, Any adverse events occurring during the study period will be recorded in free text format by the staff for all participants., After their participation in the study has ended, on average after 2-4 weeks.|The Clavien-Dindo Classification, The therapy used to correct a specific complication is the basis of this classification in order to rank a complication in an objective and reproducible manner. The scale consists of 7 grades (I, II, IIIa, IIIb, IVa, IVb and V). A high grade indicates a more severe problem., After their participation in the study has ended, on average after 2-4 weeks.|Length of hospital stay, Days, After their participation in the study has ended, on average after 2-4 weeks.| Number of routine and acute visits, Number of routine and acute visits, After their participation in the study has ended, on average after 2-4 weeks.|Health economic variables: Family time, Distribution of family time use, After their participation in the study has ended, on average after 2-4 weeks.|Health economic variables: Family economy, Family economy, After their participation in the study has ended, on average after 2-4 weeks.|Health economic variables: Hopsital resources, Use of hospital resources, After their participation in the study has ended, on average after 2-4 weeks.|Health economic variables: Health care resources, Use of other healthcare resources, After their participation in the study has ended, on average after 2-4 weeks.|Health economic variables: Health care expenditures, Healthcare expenditures by type of resource, After their participation in the study has ended, on average after 2-4 weeks.|Health economic variables: Productivity, Loss of production, After their participation in the study has ended, on average after 2-4 weeks.|Health economic variables: Utility, Utility scores., After their participation in the study has ended, on average after 2-4 weeks.|EQ-5D-3L, The EQ-5D-3L descriptive system comprises the following five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, and extreme problems. The patient is asked to indicate his/her health state by

ticking the box next to the most appropriate statement in each of the five dimensions. This decision results into a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state., After their participation in the study has ended, on average after 2-4 weeks.
Other Outcome Measures:
Sponsor: Lund University
Collaborators: Skane University Hospital|Rigshospitalet, Denmark|Arba Minch University|University of Iceland
Sex: ALL
Age: CHILD
Phases: NA
Enrollment: 420
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 2018-01399
Start Date: 2019-10-15
Primary Completion Date: 2024-10-15
Completion Date: 2024-12-31
First Posted: 2019-11-04
Results First Posted:
Last Update Posted: 2022-12-09
Locations: Rigshospitalet, Copenhagen, Denmark|Hillerød Hospital, Hillerød, Denmark|Neonatal Department, Skåne University Hospital, Lund, Skåne, Sweden|Paediatric Cardiology Department, Skåne University Hospital, Lund, Skåne, Sweden|Paediatric Oncology Department, Skåne University Hospital, Lund, Skåne, Sweden|Paediatric Surgery Department, Skåne University Hospital, Lund, Skåne, Sweden
Study Documents:

NCT Number: NCT00001620
Study Title: Screening for Hematology Branch Protocols
Study URL: https://beta.clinicaltrials.gov/study/NCT00001620
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: This study allows the evaluation of subjects in order to determine their ability to safely participate in other active research studies.

After subjects complete the screening process, they will be offered the opportunity to participate in an active research study, or if no appropriate studies are available information and recommendations will be provided for other treatment options....
Study Results: NO
Conditions: Hematologic Disease and Disorders|Donors|Healthy Volunteer
Interventions:
Primary Outcome Measures: Primary endpoint is the results of clinical,

imaging and laboratory assessments., Results of clinical, imaging and laboratory assessments, ongoing
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 10000
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 970041|97-H-0041
Start Date: 1996-12-31
Primary Completion Date:
Completion Date:
First Posted: 1999-11-04
Results First Posted:
Last Update Posted: 2023-06-22
Locations: National Institutes of Health Clinical Center, Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT03830320
Study Title: Positron Emission Tomography (PET) Imaging of Thrombosis
Study URL: https://beta.clinicaltrials.gov/study/NCT03830320
Acronym:
Study Status: RECRUITING
Brief Summary: The purpose of the study is to evaluate a new radiotracer called 64Cu-FBP8 for PET-MR imaging of thrombosis. The tracer has the potential of detecting thrombosis anywhere in the body, for instance in the left atrial appendage of patients with atrial fibrillation, and thereby may provide a non-invasive alternative to the current standard-of-care methods.
Study Results: NO
Conditions: Atrial Fibrillation|COVID-19|Cancer|Thrombosis
Interventions: DRUG: [64Cu]FBP8|DEVICE: PET/MR|PROCEDURE: Blood Collection|PROCEDURE: Electrocardiogram
Primary Outcome Measures: Complete blood count, To model pharmacokinetics of \[64Cu\]FBP8 metabolism in healthy volunteers., 36 hours|Target to Background Ratio LAA, To determine the signal threshold of \[64Cu\]FBP8 that produces the highest accuracy of \[64Cu\]FBP8 -PET to detect left atrial thrombosis in patients with atrial fibrillation., 4 hours|Target to Background Ratio, To determine the signal threshold of \[64Cu\]FBP8 that produces the highest accuracy of \[64Cu\]FBP8 -PET to detect thrombosis in patients with known thrombus or suspicion of thrombus., 4 hours|Time activity curve, To evaluate human dosimetry and radiation burden in healthy volunteers., 48 hours

Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Massachusetts General Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 240
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 2015P002385
Start Date: 2016-08-01
Primary Completion Date: 2025-10-31
Completion Date: 2026-01-30
First Posted: 2019-02-05
Results First Posted:
Last Update Posted: 2022-12-21
Locations: Massachusetts General Hospital, Boston, Massachusetts, 02114, United States
Study Documents:

NCT Number: NCT02440620
Study Title: Cardiac Toxicity in Medical Treatment of Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02440620
Acronym: CaTOB
Study Status: COMPLETED
Brief Summary: This study will describe the epidemiology including prognosis of heart failure related to treatment with anthracycline and trastuzumab for breast cancer.

In a prospective study Human Epidermal Growth Factor Receptor 2 (HER2) positive breast cancer patients scheduled for trastuzumab treatment at Odense University Hospital, will be offered advanced echocardiographic examination, test of bio-markers and genetic markers for the purpose of investigating if early identification of patients in particular risk of developing heart failure is feasible.
Study Results: NO
Conditions: Heart Failure|Breast Cancer
Interventions:
Primary Outcome Measures: Global longitudinal strain by two dimentional speckle tracking., Change in outcome from initiation of trastuzumab treatment and after 3,6, and 9 month.|Ratio between the mitral E velocity and early diastolic maximum global strain rate (E/SRE)., Change in outcome from initiation of trastuzumab treatment and after 3,6, and 9 month.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Odense University Hospital

Collaborators: University of Southern Denmark
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 45
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: S-20140090
Start Date: 2014-10
Primary Completion Date: 2018-08
Completion Date: 2018-08
First Posted: 2015-05-12
Results First Posted:
Last Update Posted: 2019-05-01
Locations: Odense University Hospital, Odense c, 5000, Denmark
Study Documents:

NCT Number: NCT04466020
Study Title: SELF - BREATHE for Chronic Breathlessness
Study URL: https://beta.clinicaltrials.gov/study/NCT04466020
Acronym:
Study Status: COMPLETED
Brief Summary: Semi-structured qualitative interviews will be conducted to understand key factors that would enable / facilitate patients with chronic breathlessness to potentially use an online breathlessness intervention (SELF-BREATHE).
Study Results: NO
Conditions: COPD|Cancer|Heart Failure|Interstitial Disease|Dyspnea
Interventions: OTHER: Qualitative research interviews to be conducted
Primary Outcome Measures: Descriptive qualitative analysis of patients' preferences, values and motivations that would influence the use of an online self - management intervention for chronic breathlessness (SELF-BREATHE)., Qualitative data, 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: King's College Hospital NHS Trust
Collaborators: King's College London
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 25
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: KCH20-056|ICA-CL-2018-04-ST2-001
Start Date: 2020-06-03
Primary Completion Date: 2020-11-11
Completion Date: 2020-11-11
First Posted: 2020-07-10

Results First Posted:
Last Update Posted: 2021-09-02
Locations: King's College Hospital NHS Foundation Trust, London, SE5 9RS, United Kingdom
Study Documents:

NCT Number: NCT05377320
Study Title: PAtient Similarity for Decision-Making in Prevention of Cardiovascular Toxicity (PACT): A Feasibility Study
Study URL: https://beta.clinicaltrials.gov/study/NCT05377320
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: This is a single-center, double-arm, open-label, randomized feasibility study that will determine whether a novel clinical decision aid accessed via the electronic health record will be acceptable to both cancer survivors and their cardiologists, will favorably impact appropriate medication use and cardiac imaging surveillance, and will improve clinician and patient decision-making, perception, and behavior towards cardioprotective medication usage and cardiovascular disease imaging utilization.
Study Results: NO
Conditions: Heart Failure|Coronary Artery Disease|Peripheral Artery Disease|Ischemia|Hypertension|Diabetes Mellitus|Cardiomyopathies|Cardiotoxicity
Interventions: OTHER: Clinical Decision Aid|OTHER: Standard Care
Primary Outcome Measures: Medication use, The number of subjects in which medication use pursued is consistent with current medical society recommendations appropriate for the subject., Week 0|Medication use, The number of subjects in which medication use pursued is consistent with current medical society recommendations appropriate for the subject., Week 12|Medication use, The number of subjects in which medication use pursued is consistent with current medical society recommendations appropriate for the subject., Week 24|Imaging surveillance, The number of subjects in which imaging surveillance pursued is consistent with current medical society recommendations appropriate for the subject., Week 0|Imaging surveillance, The number of subjects in which imaging surveillance pursued is consistent with current medical society recommendations appropriate for the subject., Week 12|Imaging surveillance, The number of subjects in which imaging surveillance pursued is consistent with current medical society recommendations appropriate for the subject., Week 24
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Medical College of Wisconsin
Collaborators: The Cleveland Clinic
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 60
Funder Type: OTHER

Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PRO00039290
Start Date: 2024-06
Primary Completion Date: 2025-12
Completion Date: 2026-12
First Posted: 2022-05-17
Results First Posted:
Last Update Posted: 2023-07-03
Locations: Froedtert & the Medical College of Wisconsin, Milwaukee, Wisconsin, 53226, United States
Study Documents:

NCT Number: NCT00005605
Study Title: Tamoxifen to Prevent Bone Loss and Heart Disease in Premenopausal Women Receiving Chemotherapy for Stage I or Stage II Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00005605
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Tamoxifen may be able to increase bone density and decrease cholesterol in women who are undergoing chemotherapy for breast cancer.

PURPOSE: Clinical trial to study the effectiveness of tamoxifen in preventing bone loss and heart disease caused by chemotherapy treatment in premenopausal women who have stage I or stage II breast cancer.
Study Results: NO
Conditions: Breast Cancer|Osteoporosis
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Northwestern University
Collaborators: National Cancer Institute (NCI)
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 79
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NU 95B2|NU-95B2|NCI-G00-1737
Start Date: 2000-02
Primary Completion Date: 2005-10
Completion Date: 2005-10
First Posted: 2003-01-27
Results First Posted:
Last Update Posted: 2011-02-21

Locations: Robert H. Lurie Comprehensive Cancer Center at Northwestern University, Chicago, Illinois, 60611, United States
Study Documents:

NCT Number: NCT03935282
Study Title: Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT03935282
Acronym: AH-HA
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The objective of this hybrid effectiveness-implementation study is to examine the effects of an EHR-based cardiovascular health assessment tool (AH-HA) among breast, prostate, colorectal, endometrial, and Hodgkin and non-Hodgkin lymphoma cancer survivors (N=600) receiving survivorship care in community oncology practices, using a group-randomized trial design (6 intervention practices and 6 usual care practices). Our central hypothesis is that the AH-HA tool will increase (1) cardiovascular health (CVH) discussions among survivors and oncology providers, (2) referrals and visits to primary care and cardiology (care coordination), and (3) cardiovascular (CV) risk reduction and health promotion activities compared to usual care.
Study Results: NO
Conditions: Breast Neoplasm|Prostatic Neoplasm|Colorectal Neoplasms|Endometrial Neoplasms|Hodgkin Disease|Non Hodgkin Lymphoma
Interventions: OTHER: AH-HA Tool in the EPIC EHR
Primary Outcome Measures: Proportion of patients reporting at least one non-ideal or missing CVH topic, Discussion of non-ideal cardiovascular health (CVH) factors (yes or no). CVH discussions will be defined as patient-reported discussions with their provider for any of the seven non-ideal CVH conditions identified for that patient. Conditions include CVH factors (cholesterol, blood pressure, glucose/hemoglobin A1c) and CVH behaviors (body mass index, smoking, diet, and physical activity). Measured using survivor survey (discussions, diet, and primary care) and EHR for other CVH factors., Baseline
Secondary Outcome Measures: Number of referrals to primary care and cardiology to manage CV risk, Medical chart abstraction of referrals and communication with providers regarding CVH at each survivor visit., 1 year|Number of CVH-relevant labs and treatments to manage CV risk, Medical chart abstraction., 1 year|Completed visits with primary care providers and cardiology, Medical chart abstraction of referrals and communication with providers regarding CVH at each survivor visit., 1 year|CVH behaviors recorded in the past year, Medical chart abstraction; Patient survey as secondary, verification source. Measured using smoking status, BMI, physical activity, and healthy diet., 1 year|CVH factors recorded in the past year, Medical chart abstraction; Patient survey as secondary, verification source. Measured using total cholesterol, blood pressure, and fasting plasma glucose/Alc., 1 year|Patient perception and knowledge of CV risks, Measured using structured survivor survey. Health knowledge questions

were adapted from a survey assessing the relative risk of cancer and cardiovascular disease in United States populations.Minimum score is 0, maximum score is 3 and answer is the total number of questions where a patient responded agree or strongly agree., Baseline, 6 months, 1 year|Proportion of survivors for whom AH-HA is utilized, We will capture the number of eligible patient visits during which the AH-HA tool was used in intervention clinics and the total number of eligible visits to calculate the proportion of patients where AH-HA was utilized., 1 year|Measure of tool acceptability with Tool Assessment, In the Baseline: Post-Visit Survey, survivors will complete a Tool Assessment questionnaire assessing whether or not they recall seeing or discussing the AH-HA tool with their provider and five questions assessing: how much they liked the tool, how helpful it was, how easy it was to understand, how much it improved their understanding, and if they would like to use this tool in the future. Patients will respond to 5 questions on a scale from strongly agree to strongly disagree., Baseline
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators: National Cancer Institute (NCI)|Washington University School of Medicine|University of Texas Southwestern Medical Center
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 645
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IRB00056774|NCI-2019-01362|R01CA226078|NCI-2019-01362
Start Date: 2020-10-01
Primary Completion Date: 2024-03-07
Completion Date: 2024-03-07
First Posted: 2019-05-02
Results First Posted:
Last Update Posted: 2023-03-03
Locations: Mercy Hospital Fort Smith, Fort Smith, Arkansas, 72903, United States|Oncology Associates at Mercy Medical Center, Cedar Rapids, Iowa, 52403, United States|Saint Louis Cancer and Breast Institute-Ballwin, Ballwin, Missouri, 63011, United States|Mercy Hospital Saint Louis, Saint Louis, Missouri, 63141, United States|Mercy Hospital Springfield, Springfield, Missouri, 65804, United States|Mercy Hospital Oklahoma City, Oklahoma City, Oklahoma, 73120, United States|Community Medical Center, Scranton, Pennsylvania, 18510, United States|Geisinger Wyoming Valley/Henry Cancer Center, Wilkes-Barre, Pennsylvania, 18711, United States|Baptist Memorial Hospital and Cancer Center-Memphis, Memphis, Tennessee, 38120, United States|Baptist Memorial Hospital for Women, Memphis, Tennessee, 38120, United States|Virginia Commonwealth University/Massey Cancer Center, Richmond, Virginia, 23298, United States|ThedaCare Regional Cancer

Center, Appleton, Wisconsin, 54911, United States
Study Documents:

NCT Number: NCT02780882
Study Title: SOM230 Ectopic ACTH-producing Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT02780882
Acronym:
Study Status: WITHDRAWN
Brief Summary: The purpose of this prospective open-label phase II study, is to evaluate the efficacy of pasireotide twice daily subcutaneous injections for normalizing 24 hour urine free cortisol in patients with ectopic ACTH-producing tumors as measured by the proportion of patients achieving normal UFC at the end of the study period.
Study Results: NO
Conditions: Ectopic ACTH Syndrome
Interventions: DRUG: Pasireotide
Primary Outcome Measures: Evaluate the efficacy of pasireotide twice daily subcutaneous injections for normalizing 24 hour urine free cortisol in patients with ectopic ACTH-producing tumors, Effectiveness of pasireotide as measured by 24 hour urine free cortisol, 6 months
Secondary Outcome Measures: Number of participants with abnormal laboratory values for urine free cortisol, Number of participants with abnormal laboratory values for hormones and metabolism as assessed by urine free cortisol, 6 months|Number of participants with abnormal laboratory values for serum cortisol levels, Number of participants with abnormal laboratory values for hormones and metabolism as assessed by serum cortisol levels, 6 months|Number of participants with abnormal laboratory values for salivary cortisol levels, Number of participants with abnormal laboratory values for hormones and metabolism as assessed by salivary cortisol levels, 6 months|Number of participants with abnormal laboratory values for Hemoglobin A1C (HbA1C), Number of participants with abnormal laboratory values for hormones and metabolism as assessed by Hemoglobin A1C (HbA1C), 6 months|Number of participants with abnormal laboratory values for fasting blood glucose, Number of participants with abnormal laboratory values for hormones and metabolism as assessed by fasting blood glucose, 6 months|Number of participants with abnormal laboratory values for blood electrolytes, Number of participants with abnormal laboratory values for hormones and metabolism as assessed by blood electrolytes, 6 months|Number of participants with abnormal laboratory values for plasma adrenocorticotropic hormone (ACTH), Number of participants with abnormal laboratory values for hormones and metabolism as assessed by plasma adrenocorticotropic hormone (ACTH), 6 months|Number of participants with abnormal laboratory values for plasma beta-lipotropin, Number of participants with abnormal laboratory values for hormones and metabolism as assessed by plasma beta-lipotropin, 6 months|Number of participants with changes in clinical signs and symptoms, Number of participants with changes in clinical signs and symptoms of Cushing's disease as defined by changes

in weight, body mass index, and blood pressure, 6 months|Changes in Tumor Size, To evaluate changes in tumor size, From baseline at months 3 and 6|Number of participants with changes in blood chemistry (safety), Number of participants with abnormal laboratory values for blood chemistry as assessed by total proteins, amylase, lipase, total cholesterol (TC), low-density lipids (LDL)-cholesterol, m creatinine, creatinine clearance, alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, albumin, alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), Baseline and 6 months|Number of participants with changes in hematology (safety), Number of participants with abnormal laboratory values for hematology as assessed by prothrombin time (PT), and international normalized ratio (INR), Baseline and 6 months|Number of participants with changes in cardiac activity, Number of participants with changes in cardiac activity as measured by electrocardiogram (ECG), Baseline and 6 months|Number of participants with changes in liver health, Number of participants with changes in liver health as determined by an abdominal ultrasound, Baseline and 6 months
Other Outcome Measures:
Sponsor: Cedars-Sinai Medical Center
Collaborators: Novartis
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: Pro34493
Start Date: 2015-12
Primary Completion Date: 2018-12
Completion Date: 2019-06
First Posted: 2016-05-24
Results First Posted:
Last Update Posted: 2018-01-26
Locations: Cedars-Sinai Medical Center, Los Angeles, California, 90048, United States
Study Documents:

NCT Number: NCT00968682
Study Title: CADY Study ICORG 08-01
Study URL: https://beta.clinicaltrials.gov/study/NCT00968682
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Studying samples of blood in the laboratory from patients with cancer treated with trastuzumab may help doctors learn more about biomarkers related to heart dysfunction. It may also help doctors predict which patients will develop heart dysfunction.

PURPOSE: This clinical trial is studying biomarkers to see how well they predict heart dysfunction in women with breast cancer treated with trastuzumab.
Study Results: NO
Conditions: Breast Cancer|Cardiac Toxicity
Interventions: BIOLOGICAL: trastuzumab|OTHER: laboratory biomarker analysis|PROCEDURE: assessment of therapy complications
Primary Outcome Measures: Cardiac biomarker levels in predicting cardiac dysfunction, End of trial|Development of a predictive model for use based on the most accurate and sensitive combination of biomarkers, End of trial
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Cancer Trials Ireland
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 480
Funder Type: NETWORK
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 08-01 ICORG|ICORG-08-01|EU-20948
Start Date: 2008-04
Primary Completion Date: 2014-04
Completion Date:
First Posted: 2009-08-31
Results First Posted:
Last Update Posted: 2014-12-31
Locations: Bons Secours Hospital, Cork, Ireland|Cork University Hospital, Cork, Ireland|Our Ladies of Lourdes Hospital, Drogheda, Ireland|Adelaide and Meath Hospital, Dublin Incorporating the National Children's Hospital, Dublin, 24, Ireland|St. Vincent's University Hospital, Dublin, 4, Ireland|Mater Misericordiae University Hospital, Dublin, 7, Ireland|St. James's Hospital, Dublin, 8, Ireland|Beaumont Hospital, Dublin, 9, Ireland|Mater Private Hospital, Dublin, Ireland|University College Hospital, Galway, Ireland|Letterkenny General Hospital, Letterkenny, Ireland|Mid- Western Regional Hospital, Limerick, Ireland|Sligo General Hospital, Sligo, Ireland|Waterford Regional Hospital, Waterford, Ireland
Study Documents:

NCT Number: NCT01758445
Study Title: Proton Radiation for Stage II/III Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01758445
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The purpose of this study is to look at the rates of acute and long term adverse events of postoperative proton radiotherapy for complex loco-regional irradiation in women with loco-

regionally advanced breast cancer. This study specifically includes longitudinal follow up to assess the incidence of cardiac mortality and second malignant neoplasms at 10 and 15 years following proton therapy(PT).
Study Results: NO
Conditions: Breast Cancer|Breast Neoplasm|Breast Tumor|Cancer of the Breast
Interventions: RADIATION: Proton Radiotherapy
Primary Outcome Measures: Determination of the rates of acute and late toxicities (acute and late adverse events) resulting from proton therapy radiation treatment., 5 years
Secondary Outcome Measures: Compare dosimetrically the dose volume histogram (DVH) of the PT plans with conventional external beam plans (either photon/electron intensity modulated radiotherapy(IMRT)plans, 3D-photon plans, or Tomotherapy plans)., On average at 9 weeks post start of treatment|Incidence rates of local control, regional control, metastatic status and disease free overall survival., 5 years|Compare the different DVH parameters for the targets (D2, Dmean, Dmin, D95, V95, V110) and different OARs (as described later) of the PT plans with the corresponding values of the 3D-conformal radiation therapy (CRT), IMRT and Tomotherapy plans., On average at 9 weeks post start of treatment|Determine dose distribution of proton therapy to coronary arteries, heart, ipsilateral and contralateral lung, and contralateral breast., On average at 9 weeks post start of treatment|Determine the incidence of clinically symptomatic coronary artery disease, cardiac morbidity and mortality in general and incidence of secondary malignancy, including contralateral breast cancer, 5 years|Evaluate quality of life results., 5 years
Other Outcome Measures:
Sponsor: Proton Collaborative Group
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 220
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: BRE008-12
Start Date: 2013-02
Primary Completion Date: 2025-01
Completion Date: 2030-01
First Posted: 2013-01-01
Results First Posted:
Last Update Posted: 2023-04-04
Locations: Northwestern Medicine Chicago Proton Center, Warrenville, Illinois, 60555, United States|Maryland Proton Treatment Center, Baltimore, Maryland, 21201, United States|Princeton ProCure Managment LLC, Somerset, New Jersey, 08873, United States|Oklahoma Proton

Center, Oklahoma City, Oklahoma, 73142, United States|Hampton University Proton Therapy Institute, Hampton, Virginia, 23666, United States
Study Documents:

NCT Number: NCT00460616
Study Title: Cardiac Valve Complications in Prolactinomas Treated With Cabergoline
Study URL: https://beta.clinicaltrials.gov/study/NCT00460616
Acronym: ValveCab
Study Status: COMPLETED
Brief Summary: Dopamine agonists are first-line agents for the treatment of prolactinomas (1) and Parkinson's disease (2). There is evidence supporting a causal relationship between the occurrence of drug-induced "restrictive" valvular heart disease and treatment with pergolide (3): in several cases, the valvulopathy improved when pergolide was discontinued (4). Valvular heart damage has also been reported with the ergot-derived dopamine agonists bromocriptine and cabergoline (5,6).

Two recent studies (7,8) have further demonstrated that both pergolide and cabergoline are associated with an increased risk of new cardiac valve regurgitation in patients treated for Parkinson's disease.

The valvular abnormalities seen with ergot-derived dopamine agonists are similar to those observed in patients receiving ergot alkaloid agents (such as ergotamine and methysergide) in the treatment of migraine, or fenfluramine and dexfenfluramine in the treatment of obesity. These abnormalities also closely resemble carcinoid-related valvulopathies (9).

Cardiac valve disease has never been reported in patients with prolactinomas who require treatment with dopamine-agonists even life-long (1). At variance with patients with Parkinson's disease, patients with prolactinomas are younger and are treated with an average dose of dopamine-agonists that is significantly lower (median bromocriptine dose 5 mg/day and median cabergoline dose 1 mg/week). Because of the young age of treatment beginning (most patients with microprolactinomas start dopamine-agonist treatment in early adulthood), treatment might be continued for over 3 decades: the cumulative risk of low doses of dopamine agonists for such a long period of treatment is currently unknown.

To assess the prevalence of cardiac valve disease in patients treated with cabergoline, we wish to perform an echocardiography screening in a large representative sample of patients with prolactinoma who were treated with cabergoline for at least 12 months and in a group of control subjects recruited prospectively. We wish to evaluate the severity of regurgitation for the mitral, aortic, and tricuspid valves. Changes in cardiac valve apparatus was compared with treatment

duration and cumulative cabergoline dose.
Study Results: NO
Conditions: Prolactinomas
Interventions: DRUG: Cabergoline
Primary Outcome Measures: Prevalence of regurgitation (graded as mild, moderate, severe) at any cardiac valve., 9 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Federico II University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 50
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NeuroendoUnit-2
Start Date: 2007-01
Primary Completion Date:
Completion Date: 2007-09
First Posted: 2007-04-16
Results First Posted:
Last Update Posted: 2008-04-16
Locations: Department of Molecular and Clinical Endocrinology and Oncology, University Federico II of Naples, via S. Pansini 5 Naples, 80131, Italy
Study Documents:

NCT Number: NCT04463316
Study Title: GROWing Up With Rare GENEtic Syndromes
Study URL: https://beta.clinicaltrials.gov/study/NCT04463316
Acronym: GROW UR GENES
Study Status: RECRUITING
Brief Summary: Introduction Rare complex syndromes Patients with complex genetic syndromes, by definition, have combined medical problems affecting multiple organ systems, and intellectual disability is often part of the syndrome. During childhood, patients with rare genetic syndromes receive multidisciplinary and specialized medical care; they usually receive medical care from 3-4 medical specialists.

Increased life expectancy Although many genetic syndromes used to cause premature death, improvement of medical care has improved life expectancy. More and more patients are now reaching adult age, and the complexity of the syndrome persists into adulthood. However, until recently, multidisciplinary care was not available for adults with rare genetic syndromes. Ideally, active and well-coordinated health management is provided to prevent, detect, and treat comorbidities that are part of the syndrome. However, after transition from pediatric to adult medical care, patients and their parents often

report fragmented poor quality care instead of adequate and integrated health management. Therefore, pediatricians express the urgent need for adequate, multidisciplinary adult follow up of their pediatric patients with rare genetic syndromes.

Medical guidelines for adults not exist and the literature on health problems in these adults is scarce. Although there is a clear explanation for the absence of adult guidelines (i.e. the fact that in the past patients with rare genetic syndromes often died before reaching adult age), there is an urgent need for an overview of medical issues at adult age, for 'best practice' and, if possible, for medical guidelines.

The aim of this study is to get an overview of medical needs of adults with rare genetic syndromes, including:

1. comorbidities
2. medical and their impact on quality of life
3. medication use
4. the need for adaption of medication dose according to each syndrome

Methods and Results This is a retrospective file study. Analysis will be performed using SPSS version 23 and R version 3.6.0.
Study Results: NO
Conditions: Prader-Willi Syndrome|PWS-like Syndrome|Silver Russel Syndrome|Congenital Hypopituitarism|Klinefelter (XXY-)Syndrome|Congenital Adrenal Hyperplasia|XXXXY Syndrome|XXYY Syndrome|XXXX Syndrome (Tetra-X Syndrome)|Disorders of Sex Development|Turner Syndrome|46, XY DSD|Tuberous Sclerosis|Neurofibromatosis|Albright Hereditaire Osteodystrofie|Cornelia de Lange Syndrome|Saethre-Chotzen Syndrome|17p- Deletiesyndrome|VCF Syndrome|POLR3A Mutatie|Ohdo Syndrome|Jacobsen Syndrome / 11 q Syndrome|Myrhe Syndrome|CHARGE Syndrome|1q25-32 Deletie|Bardet Biedl Syndrome|Rett Syndrome|22q11 Deletion Syndrome|Allan-Herndon-Dudley Syndrome|Kallmann Syndrome|Rare Bone Disorders|Noonan Syndrome|Williams-Beuren Syndrome
Interventions: DIAGNOSTIC_TEST: Retrospective file studies
Primary Outcome Measures: Presence of physical health problems, For example: presence of hypertension, diabetes mellitus, hypercholesterolemia, scoliosis, sleep apnea, hypothyroidism, obesity, psychosis etc., 1 year|Laboratory values, For example: glucose, hemoglobin, hematocrit, thyroid hormone, TSH, estrogen, testosterone, LH, FSH, LDL-cholesterol, triglycerides, ASAT, ALAT, gamma-GT, etc, 1 year|Physical and psychological complaints, For example: daytime sleepiness, obstipation, back pain, headache, behavioral problems, fatigue, nycturia, blurry vision, depressive symptoms, etc., 1 year|Medication use, Use of all medication, 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: dr. Laura C. G. de Graaff-Herder
Collaborators:

Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 600
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: MEC-2018-1389
Start Date: 2018-10-01
Primary Completion Date: 2030-01-01
Completion Date: 2030-01-01
First Posted: 2020-07-09
Results First Posted:
Last Update Posted: 2020-07-09
Locations: Erasmus Medical Center, Rotterdam, Zuid-Holland, 3015 GD, Netherlands
Study Documents:

NCT Number: NCT00790400
Study Title: Efficacy and Safety of RAD001 in Patients Aged 18 and Over With Angiomyolipoma Associated With Either Tuberous Sclerosis Complex (TSC) or Sporadic Lymphangioleiomyomatosis (LAM)
Study URL: https://beta.clinicaltrials.gov/study/NCT00790400
Acronym: EXIST-2
Study Status: COMPLETED
Brief Summary: This study will evaluate the safety and efficacy of RAD001 in treating patients with Angiomyolipoma associated with Tuberous Sclerosis Complex or Sporadic Lymphangioleiomyomatosis.
Study Results: YES
Conditions: Tuberous Sclerosis Complex (TSC)|Lymphangioleiomyomatosis (LAM)
Interventions: DRUG: Everolimus (RAD001)|DRUG: Everolimus Placebo
Primary Outcome Measures: Angiomyolipoma Response Rate as Per Central Radiology Review, Angiomyolipoma response defined as the combination of the following criteria: reduction in angiomyolipoma volume of ≥ 50% relative to baseline, where angiomyolipoma volume was sum of volumes of all target lesions identified at baseline, and with a confirmatory scan performed approximately 12 weeks later (no sooner than 8 weeks later); no new angiomyolipoma lesions ≥ 1.0 cm in longest diameter were identified; there were no kidney increases in volume \> 20% from nadir. The patient did not have any angiomyolipoma-related bleeding of ≥ grade 2.

For the everolimus (core/extension periods) treatment group, the baseline means the latest value on or before starting everolimus., From date of randomization until the earliest date of first documented AML progression, date of further anti-AML medication (including open-label Everolimus)/surgery or up to 5.7 years
Secondary Outcome Measures: Time to Angiomyolipoma Progression as Per Central Radiology Review, Time to angiomyolipoma progression (TTAP) is

defined as time from date of randomization to date of first documented angiomyolipoma progression. Angiomyolipoma progression was defined as one or more of the following: Increase from nadir of ≥ 25% in angiomyolipoma volume to value greater than baseline; the appearance of a new angiomyolipoma ≥ 1.0 cm in longest diameter; an increase from nadir of 20% or more in the volume of either kidney to a value greater than baseline; angiomyolipoma-related bleeding grade ≥ 2.

For the everolimus (core/extension periods) treatment group, the time to angiomyolipoma progression is defined starting from the start of everolimus. The baseline means the latest value on or before starting everolimus., From date of randomization until the earliest date of first documented AML progression, date of further anti-AML medication (including open-label Everolimus)/surgery or up to about 5.7 years| Skin Lesion Response Rate as Per Investigator (Only Patients With at Least One Skin Lesion at Baseline), Skin lesion response rate in the double-blind period was determined only among patients with at least one skin lesion at baseline, and is the percentage of this group of patients with a best overall skin lesion response on the Physician's Global Assessment of Clinical Condition (PGA) of either complete clinical response (CCR) or partial response (PR). A complete clinical response (CCR) requires a grading of 0 indicating the absence of disease (histological confirmation is not required). Grades 1, 2, and 3 constitute partial response, indicating improvement of at least 50 percent, but less than 100 percent improvement. For the everolimus (core/extension periods) treatment group, the baseline means the latest value on or before starting everolimus., From date of randomization until the earliest date of first documented AML progression, date of further anti-AML medication (including open-label Everolimus)/surgery or up to 5.7 years|Percentage of Participants With Renal Impairment, Renal Impairment was measured by glomerular filtration rate which was calculated using the Modification of Diet in Renal Disease formula. Percentage of participants with renal impairment was reported. Severe renal impairment was defined as a GFR of \<30ml/min/1.73m2., Day 1 up to 28 days after end of treatment| Change From Baseline in Plasma Angiogenic Molecules - Vascular Endothelial Growth Factor (VEGF) Marker, Blood samples for biomarker assessment were collected immediately prior to study administration. On-treatment samples was compared to baseline samples with the change from baseline., 4 weeks, 12 weeks, 24 weeks, 36 weeks 48 weeks, 60 weeks, 72 weeks|Everolimus Trough Concentrations (Cmin), Cmin values collected prior to dose administration on the same study day and at 20-28 hours after previous dose, at steady state, and patient did not vomit within 4 hours of previous dose. Samples collected during the first 4 days of dosing were excluded from all analyses., Prior to dosing at weeks 2, 4, 12, 24, 48|Everolimus Blood Concentrations (C2h) at 2 Hours Post-dose, C2h values collected 1-3 hours after dose administration on the same study day, at steady state, and patient did not vomit between taking previous dose and blood collection. Samples collected during the first 4 days of dosing will be excluded from all

analyses., 2 hours post-dose administration at Weeks 2, 4, 12, 24, 48|Time to Angiomyolipoma Response - Only Everolimus Patients With Angiomyolipoma Response, Time to angiomyolipoma response was defined as the time from the date of randomization until the date of the first documented angiomyolipoma response. Angiomyolipoma response defined as the combination of the following criteria: reduction in angiomyolipoma volume of ≥ 50% relative to baseline, where angiomyolipoma volume was sum of volumes of all target lesions identified at baseline, and with a confirmatory scan performed approximately 12 weeks later (no sooner than 8 weeks later); no new angiomyolipoma lesions ≥ 1.0 cm in longest diameter were identified; no kidney increases in volume \> 20% from nadir; no angiomyolipoma-related bleeding of ≥ grade 2.

For the everolimus (core/extension periods) treatment group, the time to angiomyolipoma response is from the start of everolimus. The baseline in the response definition means the latest value on or before starting everolimus., From date of randomization until the earliest date of first documented AML progression, date of further anti-AML medication (including open-label Everolimus)/surgery or up to 5.7 years|Duration of Angiomyolipoma Response - Only Everolimus Patients With Angiomyolipoma Response, Duration of angiomyolipoma response was defined as the time from the date of the first documented angiomyolipoma response until the date of the first documented angiomyolipoma progression . Angiomyolipoma response was defined as the combination of the following criteria: reduction in angiomyolipoma volume of ≥ 50% relative to baseline, where angiomyolipoma volume was sum of volumes of all target lesions identified at baseline, and with a confirmatory scan performed approximately 12 weeks later (no sooner than 8 weeks later); no new angiomyolipoma lesions ≥ 1.0 cm in longest diameter were identified; there were no kidney increases in volume \> 20% from nadir. The patient did not have any angiomyolipoma-related bleeding of ≥ grade 2., From date of randomization until the earliest date of first documented AML progression, date of further anti-AML medication (including open-label Everolimus)/surgery or up to about 5.7 years|Duration of Skin Lesion Response - Only Everolimus Patients With Best Overall Skin Lesion Response of Complete Clinical Response (CCR) or Partial Response (PR), Duration of skin lesion response is defined as the time from the date of the first skin lesion response until the date of the first skin lesion progression, according to the PGA (physician's global assessment of clinical condition). A progression is when the disease is worse than at baseline evaluation by \>=25% or more., From date of randomization until the earliest date of first documented AML progression, date of further anti-AML medication (including open-label Everolimus)/surgery or up to about 5.7 years
Other Outcome Measures:
Sponsor: Novartis Pharmaceuticals
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: PHASE3
Enrollment: 118
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR,
OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: CRAD001M2302|2008-002113-48
Start Date: 2009-04
Primary Completion Date: 2011-06
Completion Date: 2015-11
First Posted: 2008-11-13
Results First Posted: 2012-05-23
Last Update Posted: 2017-02-17
Locations: University of Alabama at Birmingham, Birmingham, Alabama,
35294, United States|Barrow Tuberous Sclerosis Center, Phoenix,
Arizona, 85013, United States|Massachusetts General Hospital
Massachussetts General Hospita, Boston, Massachusetts, 02114, United
States|Minnesota Epilepsy Group, St. Paul, Minnesota, 55102-2383,
United States|Cincinnati Children's Hospital Medical Center,
Cincinnati, Ohio, 45229-3039, United States|LeBonheur Childrens
Medical Group SC-2, Memphis, Tennessee, 38103, United States|Novartis
Investigative Site, Torono, Ontario, M5G 2C4, Canada|Novartis
Investigative Site, Lyon, 69003, France|Novartis Investigative Site,
Berlin, 10098, Germany|Novartis Investigative Site, München, 80336,
Germany|Novartis Investigative Site, Siena, SI, 53100, Italy|Novartis
Investigative Site, Torino, TO, 10126, Italy|Novartis Investigative
Site, Roma, 00137, Italy|Novartis Investigative Site, Sapporo-city,
Hokkaido, 060-8648, Japan|Novartis Investigative Site, Suita-city,
Osaka, 565-0871, Japan|Novartis Investigative Site, Yamagata,
990-9585, Japan|Novartis Investigative Site, Utrecht, 3584CX,
Netherlands|Novartis Investigative Site, Warszawa, 01138, Poland|
Novartis Investigative Site, Warszawa, 04-730, Poland|Novartis
Investigative Site, Moscow, 127412, Russian Federation|Novartis
Investigative Site, Barcelona, Catalunya, 08025, Spain|Novartis
Investigative Site, Brighton, East Sussex, BN2 5BE, United Kingdom|
Novartis Investigative Site, Craigavon, Northern Ireland, BT63 5QQ,
United Kingdom|Novartis Investigative Site, Cardiff, Wales, CF14 4XN,
United Kingdom|Novartis Investigative Site, London, SW17 0QT, United
Kingdom
Study Documents:

NCT Number: NCT05775822
Study Title: Coronary Artery Calcium and Cardiovascular Risk Factors
Analysis After RT or Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05775822
Acronym: RadioTherapy
Study Status: RECRUITING
Brief Summary: This is a no-profit, national, monocenter,
retrospective, and prospective low-intervention study. It is a low-

intervention study in terms of diagnostic additional procedure (CT scan). It is planned to recruit a maximum of 100 women diagnosed with early-stage breast cancer and treated with adjuvant breast radiotherapy from 2010 to 2017 at the European Institute of Oncology who meet all the inclusion and exclusion criteria. The aim of the Study is to analyze a population of breast cancer patients treated by adjuvant whole breast radiotherapy to identify the most important cardiovascular (CV) risk factors linked to coronary artery disease (CAD) development, in a cure-without-complications oncology strategy.
Study Results: NO
Conditions: Breast Cancer
Interventions: DIAGNOSTIC_TEST: CT scan and blood sample collection
Primary Outcome Measures: Primary Outcome Coronary calcium (CAC), Coronary calcium (CAC) assessment and its relationship with left-side or right-side breast radiation therapy and previously known cardiovascular risk factors. The quantification of CAC will be performed according to the Agatston score by multiplying the total CAC area in mm2 by a density factor ranging from 1 to 4 (1 for lesions with a density of 130-199 HU; 2 if the lesion has a density of 200-299 HU; 3 for lesions with a density of 300-399 HU; 4 for densities ≥400 HU), 2 years
Secondary Outcome Measures: Outcome 2 circulating markers, Evaluate circulating markers, mostly related to radiation-induced oxidative stress and correlate them to previous CV events and CT data obtained. Patients will undergo a blood sample withdrawal focused on evaluation of albumin isoforms in human plasma and protein signatures.

Albumin thiolation: Mercaptoalbumin (HSA-SH) and thiolated albumin (+120 ± 2 Da, Thio-HSA) will be detected and their intensities used to calculate the relative abundances. Targeted Proteomics will be performed and relative quantitation will be expressed in Normalized protein expression (NPX), Normalized Protein eXpression, is Olink's arbitrary unit which is in Log2 scale. It is calculated from Ct values and data pre-processing (normalization) is performed to minimize both intra- and inter-assay variation. NPX data allows users to identify changes for individual protein levels across their sample set, and then use this data to establish protein signatures., 2 years|Outcome 3 Incidence of CV events, Incidence of CV events in relationship to left vs right-side breast radiation, 2 years
Other Outcome Measures:
Sponsor: Centro Cardiologico Monzino
Collaborators: Istituto Europeo di Oncologia
Sex: FEMALE
Age: ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING

Other IDs: CCM 1505
Start Date: 2022-03-24
Primary Completion Date: 2023-12
Completion Date: 2024-06
First Posted: 2023-03-20
Results First Posted:
Last Update Posted: 2023-03-20
Locations: IRCCS Centro Cardiologico Monzino, Milan, 20138, Italy
Study Documents:

NCT Number: NCT04026737
Study Title: Cardiovascular Effects of CART Cell Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04026737
Acronym: CVE-CART
Study Status: COMPLETED
Brief Summary: This is an observational study aiming to prospectively define the rate of occurrence, natural history and progression of cardiac dysfunction in adults, and to identify the patients at high risk of developing cardiovascular events. The study enrolls patients prior to infusion with CART cell therapy and follows them with serial echocardiography, cardiac biomarkers, clinical data, and quality of life questionnaire.
Study Results: NO
Conditions: Leukemia|Lymphoma|Cardiotoxicity|Risk Factor, Cardiovascular|Immunotherapy
Interventions:
Primary Outcome Measures: Incidence of Left Ventricular (LV) Dysfunction, LV dysfunction, defined as a decrease in LV ejection fraction of at least 10% to less than or equal to 53%, 6 months
Secondary Outcome Measures: Incidence of Cardiovascular Events, Cardiovascular events are defined as hospitalization for symptomatic congestive heart disease, nonfatal acute coronary syndrome, cardiovascular death, nonfatal stroke, and all-cause mortality, 6 months
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 44
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC01419
Start Date: 2019-07-22
Primary Completion Date: 2022-11-16
Completion Date: 2022-11-16
First Posted: 2019-07-19
Results First Posted:

Last Update Posted: 2023-01-20
Locations: Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT01906437
Study Title: Cardiac Fibrosis by CMR in Patients With Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01906437
Acronym:
Study Status: WITHDRAWN
Brief Summary: A study to test the effectiveness of an investigational imaging technique for detecting cardiac injury after the administration of certain chemotherapies, such as doxorubicin. "Investigational" means that the imaging technique is still being studied and that research doctors are trying to find out more about it- such as whether the technique can detect lower levels of cardiac injury after treatment with doxorubicin. It also means that the FDA (the U.S. Food and Drug Administration) has not yet approved the use of gadolinium or approved the use of CMR studies for detection of cardiac toxicity after doxorubicin.

The chemotherapy drug that you have been scheduled to be treated with, doxorubicin, has been associated with the development of heart failure in some patients. Cardiac Magnetic Resonance (CMR) is a type of MRI scan that uses a magnetic field to produce pictures of the heart. The CMR scan has been used in other studies and information from those other research studies suggest that this imaging technique may help to better detect differences in the structure of the heart muscle after treatment with doxorubicin. In this research study, we hope that we can better detect changes in the heart muscle after treatment with doxorubicin with a CMR scan in the hopes that cardiac injury can be detected and treated earlier to ultimately prevent the possible development of heart failure
Study Results: NO
Conditions: Lymphoma
Interventions: DEVICE: Cardiac Magnetic Resonance Scan
Primary Outcome Measures: Myocardial ECV, - To determine if a novel cardiac magnetic resonance-based index, the extracellular volume fraction (ECV), of myocardial fibrosis is altered early after doxorubicin-based chemotherapy., 2 Years
Secondary Outcome Measures: Alteration of serum biomarkers after doxorubicin based chemotherapy, - To determine if serum biomarkers of cardiac stress, collagen turn-over, and myocardial injury are altered after doxorubicin-based chemotherapy, 2 years|Alteration of echocardiographic indices after doxorubicin-based chemotherapy, - To determine if conventional and novel echocardiographic indices are altered after doxorubicin-based chemotherapy., 2 Years|Measurement of cardiopulmonary functional capacity, - To determine if measures of cardiopulmonary functional capacity are abnormal after doxorubicin-based chemotherapy., 2 years|Determine association between

measurements pre- and post-doxorubicin-based chemotherapy, - To determine if there is an association between CMR, echocardiographic, serum, and functional measures pre- and post doxorubicin-based chemotherapy, 2 Years
Other Outcome Measures:
Sponsor: Massachusetts General Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 0
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 11-443
Start Date: 2013-03
Primary Completion Date: 2018-08-25
Completion Date: 2018-08-25
First Posted: 2013-07-24
Results First Posted:
Last Update Posted: 2018-09-14
Locations: Massachusetts General Hospital, Boston, Massachusetts, 02114, United States|Brigham and Women's Hospital, Boston, Massachusetts, 02215, United States|Dana Farber Cancer Insitute, Boston, Massachusetts, 02215, United States
Study Documents:

NCT Number: NCT00003937
Study Title: Combination Chemotherapy Plus Dexrazoxane in Treating Patients With Newly Diagnosed Nonmetastatic Osteosarcoma
Study URL: https://beta.clinicaltrials.gov/study/NCT00003937
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug may kill more tumor cells. Chemoprotective drugs such as dexrazoxane may protect normal cells from the side effects of chemotherapy.

PURPOSE: Phase III trial to study the effectiveness of three combination chemotherapy regimens plus dexrazoxane in treating patients who have newly diagnosed nonmetastatic osteosarcoma.
Study Results: NO
Conditions: Cardiac Toxicity|Sarcoma
Interventions: DRUG: cisplatin|DRUG: dexrazoxane hydrochloride|DRUG: doxorubicin hydrochloride|DRUG: etoposide|DRUG: ifosfamide|DRUG: methotrexate|PROCEDURE: conventional surgery
Primary Outcome Measures: Event Free Survival
Secondary Outcome Measures:
Other Outcome Measures:

Sponsor: Children's Oncology Group
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE3
Enrollment: 253
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: P9754|COG-P9754|POG-P9754|CCG-P9754|CDR0000067129
Start Date: 1999-09
Primary Completion Date: 2004-03
Completion Date: 2008-06
First Posted: 2004-02-09
Results First Posted:
Last Update Posted: 2014-08-05
Locations: University of Alabama at Birmingham Comprehensive Cancer Center, Birmingham, Alabama, 35294-3300, United States|MBCCOP - Gulf Coast, Mobile, Alabama, 36688, United States|Arizona Cancer Center, Tucson, Arizona, 85724, United States|University of Arkansas for Medical Sciences, Little Rock, Arkansas, 72205, United States|University of California San Diego Cancer Center, La Jolla, California, 92093-0658, United States|Long Beach Memorial Medical Center, Long Beach, California, 90806, United States|Children's Hospital Los Angeles, Los Angeles, California, 90027-0700, United States|Jonsson Comprehensive Cancer Center, UCLA, Los Angeles, California, 90095-1781, United States|Children's Hospital of Orange County, Orange, California, 92868, United States|Lucile Packard Children's Hospital at Stanford, Palo Alto, California, 94304, United States|Sutter Cancer Center, Sacramento, California, 95816, United States|University of California Davis Medical Center, Sacramento, California, 95817, United States|Kaiser Permanente-Southern California Permanente Medical Group, San Diego, California, 92120, United States|Children's Hospital and Health Center, San Diego, California, 92123-4282, United States|UCSF Cancer Center and Cancer Research Institute, San Francisco, California, 94143-0128, United States|Kaiser Permanente Medical Center - Santa Clara, Santa Clara, California, 95051-5386, United States|David Grant Medical Center, Travis Air Force Base, California, 94535, United States|Children's Hospital of Denver, Denver, Colorado, 80218, United States|Yale Comprehensive Cancer Center, New Haven, Connecticut, 06520-8028, United States|Children's National Medical Center, Washington, District of Columbia, 20010-2970, United States|Walter Reed Army Medical Center, Washington, District of Columbia, 20307-5000, United States|Shands Hospital and Clinics, University of Florida, Gainesville, Florida, 32610-100277, United States|Nemours Children's Clinic, Jacksonville, Florida, 32207, United States|Sylvester Cancer Center, University of Miami, Miami, Florida, 33136, United States|Miami Children's Hospital, Miami, Florida, 33155, United States|Baptist Hospital of Miami, Miami, Florida, 33176-2197,

United States|Walt Disney Memorial Cancer Institute, Orlando, Florida, 32803, United States|All Children's Hospital, St. Petersburg, Florida, 33701, United States|CCOP - Florida Pediatric, Tampa, Florida, 33682-7757, United States|St. Mary's Hospital, West Palm Beach, Florida, 33407, United States|Emory University Hospital - Atlanta, Atlanta, Georgia, 30322, United States|Cancer Research Center of Hawaii, Honolulu, Hawaii, 96813, United States|Tripler Army Medical Center, Honolulu, Hawaii, 96859-5000, United States|Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois, 60612, United States|Children's Memorial Hospital, Chicago, Chicago, Illinois, 60614, United States|University of Chicago Cancer Research Center, Chicago, Illinois, 60637-1470, United States|Hope Children's Hospital, Oak Lawn, Illinois, 60453, United States|CCOP - Illinois Oncology Research Association, Peoria, Illinois, 61602, United States|Saint Jude Midwest Affiliate, Peoria, Illinois, 61637, United States|Indiana University Cancer Center, Indianapolis, Indiana, 46202-5289, United States|Holden Comprehensive Cancer Center at The University of Iowa, Iowa City, Iowa, 52242-1009, United States|University of Kansas Medical Center, Kansas City, Kansas, 66160-7357, United States|CCOP - Wichita, Wichita, Kansas, 67214-3882, United States|Via Christi Regional Medical Center, Wichita, Kansas, 67214, United States|MBCCOP - LSU Health Sciences Center, New Orleans, Louisiana, 70112, United States|Tulane University School of Medicine, New Orleans, Louisiana, 70112, United States|CCOP - Ochsner, New Orleans, Louisiana, 70121, United States|Eastern Maine Medical Center, Bangor, Maine, 04401, United States|Maine Children's Cancer Program, Portland, Maine, 04101, United States|Marlene & Stewart Greenebaum Cancer Center, University of Maryland, Baltimore, Maryland, 21201, United States|Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, Maryland, 21231-2410, United States|Boston Floating Hospital Infants and Children, Boston, Massachusetts, 02111, United States|Massachusetts General Hospital Cancer Center, Boston, Massachusetts, 02114, United States|Dana-Farber Cancer Institute, Boston, Massachusetts, 02115, United States|University of Massachusetts Memorial Medical Center, Worcester, Massachusetts, 01655, United States|University of Michigan Comprehensive Cancer Center, Ann Arbor, Michigan, 48109-0752, United States|Children's Hospital of Michigan, Detroit, Michigan, 48201, United States|St. John's Hospital and Medical Center, Detroit, Michigan, 48236, United States|Hurley Medical Center, Flint, Michigan, 48503, United States|CCOP - Kalamazoo, Kalamazoo, Michigan, 49007-3731, United States|University of Minnesota Cancer Center, Minneapolis, Minnesota, 55455, United States|Mayo Clinic Cancer Center, Rochester, Minnesota, 55905, United States|University of Mississippi Medical Center, Jackson, Mississippi, 39216-4505, United States|Keesler Medical Center - Keesler AFB, Keesler AFB, Mississippi, 39534-2576, United States|University of Missouri-Columbia Hospital and Clinics, Columbia, Missouri, 65212, United States|Children's Mercy Hospital, Kansas City, Missouri, 64108, United States|Cardinal Glennon Children's Hospital, Saint Louis, Missouri, 63104, United States|Washington University School of Medicine, Saint Louis, Missouri,

63110, United States|University of Nebraska Medical Center, Omaha, Nebraska, 68198-3330, United States|Norris Cotton Cancer Center, Lebanon, New Hampshire, 03756-0002, United States|CCOP - Northern New Jersey, Hackensack, New Jersey, 07601, United States|Hackensack University Medical Center, Hackensack, New Jersey, 07601, United States|Cancer Institute of New Jersey, New Brunswick, New Jersey, 08901, United States|University of New Mexico School of Medicine, Albuquerque, New Mexico, 87131, United States|Roswell Park Cancer Institute, Buffalo, New York, 14263-0001, United States|Schneider Children's Hospital, New Hyde Park, New York, 11042, United States|NYU School of Medicine's Kaplan Comprehensive Cancer Center, New York, New York, 10016, United States|Memorial Sloan-Kettering Cancer Center, New York, New York, 10021, United States|Mount Sinai School of Medicine, New York, New York, 10029, United States|Herbert Irving Comprehensive Cancer Center, New York, New York, 10032, United States|University of Rochester Cancer Center, Rochester, New York, 14642, United States|State University of New York Health Sciences Center - Stony Brook, Stony Brook, New York, 11790-7775, United States|State University of New York - Upstate Medical University, Syracuse, New York, 13210, United States|Mission Saint Joseph's Health System, Asheville, North Carolina, 28801, United States|Lineberger Comprehensive Cancer Center, UNC, Chapel Hill, North Carolina, 27599-7295, United States|Carolinas Medical Center, Charlotte, North Carolina, 28232-2861, United States|Presbyterian Healthcare, Charlotte, North Carolina, 28233-3549, United States|Duke Comprehensive Cancer Center, Durham, North Carolina, 27710, United States|East Carolina University School of Medicine, Greenville, North Carolina, 27858-4354, United States|Comprehensive Cancer Center at Wake Forest University, Winston-Salem, North Carolina, 27157-1082, United States|Veterans Affairs Medical Center - Fargo, Fargo, North Dakota, 58102, United States|CCOP - Merit Care Hospital, Fargo, North Dakota, 58122, United States|Children's Hospital Medical Center - Cincinnati, Cincinnati, Ohio, 45229-3039, United States|Ireland Cancer Center, Cleveland, Ohio, 44106-5065, United States|Children's Hospital of Columbus, Columbus, Ohio, 43205-2696, United States|Oklahoma Memorial Hospital, Oklahoma City, Oklahoma, 73126-0307, United States|Natalie Warren Bryant Cancer Center, Tulsa, Oklahoma, 74136, United States|Doernbecher Children's Hospital, Portland, Oregon, 97201-3098, United States|CCOP - Columbia River Program, Portland, Oregon, 97213, United States|Legacy Emanuel Hospital and Health Center, Portland, Oregon, 97227, United States|Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, 19104, United States|St. Christopher's Hospital for Children, Philadelphia, Pennsylvania, 19134-1095, United States|Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania, 15213, United States|Medical University of South Carolina, Charleston, South Carolina, 29425-0721, United States|Children's Hospital of Greenville Hospital System, Greenville, South Carolina, 29605, United States|James H. Quillen College of Medicine, Johnson City, Tennessee, 37614-0622, United States|Saint Jude Children's Research Hospital, Memphis, Tennessee, 38105-2794, United States|Vanderbilt-Ingram Cancer

Center, Nashville, Tennessee, 37232-6838, United States|Texas Oncology P.A., Dallas, Texas, 75230-2503, United States|Medical City Dallas Hospital, Dallas, Texas, 75230, United States|Simmons Cancer Center - Dallas, Dallas, Texas, 75235-9154, United States|University of Texas Medical Branch, Galveston, Texas, 77555-0209, United States|University of Texas - MD Anderson Cancer Center, Houston, Texas, 77030-4009, United States|Baylor College of Medicine, Houston, Texas, 77030, United States|San Antonio Military Pediatric Cancer and Blood Disorders Center, Lackland Air Force Base, Texas, 78236-5300, United States|MBCCOP - South Texas Pediatric, San Antonio, Texas, 78229-3900, United States|University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78284-7811, United States|Scott and White Clinic, Temple, Texas, 76508, United States|Vermont Cancer Center, Burlington, Vermont, 05401-3498, United States|Cancer Center at the University of Virginia, Charlottesville, Virginia, 22908, United States|Inova Fairfax Hospital, Falls Church, Virginia, 22042-3300, United States|Naval Medical Center, Portsmouth, Portsmouth, Virginia, 23708-2197, United States|Massey Cancer Center, Richmond, Virginia, 23298-0037, United States|Carilion Roanoke Community Hospital, Roanoke, Virginia, 24029, United States|Children's Hospital and Regional Medical Center - Seattle, Seattle, Washington, 98105, United States|Fred Hutchinson Cancer Research Center, Seattle, Washington, 98109-1024, United States|Madigan Army Medical Center, Tacoma, Washington, 98431-5000, United States|West Virginia University Medical School-Charleston, Charleston, West Virginia, 25304, United States| West Virginia University Hospitals, Morgantown, West Virginia, 26506-9300, United States|St. Vincent Hospital, Green Bay, Wisconsin, 54307-3508, United States|University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin, 53792-6164, United States|Midwest Children's Cancer Center, Milwaukee, Wisconsin, 53226, United States| Royal Children's Hospital, Parkville, Victoria, 3052, Australia| Princess Margaret Hospital for Children, Perth, Western Australia, 6001, Australia|Alberta Children's Hospital, Calgary, Alberta, T2T 5C7, Canada|Cross Cancer Institute, Edmonton, Alberta, T6G 1Z2, Canada|British Columbia Children's Hospital, Vancouver, British Columbia, V6H 3V4, Canada|IWK Health Centre, Halifax, Nova Scotia, B3J 3G9, Canada|Children's Hospital, Hamilton, Ontario, L8N 3Z5, Canada| Children's Hospital of Eastern Ontario, Ottawa, Ontario, K1H 8L1, Canada|Hospital for Sick Children, Toronto, Ontario, M5G 1X8, Canada| McGill University Health Center - Montreal Children's Hospital, Montreal, Quebec, H3H 1P3, Canada|Hopital Sainte Justine, Montreal, Quebec, H3T 1C5, Canada|Centre Hospitalier de L'Universite Laval, Sainte Foy, Quebec, GIV 4G2, Canada|Academisch Ziekenhuis Groningen, Groningen, 9713 EZ, Netherlands|San Jorge Childrens Hospital, Santurce, 00912, Puerto Rico|Swiss Pediatric Oncology Group Bern, Bern, CH 3010, Switzerland|Clinique de Pediatrie, Geneva, 1211, Switzerland
Study Documents:

NCT Number: NCT03678337

Study Title: Prevention and Pharmacological Management of Cardiac Adverse Drug Reactions Induced by Drugs Used in Oncology.
Study URL: https://beta.clinicaltrials.gov/study/NCT03678337
Acronym: PICARO
Study Status: UNKNOWN
Brief Summary: Recently, the medical management of cancer patients has considerably improved the prognosis of these patients and today some cancers are becoming "chronic diseases". As a result, new adverse effects (AEs) are observed, particularly cardiac.

These "new" cardiac AEs are the consequence of a significant increase in patients life expectancy (delayed AEs not previously seen) but also the use of new pharmacological classes of anticancer drugs such as kinase inhibitors. The incidence of these cardiac AEs varies according to the patient profile and the anticancer molecules used, but their impact on the morbidity and mortality of the patients is significant.

In this context, we started at the University Hospital of Caen Normandy in September 2017 a cardio-oncology program entitled "prevention and pharmacological management of cardiac adverse effects induced by drugs used in Oncology" (PICARO program). This program involves the pharmacology department (opening of a dedicated consultation), the cardiology department (opening of a dedicated ultrasound consultation), vascular medicine departement (opening of a dedicated consultation) and the oncology federation. This program aims to be regional in the future. We therefore propose to build a cohort backed up to the PICARO program to assess the regional impact of cardiac AEs of anticancer drugs and thus to be better able to specify the number of AEs, the incidence and regional prevalence of these drugs. .

The constitution of this cohort is only the first step towards the constitution in the near future (2 years) of an observatory and then a regional registry of cardiac AEs induced by anticancer drugs. The objectives associated with the establishment of such a registry would be to reduce the number of cardiac AEs, the hospitalizations caused by these AEs, a better information of health professionals and patients, an improvement in the screening of patients at risk, all coming back in the context of health, clinical, epidemiological and pharmacological surveillance.
Study Results: NO
Conditions: Cardio-oncology
Interventions: OTHER: observational cohort with plasma samples
Primary Outcome Measures: Number of Participants With AntiCancer Drugs-Related Cardiac Adverse Events during the follow-up, 2 years
Secondary Outcome Measures: Plasmatic tests to predict anticancer drugs-related cardiac adverse events from the constitution of the plasma biobank, 2 years
Other Outcome Measures:
Sponsor: University Hospital, Caen

Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 200
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2018-A00429-46
Start Date: 2019-02-26
Primary Completion Date: 2020-09-10
Completion Date: 2021-01
First Posted: 2018-09-19
Results First Posted:
Last Update Posted: 2019-04-04
Locations: CHU Caen, Caen, Normandy, 14000, France
Study Documents:

NCT Number: NCT05786014
Study Title: The Effects of Two Exercise Interventions on Breast Cancer Patients Undergoing Cardiotoxic Chemotherapies
Study URL: https://beta.clinicaltrials.gov/study/NCT05786014
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: The purpose of this study is to determine if exercise preconditioning can mitigate the off target effects of chemotherapy treatment on measures of cardiovascular function, inflammatory responses, and quality of life.
Study Results: NO
Conditions: Breast Cancer|Cardiotoxicity|Cardiovascular Diseases
Interventions: BEHAVIORAL: High Intensity Interval Exercise|
BEHAVIORAL: Moderate Intensity Walking
Primary Outcome Measures: Subject Retention Percentage, This is a feasibility study designed to determine the extent to which eligible patients can be successfully recruited, randomized, and retained. Endpoint data will be used to justify and provide point estimates for a fully powered study. Retention will be measured as a percentage of those enrolled who complete the study interventions., 22 Weeks
Secondary Outcome Measures: VO2peak, Change in VO2peak (L/min) measured at pre-chemotherapy and post chemotherapy, 22 Weeks|Global Longitudinal Strain, Global longitudinal strain (%) will be used to assess changes in cardiac contractile function and be measured by echocardiogram at pre-chemotherapy and post-chemotherapy, 22 Weeks|
Ejection Fraction, Ejection fraction (%) will be used to assess changes in cardiac contractile function and be measured by echocardiogram at pre-chemotherapy and post-chemotherapy, 22 Weeks|
Diastolic Function, E' and A' (cm/s) will be used to calculate the E'/A' ratio to assess for diastolic dysfunction and be measured by echocardiogram at pre-chemotherapy and post-chemotherapy, 22 Weeks|
Brachial Artery Endothelium-Dependent Flow-Mediated Dilation, Changes

in endothelial function as measured by brachial artery endothelium-dependent flow-mediated dilation (%) at pre-chemotherapy and post-chemotherapy, 22 Weeks|Carotid-Femoral Pulse Wave Velocity, Changes in arterial stiffness as measured by carotid-femoral pulse wave velocity (m/s) at pre-chemotherapy and post-chemotherapy, 22 Weeks|Blood pressure, Brachial systolic and diastolic blood pressures (mmHg) will be measured at baseline and post-chemotherapy., 22 Weeks|Lipid panels, A lipid panel will be performed to measure total cholesterol, triglycerides, high-density lipoproteins, and low-density lipoprotein (mg/dl) to assess changes in cardiometabolic health at pre-chemotherapy and post-chemotherapy, 22 Weeks|Inflammation/Immune cell concentrations in peripheral circulation., Various markers of inflammation and immune cells will be measured at baseline, pre-chemo (following exercise pre-conditioning), midway through patient's prescribed treatment, and post-intervention to determine changes., 22 Weeks
Other Outcome Measures:
Sponsor: University of Virginia
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 25
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 220287
Start Date: 2023-04-01
Primary Completion Date: 2025-01-15
Completion Date: 2025-03-15
First Posted: 2023-03-27
Results First Posted:
Last Update Posted: 2023-03-27
Locations: University of Virginia University Hospital, Charlottesville, Virginia, 22903, United States
Study Documents:

NCT Number: NCT01462383
Study Title: The Role of the EKG in Anticancer Drug Development
Study URL: https://beta.clinicaltrials.gov/study/NCT01462383
Acronym:
Study Status: COMPLETED
Brief Summary: Primary Objective:

-Evaluate incidence of cardiac complications in Phase I patients.

Secondary Objective:

-To identify variables (i.e. number of electrocardiograms (EKG)

performed) that lead to the detection of cardiac events.
Study Results: NO
Conditions: Advanced Cancer
Interventions:
Primary Outcome Measures: Incidence of Cardiac Complications in Participants on Phase I Protocols, Data review of studies, active between January 1, 2006 and December 31, 2009, who included ECGs in their safety evaluations. Use of identification and descriptive analysis of cardiac events occurrence in the phase I population to define role of protocol required EKGs in their detection. Statistical analysis performed in a descriptive fashion with paired and multivariable analyses., 3 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 525
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: DR11-0061
Start Date: 2011-01
Primary Completion Date: 2011-11
Completion Date: 2011-11
First Posted: 2011-10-31
Results First Posted:
Last Update Posted: 2011-12-12
Locations: UT MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT04429633
Study Title: Strain vs. Left Ventricular Ejection Fraction-based Cardiotoxicity Prevention in Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT04429633
Acronym:
Study Status: RECRUITING
Brief Summary: Comparing preventive effect of myocardial global longitudinal strain-based cardioprotective stragety (angiotensin receptor blocker prophylaxis) with left ventricular ejection fraction-based strategy in breast cancer patients treated with adjuvant trastuzumab.
Study Results: NO
Conditions: Cardiotoxicity|Breast Cancer|Prevention|Adjuvant|Trastuzumab
Interventions: DRUG: Candesartan
Primary Outcome Measures: Left ventricular ejection fraction (LVEF),

Maximum change in LVEF, at months 3,6,9,12,18
Secondary Outcome Measures: Overt chemotherapy induced cardiotoxicity, LVEF \< 45%, decline in LVEF by \>10% to a value to 45-49%, symptomatic congestive heart failure, any time|Changes in cardiac biomarker, NT-pro BNP, cardiac troponin, at months 3,6,9,12,18
Other Outcome Measures:
Sponsor: Samsung Medical Center
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 136
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 2018-11-128
Start Date: 2019-07-19
Primary Completion Date: 2022-07-18
Completion Date: 2023-07-18
First Posted: 2020-06-12
Results First Posted:
Last Update Posted: 2020-06-12
Locations: Samsung Medical Center, Seoul, 06351, Korea, Republic of
Study Documents:

NCT Number: NCT00633633
Study Title: Lifestyle Intervention for Heart Failure
Study URL: https://beta.clinicaltrials.gov/study/NCT00633633
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The goal of this behavioral research study is to learn if education and training about exercise can help to change the lifestyle of cancer survivors with symptoms of heart failure.
Study Results: NO
Conditions: Heart Failure
Interventions: OTHER: Usual Care|BEHAVIORAL: Exercise Training|BEHAVIORAL: Dietary Counseling
Primary Outcome Measures: Recruitment/Attendance/Drop-Out Rates, 1 Year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 85
Funder Type: OTHER
Study Type: INTERVENTIONAL

Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 2007-0822|NCI-2011-02123
Start Date: 2008-02-11
Primary Completion Date: 2024-05-31
Completion Date: 2024-05-31
First Posted: 2008-03-12
Results First Posted:
Last Update Posted: 2023-06-02
Locations: University of Texas MD Anderson Cancer Center, Houston, Texas, 77030, United States|The University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78249, United States
Study Documents:

NCT Number: NCT01262222
Study Title: Patients Undergoing Major Cancer Surgery: Incidence and Predictive Value for Postoperative Cardiac Events
Study URL: https://beta.clinicaltrials.gov/study/NCT01262222
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to look at a new method for finding out if patients have a risk of heart complications from surgery. At the present, to find out if patients have a risk of heart complications from surgery, look at whether the patient has heart disease, diabetes, kidney problems, and stroke. The investigators hope that this study will confirm a new, safe test to help us predict the risk of surgery.
Study Results: NO
Conditions: High Risk for Postoperative Cardiovascular Events
Interventions: OTHER: endothelial function testing
Primary Outcome Measures: To determine whether endothelial dysfunction as measured by abnormal flow mediated dilation (FMD)., Identifies patients at high risk of cardiovascular complications after major thoracic or abdominal cancer surgery., 1 year
Secondary Outcome Measures: To obtain preliminary information on whether abnormal FMD adds predictive information beyond risk algorithms, proposed by the American Heart Association/American College of Cardiology., 1 year|To determine whether abnormal flow mediated dilation (FMD) correlates to abnormal brain natriuretic enzyme BNP levels prior to surgery., 1 year|To survey whether FMD prior to surgery is affected by treatment with chemotherapy and/or radiation prior to major cancer surgery, 1 year
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 67
Funder Type: OTHER

Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 10-206
Start Date: 2010-12
Primary Completion Date: 2018-07-11
Completion Date: 2018-07-11
First Posted: 2010-12-17
Results First Posted:
Last Update Posted: 2018-07-13
Locations: Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States
Study Documents:

NCT Number: NCT00002900
Study Title: SWOG-9342 Chemotherapy in Treating Women Enrolled in the SWOG-8897 Clinical Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT00002900
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die.

PURPOSE: This clinical trial is studying the effect of chemotherapy on heart function in treating women who have breast cancer with negative axillary lymph nodes and who are undergoing treatment on the SWOG-8897 clinical trial.
Study Results: NO
Conditions: Breast Cancer|Cardiac Toxicity
Interventions: PROCEDURE: management of therapy complications
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: SWOG Cancer Research Network
Collaborators: National Cancer Institute (NCI)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 180
Funder Type: NETWORK
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CDR0000065237|U10CA032102|SWOG-9342
Start Date: 1997-02
Primary Completion Date: 2008-03
Completion Date:
First Posted: 2003-01-27
Results First Posted:
Last Update Posted: 2015-10-19
Locations: MBCCOP - Gulf Coast, Mobile, Alabama, 36688, United States| CCOP - Western Regional, Arizona, Phoenix, Arizona, 85006-2726, United

States|Veterans Affairs Medical Center - Phoenix (Carl T. Hayden), Phoenix, Arizona, 85012, United States|Veterans Affairs Medical Center - Tucson, Tucson, Arizona, 85723, United States|Arizona Cancer Center at University of Arizona Health Sciences Center, Tucson, Arizona, 85724, United States|University of Arkansas for Medical Sciences, Little Rock, Arkansas, 72205, United States|Veterans Affairs Medical Center - Little Rock (McClellan), Little Rock, Arkansas, 72205, United States|City of Hope Comprehensive Cancer Center, Duarte, California, 91010, United States|Veterans Affairs Medical Center - Long Beach, Long Beach, California, 90822, United States|USC/Norris Comprehensive Cancer Center and Hospital, Los Angeles, California, 90033-0804, United States|Veterans Affairs Medical Center - West Los Angeles, Los Angeles, California, 90073, United States|Jonsson Comprehensive Cancer Center, UCLA, Los Angeles, California, 90095-1781, United States|Veterans Affairs Outpatient Clinic - Martinez, Martinez, California, 94553, United States|CCOP - Bay Area Tumor Institute, Oakland, California, 94609-3305, United States|Chao Family Comprehensive Cancer Center, Orange, California, 92868, United States|University of California Davis Cancer Center, Sacramento, California, 95817, United States|UCSF Comprehensive Cancer Center, San Francisco, California, 94143-0128, United States|CCOP - Santa Rosa Memorial Hospital, Santa Rosa, California, 95403, United States|David Grant Medical Center, Travis Air Force Base, California, 94535, United States|University of Colorado Cancer Center at University of Colorado Health Sciences Center, Denver, Colorado, 80010, United States|Veterans Affairs Medical Center - Denver, Denver, Colorado, 80220, United States|MBCCOP - Howard University Cancer Center, Washington, District of Columbia, 20060, United States|CCOP - Atlanta Regional, Atlanta, Georgia, 30342-1701, United States|Dwight David Eisenhower Army Medical Center, Fort Gordon, Georgia, 30905-5650, United States|Cancer Research Center of Hawaii, Honolulu, Hawaii, 96813-2424, United States|MBCCOP - Hawaii, Honolulu, Hawaii, 96813, United States|Tripler Army Medical Center, Honolulu, Hawaii, 96859-5000, United States|MBCCOP - University of Illinois at Chicago, Chicago, Illinois, 60612-7323, United States|Veterans Affairs Medical Center - Chicago (Westside Hospital), Chicago, Illinois, 60612, United States|CCOP - Central Illinois, Decatur, Illinois, 62526, United States|Veterans Affairs Medical Center - Hines (Hines Junior VA Hospital), Hines, Illinois, 60141, United States|Loyola University Medical Center, Maywood, Illinois, 60153-5500, United States|University of Kansas Medical Center, Kansas City, Kansas, 66160-7353, United States|CCOP - Wichita, Wichita, Kansas, 67214-3882, United States|Veterans Affairs Medical Center - Wichita, Wichita, Kansas, 67218, United States|Veterans Affairs Medical Center - Lexington, Lexington, Kentucky, 40502-2236, United States|Albert B. Chandler Medical Center, University of Kentucky, Lexington, Kentucky, 40536-0084, United States|MBCCOP - LSU Health Sciences Center, New Orleans, Louisiana, 70112, United States|Tulane University School of Medicine, New Orleans, Louisiana, 70112, United States|Louisiana State University Health Sciences Center - Shreveport, Shreveport, Louisiana, 71130-3932, United States|Veterans

Affairs Medical Center - Shreveport, Shreveport, Louisiana, 71130, United States|Boston Medical Center, Boston, Massachusetts, 02118, United States|Veterans Affairs Medical Center - Boston (Jamaica Plain), Jamaica Plain, Massachusetts, 02130, United States|Veterans Affairs Medical Center - Ann Arbor, Ann Arbor, Michigan, 48105, United States|CCOP - Michigan Cancer Research Consortium, Ann Arbor, Michigan, 48106, United States|University of Michigan Comprehensive Cancer Center, Ann Arbor, Michigan, 48109-0912, United States|Barbara Ann Karmanos Cancer Institute, Detroit, Michigan, 48201-1379, United States|Veterans Affairs Medical Center - Detroit, Detroit, Michigan, 48201-1932, United States|Henry Ford Hospital, Detroit, Michigan, 48202, United States|CCOP - Grand Rapids, Grand Rapids, Michigan, 49503, United States|CCOP - Beaumont, Royal Oak, Michigan, 48073-6769, United States|Providence Hospital - Southfield, Southfield, Michigan, 48075-9975, United States|CCOP - Duluth, Duluth, Minnesota, 55805, United States|Veterans Affairs Medical Center - Biloxi, Biloxi, Mississippi, 39531-2410, United States|University of Mississippi Medical Center, Jackson, Mississippi, 39216-4505, United States| Veterans Affairs Medical Center - Jackson, Jackson, Mississippi, 39216, United States|Veterans Affairs Medical Center - Kansas City, Kansas City, Missouri, 64128, United States|CCOP - Kansas City, Kansas City, Missouri, 64131, United States|St. Louis University Health Sciences Center, Saint Louis, Missouri, 63110, United States|CCOP - St. Louis-Cape Girardeau, Saint Louis, Missouri, 63141, United States| CCOP - Cancer Research for the Ozarks, Springfield, Missouri, 65807, United States|CCOP - Montana Cancer Consortium, Billings, Montana, 59101, United States|Veterans Affairs Medical Center - Albuquerque, Albuquerque, New Mexico, 87108-5138, United States|MBCCOP - University of New Mexico HSC, Albuquerque, New Mexico, 87131, United States| Veterans Affairs Medical Center - Albany, Albany, New York, 12208, United States|Herbert Irving Comprehensive Cancer Center at Columbia University, New York, New York, 10032, United States|James P. Wilmot Cancer Center at University of Rochester Medical Center, Rochester, New York, 14642, United States|CCOP - Southeast Cancer Control Consortium, Winston-Salem, North Carolina, 27104-4241, United States| Veterans Affairs Medical Center - Cincinnati, Cincinnati, Ohio, 45220-2288, United States|Barrett Cancer Center, Cincinnati, Ohio, 45267-0501, United States|Cleveland Clinic Taussig Cancer Center, Cleveland, Ohio, 44195-9001, United States|CCOP - Columbus, Columbus, Ohio, 43206, United States|Veterans Affairs Medical Center - Dayton, Dayton, Ohio, 45428, United States|CCOP - Dayton, Dayton, Ohio, 45429, United States|CCOP - Toledo Community Hospital, Toledo, Ohio, 43623-3456, United States|University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, 73104, United States|Veterans Affairs Medical Center - Oklahoma City, Oklahoma City, Oklahoma, 73104, United States|Oregon Cancer Institute, Portland, Oregon, 97201-3098, United States|Veterans Affairs Medical Center - Portland, Portland, Oregon, 97207, United States|CCOP - Columbia River Oncology Program, Portland, Oregon, 97225, United States|Veterans Affairs Medical Center - Charleston, Charleston, South Carolina, 29401-5799, United States|

Hollings Cancer Center at Medical University of South Carolina, Charleston, South Carolina, 29425, United States|CCOP - Greenville, Greenville, South Carolina, 29615, United States|CCOP - Upstate Carolina, Spartanburg, South Carolina, 29303, United States|University of Tennessee Cancer Institute, Memphis, Tennessee, 38103, United States|Danville Radiation Therapy Center, Memphis, Tennessee, 38104, United States|Harrington Cancer Center, Amarillo, Texas, 79106, United States|Veterans Affairs Medical Center - Amarillo, Amarillo, Texas, 79106, United States|Veterans Affairs Medical Center - Dallas, Dallas, Texas, 75216, United States|Brooke Army Medical Center, Fort Sam Houston, Texas, 78234-6200, United States|University of Texas Medical Branch, Galveston, Texas, 77555-0565, United States|Veterans Affairs Medical Center - Houston, Houston, Texas, 77030, United States|University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78229-3900, United States|Veterans Affairs Medical Center - San Antonio (Murphy), San Antonio, Texas, 78229, United States|Veterans Affairs Medical Center - Temple, Temple, Texas, 76504, United States|CCOP - Scott and White Hospital, Temple, Texas, 76508, United States|Huntsman Cancer Institute, Salt Lake City, Utah, 84112-5550, United States|Veterans Affairs Medical Center - Salt Lake City, Salt Lake City, Utah, 84148, United States|Fletcher Allen Health Care - University Health Center Campus, Burlington, Vermont, 05401, United States|MBCCOP - Massey Cancer Center, Richmond, Virginia, 23298-0037, United States|CCOP - Virginia Mason Research Center, Seattle, Washington, 98101, United States|Swedish Cancer Institute at Swedish Medical Center - First Hill Campus, Seattle, Washington, 98104, United States|Veterans Affairs Medical Center - Seattle, Seattle, Washington, 98108, United States|CCOP - Northwest, Tacoma, Washington, 98405-0986, United States|Madigan Army Medical Center, Tacoma, Washington, 98431-5000, United States
Study Documents:

NCT Number: NCT03206333
Study Title: Automated Quantification of Coronary Artery Calcifications on Radiotherapy Planning CTs for Cardiovascular Risk Prediction in Breast Cancer Patients: the BRAGATSTON Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03206333
Acronym:
Study Status: UNKNOWN
Brief Summary: The aim of the BRAGATSTON study is to provide a low cost tool for measuring CAC in breast cancer patients, thereby identifying patients at increased risk of CVD. Breast cancer patients and doctors can act upon this, by adapting the treatment and/or by adopting cardioprotective interventions. Hereby, the burden of CVD in breast cancer survivors can be reduced and better overall survival rates can be achieved.
Study Results: NO
Conditions: Breast Cancer|Cardiovascular Diseases
Interventions:
Primary Outcome Measures: Incident (non-)fatal (cardiovascular)

diseases, Up to 13 years of follow-up, in hazard ratios
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: UMC Utrecht
Collaborators: Erasmus Medical Center|Radboud University Medical Center
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 16000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 16/721 (IRB UMC Utrecht)
Start Date: 2017-01-01
Primary Completion Date: 2020-03-01
Completion Date: 2020-03-01
First Posted: 2017-07-02
Results First Posted:
Last Update Posted: 2018-10-19
Locations: Radboudumc, Nijmegen, Netherlands|Erasmus Medical Center, Rotterdam, Netherlands|University Medical Center Utrecht, Utrecht, Netherlands
Study Documents:

NCT Number: NCT01026233
Study Title: Cardiac Safety Study of Brentuximab Vedotin (SGN-35)
Study URL: https://beta.clinicaltrials.gov/study/NCT01026233
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate cardiac safety of brentuximab vedotin (SGN-35) in patients with CD30-positive cancers. The study will assess electrical activity of the heart before and after brentuximab vedotin administration. Patients who have stable or improving disease may receive up to 1 year of brentuximab vedotin treatment.
Study Results: NO
Conditions: Disease, Hodgkin|Lymphoma, Large-Cell, Anaplastic|Lymphoma, Non-Hodgkin
Interventions: DRUG: brentuximab vedotin
Primary Outcome Measures: QTc interval, 2-4 days postdose
Secondary Outcome Measures: ECG parameters, 2-4 days postdose|Blood MMAE levels, Through 4 days postdose|Incidence of proarrhythmic adverse events, Through 1 month following last dose|Incidence of adverse events and laboratory abnormalities, Through 1 month following last dose
Other Outcome Measures:
Sponsor: Seagen Inc.
Collaborators: Millennium Pharmaceuticals, Inc.
Sex: ALL

Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 52
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: SGN35-007
Start Date: 2010-01
Primary Completion Date: 2010-08
Completion Date: 2011-08
First Posted: 2009-12-04
Results First Posted:
Last Update Posted: 2014-12-12
Locations: University of Alabama at Birmingham, Birmingham, Alabama, 35294-3300, United States|City of Hope National Medical Center, Duarte, California, 91010, United States|Stanford Cancer Center, Stanford, California, 94305, United States|University of Miami Hospital and Clinics, Miller School of Medicine, Miami, Florida, 33136, United States|Cardinal Bernardin Cancer Center / Loyola University Medical Center, Maywood, Illinois, 60153, United States|New York University Cancer Institute, New York, New York, 10016, United States|Fox Chase Cancer Center, Philadelphia, Pennsylvania, 19111, United States|Baylor University Medical Center, Dallas, Texas, 75246, United States|University Hospital of Cologne, Koln, 50924, Germany
Study Documents:

NCT Number: NCT02677714
Study Title: 99mTc-rhAnnexin V-128 Imaging and Cardiotoxicity in Patients With Early Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02677714
Acronym:
Study Status: TERMINATED
Brief Summary: This was a single center, proof-of-concept (PoC), Phase II study. Patients with histologically confirmed early stage (Stage I, II or III) HER-2 negative breast cancer and scheduled to receive doxorubicin-based (neo)adjuvant therapy to be followed by paclitaxel or docetaxel as per clinical practice. The planned doxorubicin-based chemotherapy treatment consisted of doxorubicin 60 mg/m2 in combination with cyclophosphamide 600 mg/m2 (AC) intravenous (IV) every 2 or 3 weeks for 4 cycles. Patients were scheduled for CMRI and 99mTc-rhAnnexin V-128 imaging (planar and SPECT / CT) at the following visits:

1. Screening/baseline, i.e. 2 weeks prior to initiating AC treatment (Visit 1)
2. After the 2nd and before the 3rd cycle of AC treatment (Visit 2)
3. After the 4th cycle of AC treatment and within 2 weeks (Visit 3)
4. At 12 weeks after the 4th cycle of AC treatment (Visit 4). The imaging procedures were conducted and analyzed. Bloodwork for

cardiotoxicity biomarkers (troponin, N terminal pro B-type natriuretic peptide \[NT-proBNP\]) was performed at each visit.
Study Results: YES
Conditions: Breast Cancer|Doxorubicin Induced Cardiomyopathy
Interventions: RADIATION: 99mTc-rhAnnexin V-128
Primary Outcome Measures: Part I / Proof of Concept (PoC): Number of Participants Evaluated for Imaging Feasibility, The feasibility of imaging apoptotic activity using 99mTc-rhAnnexin V-128 was assessed in the first 10 patients who enrolled and completed the PoC phase of the study by the data monitoring committee (visual image review and consensus). The three reviewers of the DMC did an independent visual assessment of the images using a 1 to 4 point grading system: each observer reviewed the images of each patient and scored either 1 or 2 (uptake was less than or equal to blood pool), these images were considered normal; 3 was equivocal and four equalled abnormal. Only descriptive analysis performed., Day 0 (Baseline)
Secondary Outcome Measures: 99mTc-rhAnnexin V-128 Myocardial Uptake, Single-Photon Emission Computed Tomography (SPECT)/Computed Tomography (CT) scans of the thorax were acquired with a dual head SPECT/CT gamma camera with low-energy high-resolution collimators at 1 and 2 hours post-injection at each collection time point and were to be compared to Baseline. Myocardial uptake was measured from regions of interest (ROIs) placed over the myocardium on the SPECT images coregistered with the corresponding CT images for anatomic delineation. Myocardial uptake was expressed either in absolute units (% injected dose/g) or as a standardized uptake value (SUV). Only descriptive analysis performed., 60 and 120 minutes post injection at: Day 0 (Baseline), Visit 2 (After the 2nd and before the 3rd cycle of doxorubicin), Visit 3 (After the 4th cycle of doxorubicin and within 2 weeks), Visit 4 (12 weeks after the 4th cycle of doxorubicin)|Changes in Left Ventricular (LV) Function, The worsening of LV function was to be assessed by comparing cardiac magnetic resonance imaging (CMRI) left ventricular ejection fraction (LVEF) after the 2nd and the 4th cycle of doxorubicin/cyclophosphamide chemotherapy (AC) treatment and after 12 weeks of the last dose of doxorubicin compared to Baseline. Only descriptive analysis performed., Day 0 (Baseline), Visit 2 (After the 2nd and before the 3rd cycle of doxorubicin), Visit 3 (After the 4th cycle of doxorubicin and within 2 weeks), Visit 4 (12 weeks after the 4th cycle of doxorubicin)|Changes in the Cardiotoxicity Biomarkers (Troponin and NT-proBNP), The differences of LV function after the 2nd and the 4th cycle of doxorubicin/cyclophosphamide chemotherapy (AC) treatment and after 12 weeks of the last dose of doxorubicin compared to Baseline were to be correlated with the changes in cardiotoxicity biomarkers: Troponin and N Terminal pro B-type Natriuretic Peptide (NT-proBNP). Only descriptive analysis performed., Day 0 (Baseline), Visit 2 (After the 2nd and before the 3rd cycle of doxorubicin), Visit 3 (After the 4th cycle of doxorubicin and within 2 weeks), Visit 4 (12 weeks after the 4th cycle of doxorubicin)
Other Outcome Measures:
Sponsor: Advanced Accelerator Applications

Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 14
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: AAA-Annexin-05|CAAA113A42202
Start Date: 2016-11-02
Primary Completion Date: 2018-10-12
Completion Date: 2018-10-12
First Posted: 2016-02-09
Results First Posted: 2020-09-21
Last Update Posted: 2020-12-11
Locations: University of Ottawa Heart Institute, Ottawa, Ontario, K1Y 4W7, Canada
Study Documents: Study Protocol|Statistical Analysis Plan

NCT Number: NCT01665300
Study Title: Usefulness of Myocardial Deformation Imaging for Trastuzumab-induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT01665300
Acronym:
Study Status: COMPLETED
Brief Summary: Trastuzumab prolongs survival in patients with human epidermal growth factor receptor type 2-positive breast cancer. Sequential left ventricular (LV) ejection fraction (EF) assessment has been mandated to detect myocardial dysfunction because of the risk of heart failure with this treatment. Myocardial deformation imaging is a sensitive means of detecting LV dysfunction, but this technique has not been evaluated in patients treated with trastuzumab. The aim of this study was to investigate whether changes in tissue deformation, assessed by myocardial strain and strain rate (SR), are able to identify LV dysfunction earlier than conventional echocardiographic measures in patients treated with trastuzumab.
Study Results: NO
Conditions: Left Ventricular Function Systolic Dysfunction|Cardiotoxicity
Interventions:
Primary Outcome Measures: LV systolic dysfunction, LV systolic dysfunction was defined as following;

1. An EF unit drop of ≥10% from the baseline available echocardiogram or
2. Change in strain or strain rate : drop(decrement) corresponding to ≥1 SD of the relevant parameter assessed at the baseline available echocardiogram, 3-month F/U
Secondary Outcome Measures: LV systolic dysfunction, LV systolic

dysfunction was defined as following;

1. An EF unit drop of ≥10% from the baseline available echocardiogram
or
2. Change in strain or strain rate : drop(decrement) corresponding to ≥1 SD of the relevant parameter assessed at the baseline available echocardiogram, 6,9, and 12-month F/U
Other Outcome Measures:
Sponsor: Seoul National University Hospital
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 120
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: H1106-026-365
Start Date: 2011-07
Primary Completion Date: 2013-12
Completion Date: 2014-04
First Posted: 2012-08-15
Results First Posted:
Last Update Posted: 2014-04-29
Locations: Seoul National University Hospital, Seoul, 110-744, Korea, Republic of
Study Documents:

NCT Number: NCT01892800
Study Title: Right Side of Heart Function After Lung Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT01892800
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is explore the impact of lung cancer surgery on the function of the right side of the heart.
Study Results: NO
Conditions: Lung Cancer|Ventricular Failure, Right
Interventions: PROCEDURE: Lung resection
Primary Outcome Measures: Right ventricular ejection fraction, The primary objective of this study is determine whether RVEF falls post-operatively in patients undergoing lung resection. The primary outcome is RVEF at 3 days post-lung resection compared to pre-operative values determined by CMR., 3 days
Secondary Outcome Measures: Association between RVEF and contractility / loading indices, Changes in RVEF must be interpreted in the context of changes in RV contractility and loading parameters. Changes in pre-load, contractility, afterload, ventriculo-arterial coupling, diastolic function and the position of the mediastinum could all potentially influence RVEF.The following indices will be subject to assessment as secondary endpoints:

Preload - Right ventricular end-diastolic volume (RVEDV) Contractility - Peak systolic strain and strain rate Afterload - Pulmonary artery (PA) distensibility, PA peak velocitly, PA antegrade flow, Estimated PA systolic pressure,Pulmonary artery acceleration time Ventriculo-arterial coupling: Ea/Emax(CMR) Diastolic function: E/A velocity ratio., 3 days|RVEF vs LVEF, Changes in right-sided cardiac function must be interpreted in the context of left-sided function. ΔRVEF will be compared to changes in Left Ventricular Ejection Fraction (LVEF) over the same period., 3 days|Association between biomarkers of myocardial and endothelial dysfunction, systemic inflammation, oxidative and nitrosative stress and ΔRVEF, Association between biomarkers of myocardial and endothelial dysfunction, systemic inflammation, oxidative and nitrosative stress and ΔRVEF.

Myocardial dysfunction: Brain natriuretic peptide and high sensitivity Troponin-T. Systemic inflammation: C-reactive protein and Pentraxin 3. Oxidative / Nitrosative stress: Malondialdehyde, nitrate and nitrite (determined in plasma and endobronchial aspirate and the end of surgery). Endothelial dysfunction:

Angiopoietin (Ang) 1 \& 2, Von Willebrand factor (VWf), E-selectin (ESEL) and soluble intracellular adhesion molecule (sICAM))., 3 days| Association between RVEF and functional status, Association between RVEFpreop, RVEFpostop, and RVEF3months and functional status by self report and 6-minute walk test (6MWT). Functional status will be assessed subjectively by written questionnaire. Scoring will be based on the New York Heart Association (NYHA) classification, WHO performance status classification and health related quality of life scoring by EQ-5D questionnaire., 3 months and 1 year
Other Outcome Measures:
Sponsor: University of Glasgow
Collaborators: Golden Jubilee National Hospital
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 25
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 1-shelly
Start Date: 2013-08
Primary Completion Date: 2014-09
Completion Date: 2016-08
First Posted: 2013-07-04
Results First Posted:
Last Update Posted: 2016-05-16
Locations: Golden Jubilee National Hospital, Clydebank, United Kingdom
Study Documents:

NCT Number: NCT01112800
Study Title: Markers of Anthracycline-Related Cardiac Muscle Injury
Study URL: https://beta.clinicaltrials.gov/study/NCT01112800
Acronym:
Study Status: WITHDRAWN
Brief Summary: Anthracycline antibiotics are included in the chemotherapy regimens of approximately 82% of patients with bone cancer and 44% of those with soft tissue sarcoma diagnosed in childhood or adolescence. Impaired cardiac function occurs after treatment with anthracyclines. The frequency of impairment increases with increasing cumulative dose. There are inadequate data regarding the relationship between doxorubicin administration and changes in serum levels of cardiac troponin T (cTn-T) or I (cTn-I), N-terminal (NT) brain natriuretic peptide (BNP), or tissue Doppler imaging parameters.

This non-therapeutic study proposes a prospective, single arm study of serial changes in tissue Doppler imaging parameters, cTn-T and NT-BNP in children and adolescents with malignant bone and soft tissue tumors whose planned chemotherapy includes treatment with ≥ 375 mg/m2 of doxorubicin.

The proposed study will rigorously evaluate the usefulness of serial determinations of tissue Doppler imaging, cTn-T and NT-BNP for very early identification of anthracycline-related myocardial injury. Demonstration that one or more of these markers identifies subclinical myocardial damage and that biomarker or tissue Doppler imaging parameters exhibit a dose-response relationship with cumulative doxorubicin dose would facilitate intervention trials in patients at risk for anthracycline cardiomyopathy.
Study Results: NO
Conditions: Osteosarcoma|Ewing's Sarcoma Family of Tumors|Rhabdomyosarcoma|Non-rhabdomyosarcoma Soft Tissue Sarcomas
Interventions:
Primary Outcome Measures: Imaging measurement of potential cardiac muscle injury markers before and after cumulative anthracycline exposure., This study will serially evaluate imaging tests in previously untreated patients with osteosarcoma, Ewing's sarcoma family of tumors, rhabdomyosarcoma and intermediate and high-risk non-rhabdomyosarcoma soft tissue sarcomas whose planned treatment includes a cumulative doxorubicin dose ≥ 375 mg/m2 to determine if serial levels of one or more of these potential markers of cardiac muscle injury obtained prior to each infusion of doxorubicin and at the completion of chemotherapy correlate with increasing cumulative anthracycline exposure., 3 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: St. Jude Children's Research Hospital
Collaborators:
Sex: ALL

Age: CHILD, ADULT
Phases:
Enrollment: 0
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: MARCI
Start Date: 2010-05
Primary Completion Date: 2013-01
Completion Date: 2013-01
First Posted: 2010-04-28
Results First Posted:
Last Update Posted: 2013-06-19
Locations:
Study Documents:

NCT Number: NCT05064514
Study Title: Investigation of a Transcatheter Tricuspid Valved Stent Graft in Patients With Carcinoid Heart Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT05064514
Acronym: TRICAR
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The purpose of this investigation is to see if the TRICENTO Valved Stent Graft implant reduces tricuspid regurgitation (TR) and improves the symptoms and quality of life in 15 participants with carcinoid heart disease, and who are not able to have a new valve via a surgical procedure.
Study Results: NO
Conditions: Tricuspid Regurgitation|Tricuspid Valve Disease|Carcinoid Syndrome|Carcinoid Heart Disease
Interventions: DEVICE: Transcatheter Tricuspid Valved Stent Graft
Primary Outcome Measures: The number of patients with successful implantation of the TRICENTO bioprosthesis, with a 35% change (reduction) in the V wave pressure in the Inferior Vena Cava (IVC), measured pre intervention and immediately after the intervention
Secondary Outcome Measures: To assess the safety of the Tricuspid Valved Stent Graft implantation procedure in patients with carcinoid heart disease with severe symptomatic TR and significant systolic backflow in the hepatic and caval veins, and who are not suitable for surgery., ∗ The number of procedural complications (re-interventions related to the device or access procedure, major vascular or bleeding complication (VARC), cardiac death during hospital stay (max 7 days) ∗ Rate of death all causes, At baseline, 1 month and 6 months|•To evaluate the reduced symptom burden according to New York Heart Association (NYHA) score, •NYHA assessment, At baseline, and post intervention at 1 month and 6 months|To evaluate the change in peripheral oedema experienced by patients, 1. measure of ankle circumference (cm)
2. assessment of oedema scored as: none = 0, ankle = 1, shin = 2, thigh = 3, anasarca = 4, At baseline, 1 month and 6 months|To evaluate

the change in of number of admissions to hospital for heart failure, Count of number of hospital admissions for heart failure, 6 months before procedure and 6 months post implantation.|To evaluate the change in patient reported quality of life (EuroQol- 5 Dimension - EQ5D), Measure EQ5D scores for all patients, At baseline, and post intervention at 1 month and 6 months|To evaluate the change in patient reported quality of life (Kansas City Cardiomyopathy Questionnaire (KCCQ)), Measure Kansas City Cardiomyopathy Questionnaire scores for all patients, At baseline, and post intervention at 1 month and 6 months|To evaluate the change in patient reported quality of life (Minnesota Living With Heart Failure - MLFHQ), Measure MLFHQ scores for all patients, At baseline, and post intervention at 1 month and 6 months
Other Outcome Measures:
Sponsor: Queen Mary University of London
Collaborators: Royal Free Hospital NHS Foundation Trust
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 15
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 262072
Start Date: 2022-04-06
Primary Completion Date: 2023-10
Completion Date: 2026-03
First Posted: 2021-10-01
Results First Posted:
Last Update Posted: 2023-01-13
Locations: Barts Health NHS Trust, London, England, E1 1BB, United Kingdom
Study Documents:

NCT Number: NCT03836300
Study Title: Parent-Infant Inter(X)Action Intervention (PIXI)
Study URL: https://beta.clinicaltrials.gov/study/NCT03836300
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: The objective is to develop and test, through an iterative process, an intervention to address and support the development of infants with a confirmed diagnosis of neurogenetic disorders that leave individuals at risk for developmental delays or intellectual and developmental disabilities. The proposed project will capitalize and expand upon existing empirically based interventions designed to improve outcomes for infants with suspected developmental delays.

Participants will be infants with a confirmed diagnosis of a

neurogenetic disorder (e.g., fragile X, Angelman, Prader-Willi, Dup15q, Phelan-McDermid, Rhett, Smith Magenis, Williams, Turner, Kleinfelter, Down syndromes, Duchenne muscular dystrophy) within the first year of life and their parents/caregivers.

The intervention, called Parent-infant Inter(X)action Intervention (PIXI) is a comprehensive program inclusive of parent education about early infant development and the neurogenetic disorder for which they were diagnosed, direct parent coaching around parent-child interaction, and family/parent well-being support. The protocol includes repeated comprehensive assessments of family and child functioning, along with an examination of feasibility and acceptability of the program.
Study Results: NO
Conditions: Fragile X Syndrome|Angelman Syndrome|Prader-Willi Syndrome|Dup15Q Syndrome|Duchenne Muscular Dystrophy|Phelan-McDermid Syndrome|Rett Syndrome|Smith Magenis Syndrome|Williams Syndrome|Turner Syndrome|Klinefelter Syndrome|Chromosome 22q11.2 Deletion Syndrome|Tuberous Sclerosis|Down Syndrome
Interventions: BEHAVIORAL: Parent-Infant Inter(X)action Intervention (PIXI)
Primary Outcome Measures: Social Validity and Acceptability, A social validity measure will be completed to better understand to inquire about family satisfaction with aspects of the intervention including curriculum, timing, goals targeted, and perceived effects of the intervention., Completion of Phase 1 (approximately six months of age)|Social Validity and Acceptability, A social validity measure will be completed to better understand to inquire about family satisfaction with aspects of the intervention including curriculum, timing, goals targeted, and perceived effects of the intervention. Qualitative interviewing will be also be conducted to examine parent perceptions of feasibility and acceptability., Completion of Phase 2 (approximately twelve months of age)|Fidelity, Overall intervention fidelity will be measured by determining if the following goals were achieved:

Enrollment target of 10-15 families 80% retention rate with at least 75% completing the 20 sessions across Phase 1 and Phase 2, Completion of Phase 1 (approximately six months of age)|Fidelity, Overall intervention fidelity will be measured by determining if the following goals were achieved:

Enrollment target of 10-15 families 80% retention rate with at least 75% completing the 20 sessions across Phase 1 and Phase 2, Completion of Phase 2 (approximately twelve months of age)
Secondary Outcome Measures: Parent Implementation and Engagement, Internal parent implementation and engagement forms will be used to measure parent participation across both intervention phases. These components include parent readiness for the session, attention to materials, participation in topic discussion, appropriateness of

intervention activity practice, and general presentation with their child., Across phase 1 and phase 2 engagement (approximately ages 6-months through 1-year of age)|Early Developmental Outcomes, Descriptive statistics around early learning, motor, communication skills, interpersonal, and adaptive skills in the sample will be derived from the Vineland Adaptive Behavior Scales, Third Edition: Parent/Caregiver Report (Vineland-3). Subdomain v-Scaled scores range from 1-24 with higher numbers indicating greater performance; while domain scores are presented in standard score formats with a range of 20-140 with higher scores indicating greater performance., Completion of Phase 1 (approximately 6-months of age) and completion of follow-up (approximately 36-months of age)|Autism Symptoms, A combination of measures will be used across study engagement to assess parent reported autism symptomology. These measures include the Communication and Symbolic Behavior Scale (CSBS). The parent report developmental profile is a standardized measure is completed to evaluate language and social communication predictors. A total of 57 points are available with age corresponding cutoff scores for clinical concern., Completion of Phase 1 (approximately 6-months of age) and completion of follow-up (approximately 36-months of age)|Autism Symptoms, A combination of measures will be used across study engagement to assess parent reported autism symptomology. These measures include the Modified Checklist for Autism in Toddlers (MCHAT). The Modified Checklist for Autism in Toddlers is a scientifically validated tool for screening children between 16 and 30 months of age that assesses risk for autism spectrum disorder (ASD).Scores range from 0-20 with corresponding ranges for cutoff scores warranting further follow-up., Completion of Phase 1 (approximately 6-months of age) and completion of follow-up (approximately 36-months of age)|Autism Symptoms, A combination of measures will be used across study engagement to assess parent reported autism symptomology. These measures include the Autism Diagnostic Observation Schedule, Second Edition (ADOS-2). The ADOS-2 is a semi-structured, standardized assessment of communication, social interaction, play, and restricted and repetitive behaviors. It is directly administered to the participant and behaviors are scored. Total scores range based on age of participant/module administered. Scores are calculated and compared against cutoff scores for autism spectrum and autism., Completion of Phase 1 (approximately 6-months of age) and completion of follow-up (approximately 36-months of age)|Autism Symptoms, A combination of measures will be used across study engagement to assess parent reported autism symptomology. These measures include the TELE-ASD-PEDS. The TELE-ASD-PEDS was developed by researchers at Vanderbilt University to assess remotely autism symptomology. The TELE-ASD-PEDS measures communication, social interaction, play, and restricted and repetitive behaviors. It is administered via telehealth and behaviors are scored. Total scores range based on age of participant/module administered. Scores are calculated and compared against cutoff scores for autism spectrum and autism., Completion of Phase 1 (approximately 6-months of age) and completion of follow-up (approximately 36-months of age)|Autism

Symptoms, A combination of measures will be used across study engagement to assess parent reported autism symptomology. These measures include the Repetitive Behavior Scales (RBS). The RBS-EC is a questionnaire measure of restricted and repetitive behaviors designed for use in children from infancy through early school age. It is intended to capture individual differences across a broad range of behaviors associated with the repetitive behavior domain. Total scores range from 0-136 with a higher score indicating greater need/presence of behaviors., Completion of Phase 1 (approximately 6-months of age) and completion of follow-up (approximately 36-months of age)
Other Outcome Measures:
Sponsor: RTI International
Collaborators: University of North Carolina, Chapel Hill
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 18-2079
Start Date: 2018-11-30
Primary Completion Date: 2024-12-31
Completion Date: 2025-06-30
First Posted: 2019-02-11
Results First Posted:
Last Update Posted: 2023-04-28
Locations: RTI International, Research Triangle Park, North Carolina, 27709, United States
Study Documents:

NCT Number: NCT02536014
Study Title: Effect of Dexmedetomidine on Heart-rate Corrected QT(QTc) Interval Prolongation During Robotic-assisted Laparoscopic Radical Prostatectomy -Randomized Blind Clinical Trial-
Study URL: https://beta.clinicaltrials.gov/study/NCT02536014
Acronym:
Study Status: COMPLETED
Brief Summary: Sympathetic activity could be increased during robot-assisted laparoscopic radical prostatectomy, which is performed in a steep trendelenburg position under CO2 pneumoperitoneum.

Stimulation of the sympathetic nervous system prolongs the QT interval and can increases the susceptibility to life threatening cardiac arrhythmias.

Dexmedetomidine has sympatholytic effects and potential antiarrhythmic properties. Perioperative administration of dexmedetomidine is a potential preventive and treatment strategy for tachyarrhythmia. Thus

the investigators decided to evaluate the effect of dexmedetomidine on heart-rate corrected QT interval during robot-assisted laparoscopic radical prostatectomy. Furthermore, the investigators evaluated the Tp-e, Tp-e/QT ratio and Tp-e/QTc ratio as well.
Study Results: NO
Conditions: Prostate Cancer|Robotic Surgery
Interventions: DRUG: Dexmedetomidine|DRUG: Saline
Primary Outcome Measures: Dexmedetomidine on heart-rate corrected QT(QTc) interval, QTc intervals (msec) are recorded from pre-induction until 60 min after the end of pneumoperitoneum, From pre-induciton until 60 min after the end of pneumoperitoneum
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Yonsei University
Collaborators:
Sex: MALE
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 4-2015-0337
Start Date: 2015-08
Primary Completion Date: 2016-01
Completion Date: 2016-01
First Posted: 2015-08-31
Results First Posted:
Last Update Posted: 2016-01-29
Locations: Department of Anesthesiology and Pain Medicine, Anesthesia and Pain Research Institue, Yonsei Universiy College of Medicine, Seoul, 03722, Korea, Republic of
Study Documents:

NCT Number: NCT03342300
Study Title: Pegylated Liposomal Doxorubicin Versus Pirarubicin Plus Ifosfamide, Dacarbazine in Locally Advanced, Unresectable or Metastatic Soft-tissue Sarcoma
Study URL: https://beta.clinicaltrials.gov/study/NCT03342300
Acronym: PDVPSTS
Study Status: WITHDRAWN
Brief Summary: Advanced soft tissue sarcoma patients who have previously recieved anthracyclines might still benefit from doxorubicin, ifosfamide and dacarbazine. However doxorubicin might be stopped using because of chronic cumulative heart toxicity. Several efforts have been made to improve the toxicity profile of conventional anthracyclines, including the use of liposomal encapsulation technology and the development of novel anthracycline analogs,such as

pegylated liposomal doxorubicin and pirarubicin. However their actual effectiveness and toxicity have not been studied in prospective trial. The purpose of the study is to investigate whether they are available for this group of patients.
Study Results: NO
Conditions: Progression-free Survival|Overall Survival|Toxicity
Interventions: DRUG: pegylated liposomal doxorubicin|DRUG: pirarubicin
Primary Outcome Measures: progression-free survival, Progression-free survival is defined as time from randomisation to the first occurrence of progression of disease or death from any cause within 63 days of last response assessment or randomisation., 12 weeks
Secondary Outcome Measures: overall survival, overall survival is defined as the duration from date of randomisation to the date of death from any cause., 12 months|objective response rate, ORR, objective response rate includes complete and partial responses as defined by RECIST version 1.1., 12 weeks|left ventricular ejection fraction function, We use ultrasound to routinely estimate the left ventricular ejection fraction function., 12 months
Other Outcome Measures:
Sponsor: Peking University People's Hospital
Collaborators: Peking University Shougang Hospital|Chinese PLA General Hospital|Beijing Jishuitan Hospital|Xijing Hospital|Peking Union Medical College Hospital
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: CBTRA-03
Start Date: 2017-11-06
Primary Completion Date: 2020-11-15
Completion Date: 2020-12-30
First Posted: 2017-11-14
Results First Posted:
Last Update Posted: 2020-05-19
Locations: Peking University People's Hospital, Beijing, 100044, China
Study Documents:

NCT Number: NCT02789800
Study Title: Patient-Centred Innovations for Persons With Multimorbidity - Quebec
Study URL: https://beta.clinicaltrials.gov/study/NCT02789800
Acronym: PACEinMM-QC
Study Status: COMPLETED
Brief Summary: The aim of Patient-Centred Innovations for Persons With Multimorbidity (PACE in MM) study is to reorient the health care system from a single disease focus to a multimorbidity focus; centre

on not only disease but also the patient in context; and realign the health care system from separate silos to coordinated collaborations in care. PACE in MM will propose multifaceted innovations in Chronic Disease Prevention and Management (CDPM) that will be grounded in current realities (i.e. Chronic Care Models including Self-Management Programs), that are linked to Primary Care (PC) reform efforts. The study will build on this firm foundation, will design and test promising innovations and will achieve transformation by creating structures to sustain relationships among researchers, decision-makers, practitioners, and patients. The Team will conduct inter-jurisdictional comparisons and is mainly a Quebec (QC) - Ontario (ON) collaboration with participation from 3 other provinces: British Columbia (BC); Manitoba (MB); and Nova Scotia (NS). The Team's objectives are: 1) to identify factors responsible for success or failure of current CDPM programs linked to the PC reform, by conducting a realist synthesis of their quantitative and qualitative evaluations; 2) to transform consenting CDPM programs identified in Objective 1, by aligning them to promising interventions on patient-centred care for multimorbidity patients, and to test these new innovations' in at least two jurisdictions and compare among jurisdictions; and 3) to foster the scaling-up of innovations informed by Objective 1 and tested/proven in Objective 2, and to conduct research on different approaches to scaling-up. This registration for Clinical Trials only pertains to Objective 2 of the study.
Study Results: NO
Conditions: Hypertension|Depression|Anxiety|Musculoskeletal Pain|Arthritis|Rheumatoid Arthritis|Osteoporosis|Chronic Obstructive Pulmonary Disease (COPD)|Asthma|Chronic Bronchitis|Cardiovascular Disease|Heart Failure|Stroke|Transient Ischemic Attacks|Ulcer|Gastroesophageal Reflux|Irritable Bowel|Crohn's Disease|Ulcerative Colitis|Diverticulosis|Chronic Hepatitis|Diabetes|Thyroid Disorder|Cancer|Kidney Disease|Urinary Tract Problem|Dementia|Alzheimer's Disease|Hyperlipidemia|HIV
Interventions: BEHAVIORAL: DIMAC02
Primary Outcome Measures: Evaluation of Intervention Effectiveness - Change in Self-Management outcomes, Health Education Impact Questionnaire (HeiQ). Score: Reliable improvement, T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3
Secondary Outcome Measures: Evaluation of Intervention Effectiveness - Change in Chronic Diseases, Multimorbidity/Chronic Disease (MM-21): Score: number of Chronic diseases, T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3|Evaluation of Intervention Effectiveness - Change in Health Status, Health Status (VR-12): Score: Physical Component Summary (PCS) and the Mental Component Summary (MCS), T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3|Evaluation of Intervention Effectiveness - Change in Quality of Life, Quality of Life (EQ5D-5L): Score: mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3|Evaluation of

Intervention Effectiveness - Change in Psychological Well-being, Psychological Well-being (Kessler 6 Scale).Score: mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3|Evaluation of Intervention Effectiveness - Change in Lifestyle/Health Behaviours, Lifestyle/Health Behaviours Questionnaire. Score: mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3|Evaluation of Intervention Effectiveness - Equity, T1: Baseline|Demographics, T1: Baseline|Evaluation of Intervention Effectiveness - Change in Transitions of Care, Patient Perception of Transitions of Care. Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3|Evaluation of Intervention Effectiveness - Change in Self-Efficacy, Self-Efficacy for Managing Chronic Disease Scale (SEM-CD). Score: mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3|Evaluation of Intervention Effectiveness - Change in Patient-Centredness, Patient Perception of Patient-Centredness (PPPC). Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2; T4: one year after T3
Other Outcome Measures:
Sponsor: Université de Sherbrooke
Collaborators: Canadian Institutes of Health Research (CIHR)|Western University, Canada|Agence de la Sante et des Services Sociaux du Saguenay-Lac-Saint-Jean
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 284
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: OTHER
Other IDs: 2013-010
Start Date: 2016-04-22
Primary Completion Date: 2022-11-01
Completion Date: 2022-11-01
First Posted: 2016-06-03
Results First Posted:
Last Update Posted: 2022-11-03
Locations: Université de Sherbrooke, Chicoutimi, Quebec, G7H 5H6, Canada|CIUSSS du Sageunay-Lac-Saint-Jean, Chicoutimi, Quebec, G7H 7K9, Canada
Study Documents:

NCT Number: NCT01968200
Study Title: Prevention of Anthracycline-induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT01968200
Acronym: ICOS-ONE
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Anthracycline based anti-tumoral therapies are know to

develop cardiac damage that could also lead to heart failure. Monocentric studies proved that a treatment with ACE inhibitors (ACEi) and betablockers (BB) during the first elevation of cardiac troponin is able to reduce the incidence of heart failure (HF).

ICOS-ONE trial is a multicenter randomized trial comparing two therapeutic strategies. The main objective is to assess whether enalapril started concomitantly to AC-containing treatments, can prevent cardiac toxicity more effectively than when enalapril is prescribed to selected patients showing laboratory evidences of injury after chemotherapy, during follow-up visits in 268 patients.
Study Results: NO
Conditions: Cancer
Interventions: DRUG: Enalapril
Primary Outcome Measures: the occurrence of cTn elevation above the threshold in use at the local laboratory, at any time during the study, To assess whether enalapril administered concomitantly to anthracyclines (AC) containing treatments can prevent cardiac toxicity more effectively than enalapril prescribed to selected patients showing laboratory evidences of injury after chemotherapy (CT), at follow-up visits.

Cardiac toxicity is measured on the basis of cardiac troponin levels., up to 1 year after the completion of the anthracyclines containing chemotherapy.
Secondary Outcome Measures: admissions to hospital for cardiovascular causes,, to assess whether enalapril administered concomitantly to AC-containing treatments can reduce admissions to hospital for cardiovascular causes, up to 3 years after the completion of the anthracyclines containing chemotherapy.|cardiovascular deaths, to assess whether enalapril administered concomitantly to AC-containing treatments can reduce cardiovascular deaths, up to 1 year after the completion of the anthracyclines containing chemotherapy.|occurrence of hypo- or hyperkinetic arrhythmias, to assess whether enalapril administered concomitantly to AC-containing treatments can reduce new occurrence of hypo- or hyperkinetic arrhythmias, up to 1 year after the completion of the anthracyclines containing chemotherapy.
Other Outcome Measures:
Sponsor: European Institute of Oncology
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 268
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: IEO S701/412|2012-002248-26
Start Date: 2012-12

Primary Completion Date: 2019-12
Completion Date: 2023-12
First Posted: 2013-10-23
Results First Posted:
Last Update Posted: 2023-06-28
Locations: European Institute of Oncology, Milan, Italy
Study Documents:

NCT Number: NCT05201014
Study Title: Cancer Survivor Cardiomyopathy Detection
Study URL: https://beta.clinicaltrials.gov/study/NCT05201014
Acronym: CASCADE
Study Status: RECRUITING
Brief Summary: The purpose of this study is to improve the cardiovascular care of adult cancer survivors. The goal is to obtain the data necessary to plan and develop a nation-wide network of a screening program that can help provide cost-effective and long-term monitoring.
Study Results: NO
Conditions: Cardiovascular Diseases|Cancer
Interventions: DIAGNOSTIC_TEST: NT-pro-BNP|DIAGNOSTIC_TEST: Electrocardiogram|DIAGNOSTIC_TEST: Echocardiogram
Primary Outcome Measures: Diagnostic performance of AI-ECG for left ventricular ejection fraction (LVEF) < 50%, Determination of the sensitivity, specificity, positive and negative prediction value as well as area under the curve for receiver operating characteristics for the 12-lead AI ECG algorithm for an LVEF \<50%, 1 year post anthracycline therapy|Diagnostic performance of NT-pro-BNP for left ventricular ejection fraction (LVEF) < 50%, Determination of the sensitivity, specificity, positive and negative prediction value as well as area under the curve for receiver operating characteristics for NT-pro-BNP \>125 for an LVEF \<50%, 1 year post anthracycline therapy|Diagnostic performance of AI-ECG and NT-pro-BNP for left ventricular ejection fraction (LVEF) < 50%, Determination of the sensitivity, specificity, positive and negative prediction value as well as area under the curve for receiver operating characteristics for the 12-lead AI ECG algorithm and NT-pro-BNP \>125 combined for an LVEF \<50%, 1 year post anthracycline therapy
Secondary Outcome Measures: Absolute change in LVEF from baseline to 1 year from anthracycline-based therapy, Calculation of the the change in LVEF from baseline to 1 year from anthracycline-based therapy, 1 year|Absolute change in AI-ECG probability for LVEF <50% from baseline to 1 year from anthracycline-based therapy, Calculation of the change in AI-ECG probability of LVEF \<50% from baseline to 1 year from anthracycline-based therapy, 1 year|Correlation of change in LVEF and AI-ECG probability of LVEF <50% from baseline to 1 year from anthracycline-based therapy, Calculation of the correlation coefficient of change in LVEF and AI-ECG probability of LVEF \<50% from baseline to 1 year from anthracycline-based therapy, 1 year|Absolute change in NT-pro-BNP from baseline to 1 year from

anthracycline-based therapy, Calculation of the change NT-pro-BNP from baseline to 1 year from anthracycline-based therapy, 1 year| Correlation of change in LVEF and NT-pro-BNP from baseline to 1 year from anthracycline-based therapy, Calculation of the correlation coefficient of change in LVEF and NT-pro-BNP from baseline to 1 year from anthracycline-based therapy, 1 year
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators: Miami Heart Research Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 200
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 21-006790
Start Date: 2022-03-03
Primary Completion Date: 2024-01
Completion Date: 2024-01
First Posted: 2022-01-21
Results First Posted:
Last Update Posted: 2023-05-03
Locations: Mayo Clinic in Rochester, Rochester, Minnesota, 55905, United States
Study Documents:

NCT Number: NCT01016756
Study Title: Genetic Analysis of PHACE Syndrome (Hemangioma With Other Congenital Anomalies)
Study URL: https://beta.clinicaltrials.gov/study/NCT01016756
Acronym: PHACE
Study Status: COMPLETED
Brief Summary: 1. PHACE syndrome(OMIM database number 606519) is the association of a vascular birthmark (hemangioma) on the face along with one or more of the following conditions: congenital heart defects, congenital anomalies of the cerebral arteries,brain, eyes, or sternum.
2. A research study is currently being conducted at the Medical College of Wisconsin (MCW) to investigate if there is an inherited cause of PHACE syndrome.
3. We are hoping that this study will lead to a better understanding of how and why children develop PHACE syndrome.
Study Results: NO
Conditions: PHACE Syndrome
Interventions:
Primary Outcome Measures: Establish a DNA and tissue bank., 5 years| Determine candidate genes for PHACE syndrome using a genome-wide approach., 10 years
Secondary Outcome Measures:

Other Outcome Measures:
Sponsor: Medical College of Wisconsin
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 341
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PHACE_GENETICS
Start Date: 2007-02
Primary Completion Date: 2022-08-15
Completion Date: 2022-08-15
First Posted: 2009-11-19
Results First Posted:
Last Update Posted: 2023-03-28
Locations: Medical College of Wisconsin, Milwaukee, Wisconsin, 53226, United States
Study Documents:

NCT Number: NCT05184790
Study Title: LEARN: Learning Environment for Artificial Intelligence in Radiotherapy New Technology
Study URL: https://beta.clinicaltrials.gov/study/NCT05184790
Acronym: LEARN
Study Status: NOT_YET_RECRUITING
Brief Summary: This study will develop a whole-of-body markerless tracking method for measuring the motion of the tumour and surrounding organs during radiation therapy to enable real-time image guidance.

Routinely acquired patient data will be used to improve the training, testing and accuracy of a whole-of-body markerless tracking method. When the markerless tracking method is sufficiently advanced, according to the PI of each of the data collection sites, the markerless tracking method will be run in parallel to, but not intervening with, patient treatments during data acquisition.
Study Results: NO
Conditions: Arrhythmias, Cardiac|Breast Cancer|Prostatic Cancer|Brain Cancer|Kidney Cancer|Head and Neck Cancer|Liver Cancer|Pancreatic Cancer|Spinal Neoplasm
Interventions:
Primary Outcome Measures: Accuracy of markerless tracking, Proportion of markerless tracking within 5 mm of the ground truth for each of nine anatomical sites (cohorts), 3 years
Secondary Outcome Measures: Clinical acceptability of markerless tracking system, Proportion of radiation therapists considering the markerless tracking system acceptable using a survey, 3 years
Other Outcome Measures:
Sponsor: University of Sydney

Collaborators: Princess Alexandra Hospital, Brisbane, Australia|Calvary Mater Newcastle, Australia|Western Sydney Local Health District|Austin Health|Peter MacCallum Cancer Centre, Australia
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 300
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IX-2021-DS-LEARN
Start Date: 2023-01-31
Primary Completion Date: 2026-01-31
Completion Date: 2026-01-31
First Posted: 2022-01-11
Results First Posted:
Last Update Posted: 2022-11-09
Locations: Royal North Shore Hospital, Saint Leonards, New South Wales, 2065, Australia|Princess Alexandra Hospital, Woolloongabba, Queensland, 4102, Australia|Alfred Health, Melbourne, Victoria, 3000, Australia|Peter MacCallum Cancer Centre, Melbourne, Victoria, 3000, Australia
Study Documents:

NCT Number: NCT01384097
Study Title: An Algorithm for Intra-operative Goal-directed Haemodynamic Management in Non-cardiac Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT01384097
Acronym: ERAS_feasi
Study Status: COMPLETED
Brief Summary: A systematic literature search a goal-directed haemodynamic algorithm was created. The hypothesis of this study was that the goal-directed haemodynamic algorithm is feasible and can improve clinical outcome.
Study Results: NO
Conditions: Fracture of Surgical Neck of Humerus|Colonic Tumor|Stage IIIB Ovarian Carcinoma|Neoplasm of Head of Pancreas
Interventions:
Primary Outcome Measures: hospital length of stay, The perioperative hospital length of stay is assessed., a period of 60 days
Secondary Outcome Measures: need for ventilator therapy, The perioperative need for ventilator therapy is assessed., a period of 60 days|monetary reimbursement for prolonged hospital stay, The monetary reimbursement for prolonged hospital stay is assessed to evaluate the impact on financial consequences., a period of 60 days
Other Outcome Measures:
Sponsor: Charite University, Berlin, Germany
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases:
Enrollment: 774
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ERAS_feasibility
Start Date: 2007-09
Primary Completion Date: 2011-02
Completion Date: 2011-06
First Posted: 2011-06-28
Results First Posted:
Last Update Posted: 2011-09-08
Locations: Charité - University Medicine Berlin, Berlin, 13353, Germany
Study Documents:

NCT Number: NCT02742597
Study Title: Patient-Centred Innovations for Persons With Multimorbidity - Ontario
Study URL: https://beta.clinicaltrials.gov/study/NCT02742597
Acronym: PACEinMM-ON
Study Status: COMPLETED
Brief Summary: The aim of Patient-Centred Innovations for Persons With Multimorbidity (PACE in MM) study is to reorient the health care system from a single disease focus to a multimorbidity focus; centre on not only disease but also the patient in context; and realign the health care system from separate silos to coordinated collaborations in care. PACE in MM will propose multifaceted innovations in Chronic Disease Prevention and Management (CDPM) that will be grounded in current realities (i.e. Chronic Care Models including Self-Management Programs), that are linked to Primary Care (PC) reform efforts. The study will build on this firm foundation, will design and test promising innovations and will achieve transformation by creating structures to sustain relationships among researchers, decision-makers, practitioners, and patients. The Team will conduct inter-jurisdictional comparisons and is mainly a Quebec (QC) - Ontario (ON) collaboration with participation from 4 other provinces: British Columbia (BC); Manitoba (MB); Nova Scotia (NS); and New Brunswick (NB). The Team's objectives are: 1) to identify factors responsible for success or failure of current CDPM programs linked to the PC reform, by conducting a realist synthesis of their quantitative and qualitative evaluations; 2) to transform consenting CDPM programs identified in Objective 1, by aligning them to promising interventions on patient-centred care for multimorbidity patients, and to test these new innovations' in at least two jurisdictions and compare among jurisdictions; and 3) to foster the scaling-up of innovations informed by Objective 1 and tested/proven in Objective 2, and to conduct research on different approaches to scaling-up. This registration for Clinical Trials only pertains to Objective 2 of the study.
Study Results: NO

Conditions: Hypertension|Depression|Anxiety|Musculoskeletal Pain|Arthritis|Rheumatoid Arthritis|Osteoporosis|Chronic Obstructive Pulmonary Disease (COPD)|Asthma|Chronic Bronchitis|Cardiovascular Disease|Heart Failure|Stroke|Transient Ischemic Attacks|Ulcer|Gastroesophageal Reflux|Irritable Bowel|Crohn's Disease|Ulcerative Colitis|Diverticulosis|Chronic Hepatitis|Diabetes|Thyroid Disorder|Cancer|Kidney Disease|Urinary Tract Problem|Dementia|Alzheimer's Disease|Hyperlipidemia|HIV|Multimorbidity
Interventions: BEHAVIORAL: TIP / IMPACT Plus Care Coordination
Primary Outcome Measures: Evaluation of Intervention Effectiveness - Change in Self-Management outcomes, Health Education Impact Questionnaire (HeiQ). Score: Reliable improvement, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Transitions of Care, Patient Perception of Transitions of Care. Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Self-Efficacy, Self-Efficacy for Managing Chronic Disease Scale (SEM-CD). Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Patient-Centredness, Patient Perception of Patient-Centredness (PPPC). Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;
Secondary Outcome Measures: Evaluation of Intervention Effectiveness - Change in Chronic Diseases, Multimorbidity/Chronic Disease (MM-21): Score: Number of Chronic diseases, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Health Status, Health Status (VR-12): Score: Physical Component Summary (PCS) and the Mental Component Summary (MCS), T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Quality of Life, Quality of Life (EQ-5D-5L): Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Psychological Well-being, Psychological Well-being (Kessler 6 Scale). Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Lifestyle/Health Behaviours, Lifestyle/Health Behaviours Questionnaire. Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Equity, Vertical Equity. Score: Mean, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;|Evaluation of Intervention Effectiveness - Change in Demographics, Demographics. Score: frequencies, means, T1: Initial evaluation; T2: after 4 months; T3: one year after T2;
Other Outcome Measures:
Sponsor: Lawson Health Research Institute
Collaborators: Western University, Canada|Université de Sherbrooke|Canadian Institutes of Health Research (CIHR)|Sunnybrook Health Sciences Centre|Unity Health Toronto|University Health Network, Toronto|Michael Garron Hospital|Providence Healthcare|Mount Sinai Hospital, Canada|Toronto Central Community Care Access Centre|Women's

College Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 175
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: OTHER
Other IDs: 104191
Start Date: 2016-01-12
Primary Completion Date: 2019-04-07
Completion Date: 2022-10-19
First Posted: 2016-04-19
Results First Posted:
Last Update Posted: 2023-03-17
Locations: Western University, London, Ontario, N6A 3K7, Canada|Mount Sinai Hospital, Toronto, Ontario, Canada|Providence Healthcare, Toronto, Ontario, Canada|St. Michael's Hospital, Toronto, Ontario, Canada|Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada|Toronto Central Community Care Access Centre, Toronto, Ontario, Canada|Toronto East General Hospital, Toronto, Ontario, Canada|University Hospital Network, Toronto, Ontario, Canada|Women's College Hospital, Toronto, Ontario, Canada
Study Documents:

NCT Number: NCT05040867
Study Title: Exercise Prescription Guided by Heart Rate Variability in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05040867
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: Breast cancer is a chronic disease that has seen a boom in research into its treatments, improvements and effects in recent decades. These advances have also highlighted the need to use physical exercise as a countermeasure to reduce the cardiotoxicity of pharmacological treatments. Patients need a correct daily individualisation of the exercise dose necessary to produce the physiological, physical and psychological benefits. To this end, the present study will use, in a novel way in this population, heart rate variability (HRV) as a measure of training prescription. The primary objective of this randomised clinical trial is to analyse the effects of a physical exercise programme planned according to daily HRV in breast cancer patients after chemotherapy treatment. For this purpose, a 16-week intervention will be carried out with 90 breast cancer patients distributed in 3 groups (control group, conventional preprogrammed physical exercise training group and physical exercise group with HRV daily programming). Cardiorespiratory capacity, strength, flexibility, agility, balance, body composition, quality of life, fatigue, functionality, self-esteem, anxiety and depression of

patients before and after the intervention will be evaluated in order to compare the effects of exercise and its programming.
Study Results: NO
Conditions: Breast Cancer|Cardiotoxicity|Autonomic Imbalance
Interventions: OTHER: Physical exercise program
Primary Outcome Measures: Baseline Troponin, A haemogram will be carried out to analyse patients' Troponin I and T to detect their cardiotoxicity levels. Troponin results will be reported in ng/L., At baseline|After intervention Troponin, A haemogram will be carried out to analyse patients' Troponin I and T to detect their cardiotoxicity levels and the change produced after the intervention. Troponin results will be reported in ng/L., Immediately after the intervention|3 months after intervention Troponin, A haemogram will be carried out to analyse patients' Troponin I and T to detect their cardiotoxicity levels and the changes produced 3 months after the intervention. Troponin results will be reported in ng/L., 3 months after the intervention ending|6 months after intervention Troponin, A haemogram will be carried out to analyse patients' Troponin I and T to detect their cardiotoxicity levels and the changes produced 6 months after the intervention. Troponin results will be reported in ng/L., 6 months after the intervention ending|Baseline Brain Natriuretic Peptide, A haemogram will be carried out to analyse patients' BNP to assess their cardiotoxicity levels. BNP results will be reported in pg/ml., At baseline|After intervention Brain Natriuretic Peptide, A haemogram will be carried out to analyse patients' BNP to assess their cardiotoxicity levels and the change produced after the intervention. BNP results will be reported in pg/ml., Immediately after the intervention|3 months after intervention Brain Natriuretic Peptide, A haemogram will be carried out to analyse patients' BNP to assess their cardiotoxicity levels and the change produced 3 after the intervention. BNP results will be reported in pg/ml., 3 months after the intervention ending|6 months after intervention Brain Natriuretic Peptide, A haemogram will be carried out to analyse patients' BNP to assess their cardiotoxicity levels and the change produced 6 after the intervention. BNP results will be reported in pg/ml., 6 months after the intervention ending|Baseline left ventricular systolic and diastolic volume, An echocardiogram will be performed to measure left ventricular systolic and diastolic volume in mL., At Baseline|After intervention left ventricular systolic and diastolic volume, An echocardiogram will be performed to measure left ventricular systolic and diastolic volume in mL and it changes after the intervention., Immediately after the intervention ending|3 months after intervention left ventricular systolic and diastolic volume, An echocardiogram will be performed to measure left ventricular systolic and diastolic volume in mL and it changes 3 months after the intervention., 3 months after the intervention ending|6 months after intervention left ventricular systolic and diastolic volume, An echocardiogram will be performed to measure left ventricular systolic and diastolic volume in mL and it changes 6 months after the intervention., 6 months after the intervention ending|Baseline left ventricular ejection fraction, By an

echocardiogram, patients' % of LVEF will be assessed due to its possible modification caused by cardiotoxicity., At baseline|After intervention left ventricular ejection fraction, By an echocardiogram, patients' % of LVEF will be assessed to measure its results and its change after the intervention., Immediately after the intervention|3 months after intervention left ventricular ejection fraction, By an echocardiogram, patients' % of LVEF will be assessed to measure its results and its change 3 months after the intervention., 3 months after the intervention ending|6 months after intervention left ventricular ejection fraction, By an echocardiogram, patients' % of LVEF will be assessed to measure its results and its change 6 months after the intervention., 6 months after the intervention ending| Baseline time domain heart rate variability measures, The assessment of heart rate variability will be performed with a Polar chest strap and electrocardiogram. Participants will remain in the supine position for 10 minutes to correctly obtain 5 minutes of a stable signal. After removal of artefacts, the standard deviation time domains of all RR intervals (SDNN) in ms, the mean ad all RR intervals in ms and the root mean square of the sum of squared RR interval differences in ms (RMSSD) will be recorded., At baseline|After intervention time-domain heart rate variability measures, The assessment of heart rate variability will be performed with a Polar chest strap and electrocardiogram. Participants will remain in the supine position for 10 minutes to correctly obtain 5 minutes of a stable signal. After removal of artefacts, the standard deviation time domains of all RR intervals (SDNN) in ms, the mean ad all RR intervals in ms and the root mean square of the sum of squared RR interval differences in ms (RMSSD) will be recorded after the intervention., Immediately after the intervention|3 months after intervention time-domain heart rate variability measures, The assessment of heart rate variability will be performed with a Polar chest strap and electrocardiogram. Participants will remain in the supine position for 10 minutes to correctly obtain 5 minutes of a stable signal. After removal of artefacts, the standard deviation time domains of all RR intervals (SDNN) in ms, the mean ad all RR intervals in ms and the root mean square of the sum of squared RR interval differences in ms (RMSSD) will be recorded 3 months after the intervention., 3 months after the intervention ending|6 months after intervention time-domain heart rate variability measures, The assessment of heart rate variability will be performed with a Polar chest strap and electrocardiogram. Participants will remain in the supine position for 10 minutes to correctly obtain 5 minutes of a stable signal. After removal of artefacts, the standard deviation time domains of all RR intervals (SDNN) in ms, the mean ad all RR intervals in ms and the root mean square of the sum of squared RR interval differences in ms (RMSSD) will be recorded 6 months after the intervention., 6 months after the intervention ending|During intervention time-domain heart rate variability measures, Daily heart rate variability will be measured using the HRV4Training application, a validated mobile application that allows HRV values to be obtained by photoplethysmography (rMSSD, SDNN, AVNN, pNN50 and heart rate).,

During the intervention ending|Baseline frequency domain heart rate variability measures, The assessment of heart rate variability will be performed with a Polar chest strap and electrocardiogram. Participants will remain in the supine position for 10 minutes to correctly obtain 5 minutes of a stable signal. After removal of artefacts, the frequency measures of low frequency (LF, 0.04-0.15 Hz) in ms2 and n.u, high frequency (HF, 0.15-0.4 Hz) ms2 and n.u, total power in ms2 and LF/HF ratio will be calculated., At baseline|After intervention frequency domain heart rate variability measures, The assessment of heart rate variability will be performed with a Polar chest strap and electrocardiogram. Participants will remain in the supine position for 10 minutes to correctly obtain 5 minutes of a stable signal. After removal of artefacts, the frequency measures of low frequency (LF, 0.04-0.15 Hz) in ms2 and n.u, high frequency (HF, 0.15-0.4 Hz) ms2 and n.u, total power in ms2 and LF/HF ratio will be calculated after intervention., Immediately after the intervention|3 months after intervention frequency domain heart rate variability measures, The assessment of heart rate variability will be performed with a Polar chest strap and electrocardiogram. Participants will remain in the supine position for 10 minutes to correctly obtain 5 minutes of a stable signal. After removal of artefacts, the frequency measures of low frequency (LF, 0.04-0.15 Hz) in ms2 and n.u, high frequency (HF, 0.15-0.4 Hz) ms2 and n.u, total power in ms2 and LF/HF ratio will be calculated 3 months after the intervention., 3 months after the intervention ending|6 months after intervention frequency domain heart rate variability measures, The assessment of heart rate variability will be performed with a Polar chest strap and electrocardiogram. Participants will remain in the supine position for 10 minutes to correctly obtain 5 minutes of a stable signal. After removal of artefacts, the frequency measures of low frequency (LF, 0.04-0.15 Hz) in ms2 and n.u, high frequency (HF, 0.15-0.4 Hz) ms2 and n.u, total power in ms2 and LF/HF ratio will be calculated 6 months after the intervention., 6 months after the intervention ending|During intervention frequency domain heart rate variability measures, Daily heart rate variability will be measured using the HRV4Training application, a validated mobile application that allows HRV values to be obtained by photoplethysmography (LF, HF, TP, LF/HF and recovery points), During the intervention

Secondary Outcome Measures: Baseline heart rate rhyme, A resting electrocardiogram will be used to obtain patients' normal values for heart rate measurements in bpm, I-axis and aVF, Q-T interval, QRS complex, S-T segment and T-wave, in ms. Moreover, resting heart rate will be assessed by a Polar chest band., At baseline|After intervention heart rate rhyme, A resting electrocardiogram will be used to obtain patients' normal values for heart rate measurements in bpm, I-axis and aVF, Q-T interval, QRS complex, S-T segment and T-wave, in ms, and get after intervention results. Moreover, resting heart rate will be assessed by a Polar chest band., Immediately after the intervention|3 months after intervention heart rate rhyme, A resting electrocardiogram will be used to obtain patients' normal

values for heart rate measurements in bpm, I-axis and aVF, Q-T interval, QRS complex, S-T segment and T-wave, in ms, and get its results 3 months after the intervention. Moreover, resting heart rate will be assessed by a Polar chest band., 3 months after the intervention ending|6 months after intervention heart rate rhyme, A resting electrocardiogram will be used to obtain patients' normal values for heart rate measurements in bpm, I-axis and aVF, Q-T interval, QRS complex, S-T segment and T-wave, in ms, and get its results 6 months after the intervention. Moreover, resting heart rate will be assessed by a Polar chest band., 6 months after the intervention|Baseline tumor necrosis factor, Through a blood analysis TFN, in pg/mL, will be measured to evaluate patients' inflammation., At baseline|After intervention tumor necrosis factor, Through a blood analysis TFN, in pg/mL, will be measured to evaluate patients' inflammation after the intervention., Immediately after the intervention|3 months after intervention tumor necrosis factor, Through a blood analysis TFN, in pg/mL, will be measured to evaluate patients' inflammation 3 months after the intervention., 3 months after the intervention ending|6 months after intervention tumor necrosis factor, Through a blood analysis TFN, in pg/mL, will be measured to evaluate patients' inflammation 6 months after the intervention., 6 months after the intervention ending|Baseline interleukins measurement, The inflammation will be assessed by blood interleukins will include IL-6, IL-8, IL-1b, IL-1ra and IL-10 values, in pg/m., At baseline|After intervention interleukins measurement, The inflammation will be assessed by blood interleukins will include IL-6, IL-8, IL-1b, IL-1ra and IL-10 values, in pg/m, immediately after the intervention., Immediately after the intervention.|3 months after intervention interleukins measurement, The inflammation will be assessed by blood interleukins will include IL-6, IL-8, IL-1b, IL-1 and IL-10 values, in pg/m, 3 months after the intervention., 3 months after the intervention ending|6 months after intervention interleukins measurement, The inflammation will be assessed by blood interleukins will include IL-6, IL-8, IL-1b, IL-1ra and IL-10 values, in pg/m, 6 months after the intervention., 6 months after the intervention ending|Baseline C-reactive protein measure, C-reactive protein (CRP), measured in mg/L will be evaluated to get patients' pro-inflammatory data., At baseline|After intervention C-reactive protein measure, C-reactive protein (CRP), measured in mg/L will be evaluated to get patients' pro-inflammatory data after the intervention., Immediately after the intervention.|3 months after intervention C-reactive protein measure, C-reactive protein (CRP), measured in mg/L will be evaluated to get patients' pro-inflammatory data 3 months after the intervention., 3 months after the intervention ending|6 months after intervention C-reactive protein measure, C-reactive protein (CRP), measured in mg/L will be evaluated to get patients' pro-inflammatory data 6 months after the intervention., 6 months after the intervention ending|Baseline monocyte chemotactic protein measure, Monocyte chemotactic protein (MCP-1), measured in pg/mL will be evaluated to get patients' pro-inflammatory data., At baseline|After intervention

monocyte chemotactic protein measure, Monocyte chemotactic protein (MCP-1), measured in pg/mL will be evaluated to get patients' pro-inflammatory data after the intervention., Immediately after the intervention.|3 months after intervention monocyte chemotactic protein measure, Monocyte chemotactic protein (MCP-1), measured in pg/mL will be evaluated to get patients pro-inflammatory data 3 months after the intervention., 3 months after the intervention ending|6 months after intervention monocyte chemotactic protein measure, Monocyte chemotactic protein (MCP-1), measured in pg/mL will be evaluated to get patients pro-inflammatory data 6 months after the intervention., 6 months after the intervention ending|Baseline glucose measure, Glucose, in mg/dl, will be measure through a blood test due to be related to cancer prognosis and cardiovascular risk., At baseline|After intervention glucose measure, Glucose, in mg/dl, will be measure after intervention through a blood test due to be related to cancer prognosis and cardiovascular risk., Immediately after the intervention.|3 months after intervention glucose measure, Glucose, in mg/dl, will be measure through a blood test due to be related to cancer prognosis and cardiovascular risk., 3 months after the intervention ending|6 months after intervention glucose measure, Glucose, in mg/dl, will be measure through a blood test due to be related to cancer prognosis and cardiovascular risk., 6 months after the intervention ending|Baseline cholesterol measure, Low-density lipoprotein and high-density lipoprotein, measured in mg/dL, will be assessed by a blood test due to be related to cancer prognosis and cardiovascular risk., At baseline|After intervention cholesterol measure, Low-density lipoprotein and high-density lipoprotein, measured in mg/dL, will be measure after intervention by a blood test due to be related to cancer prognosis and cardiovascular risk., Immediately after the intervention.|3 months after intervention cholesterol measure, Low-density lipoprotein and high-density, measured in mg/dL, will be measure 3 months after the intervention by a blood test due to be related to cancer prognosis and cardiovascular risk., 3 months after the intervention ending|6 months after intervention cholesterol measure, Low-density lipoprotein and high-density, measured in mg/dL, will be measure 6 months after the intervention by a blood test due to be related to cancer prognosis and cardiovascular risk., 6 months after the intervention ending|Baseline blood pressure measures, Measurements of blood pressure will be performed using a validated oscillometer. Participants will remain at rest for five minutes before the assessment. They will place their left arm, on which the measurement will be taken, on the table so that the cuff is at the level of the heart, 2 cm from the elbow. In addition, any clothing that may alter the results shall be removed. Once in this position, the air tube of the cuff shall be placed on the front of the upper arm in line with the middle finger and the blue arrow on the cuff. Systolic and diastolic blood pressure data, measured in mmHg, shall be taken, and then the mean arterial pressure = (systolic blood pressure+ (2*diastolic blood pressure))/3 shall be calculated., At baseline|After intervention blood pressure measures,

Measurements of blood pressure after the intervention will be performed using a validated oscillometer. Participants will remain at rest for five minutes before the assessment. They will place their left arm, on which the measurement will be taken, on the table so that the cuff is at the level of the heart, 2 cm from the elbow. In addition, any clothing that may alter the results shall be removed. Once in this position, the air tube of the cuff shall be placed on the front of the upper arm in line with the middle finger and the blue arrow on the cuff. Systolic and diastolic blood pressure data, measured in mmHg, shall be taken, and then the mean arterial pressure = (systolic blood pressure+ (2*diastolic blood pressure))/3 shall be calculated., Immediately after the intervention.|3 months after intervention blood pressure measures, Measurements of blood pressure 3 months after the intervention will be performed using a validated oscillometer. Participants will remain at rest for five minutes before the assessment. They will place their left arm, on which the measurement will be taken, on the table so that the cuff is at the level of the heart, 2 cm from the elbow. In addition, any clothing that may alter the results shall be removed. Once in this position, the air tube of the cuff shall be placed on the front of the upper arm in line with the middle finger and the blue arrow on the cuff. Systolic and diastolic blood pressure data, measured in mmHg, shall be taken, and then the mean arterial pressure = (systolic blood pressure+ (2*diastolic blood pressure))/3 shall be calculated., 3 months after the intervention ending|6 months after intervention blood pressure measures, Measurements of blood pressure 6 months after the intervention will be performed using a validated oscillometer. Participants will remain at rest for five minutes before the assessment. They will place their left arm, on which the measurement will be taken, on the table so that the cuff is at the level of the heart, 2 cm from the elbow. In addition, any clothing that may alter the results shall be removed. Once in this position, the air tube of the cuff shall be placed on the front of the upper arm in line with the middle finger and the blue arrow on the cuff. Systolic and diastolic blood pressure data, measured in mmHg, shall be taken, and then the mean arterial pressure = (systolic blood pressure+ (2*diastolic blood pressure))/3 shall be calculated., 6 months after the intervention ending|Baseline body composition weight measures, The weight assessment of body composition will be performed by impedance to obtain patients' global bodyweight, musculoskeletal mass, mineral mass, fat mass and upper and lower extremities segmental fat and lean mass weight. All the measures will be reported in kilograms., At baseline|After intervention body composition weight measures, The weight assessment of body composition after the intervention will be performed by impedance to obtain patients' global bodyweight, musculoskeletal mass, mineral mass, fat mass and upper and lower extremities segmental fat and lean mass weight. All the measures will be reported in kilograms., Immediately after the intervention.|3 months after intervention body composition weight measures, The weight assessment of body composition 3 months after the intervention will be

performed by impedance to obtain patients' global bodyweight, musculoskeletal mass, mineral mass, fat mass and upper and lower extremities segmental fat and lean mass weight. All the measures will be reported in kilograms., 3 months after the intervention ending|6 months after intervention body composition weight measures, The weight assessment of body composition 6 months after the intervention will be performed by impedance to obtain patients' global bodyweight, musculoskeletal mass, mineral mass, fat mass and upper and lower extremities segmental fat and lean mass weight. All the measures will be reported in kilograms, 6 months after the intervention ending| Baseline body composition percentages measures, The assessment of the body fat percentage of the participants is a variable to be taken into consideration. Therefore, thought impedance patients' body fat percentage and upper and lower extremities segmental fat and lean mass percentages will be recorded., At baseline|After intervention body composition percentages measures, The assessment of the body percentage of the participants is a variable to be taken into consideration. Therefore, thought impedance, patients' body fat percentage and upper and lower extremities segmental fat and lean mass percentages will be recorded after the intervention., Immediately after the intervention.|3 months after intervention body composition percentages measures, The assessment of the body percentage of the participants is a variable to be taken into consideration. Therefore, thought impedance, patients' body fat percentage and upper and lower extremities segmental fat and lean mass percentages will be recorded 3 months after the intervention., 3 months after the intervention ending|6 months after intervention body composition percentages measures, The assessment of the body percentage of the participants is a variable to be taken into consideration. Therefore, thought impedance, patients' body fat percentage and upper and lower extremities segmental fat and lean mass percentages will be recorded 6 months after the intervention., 6 months after the intervention ending|Baseline body water measures, By employing also impedance body water evaluation, measured in liters, will be carried out., At baseline|After intervention body water measures, By employing also impedance, body water evaluation, measured in liters, will be carried out after the intervention., Immediately after the intervention.|3 months after intervention body water measures, By employing also impedance, body water evaluation, measured in liters, will be carried out 3 months after the intervention., 3 months after the intervention ending|6 months after intervention body water measures, By employing also impedance, body water evaluation, measured in liters, will be carried out 6 months after the intervention., 6 months after the intervention ending|Baseline anthropometric measures, Patients' height and body perimeters will be assessed in centimeters. Especially, waist circumference, hip circumference, arm circumferences, leg circumferences will be measured following the guidelines set by the American College of Sports Medicine. Afterward, patients' height will be used together with their corresponding weight to calculate patients Body Mass Index., At baseline|After intervention anthropometric

measures, Patients' height and body perimeters will be assessed in centimeters immediately after the intervention. Especially, waist circumference, hip circumference, arm circumferences, leg circumferences will be measured following the guidelines set by the American College of Sports Medicine. Afterward, patients' height will be used together with their corresponding weight to calculate patients Body Mass Index., Immediately after the intervention.|3 months after intervention anthropometric measures, Patients' height and body perimeters will be assessed in centimeters 3 months after the end of the intervention. Especially, waist circumference, hip circumference, arm circumferences, leg circumferences will be measured following the guidelines set by the American College of Sports Medicine. Afterward, patients' height will be used together with their corresponding weight to calculate patients Body Mass Index., 3 months after the intervention ending|6 months after intervention anthropometric measures, Patients' height and body perimeters will be assessed in centimeters 6 months after the end of the intervention. Especially, waist circumference, hip circumference, arm circumferences, leg circumferences will be measured following the guidelines set by the American College of Sports Medicine. Afterward, patients' height will be used together with their corresponding weight to calculate patients Body Mass Index., 6 months after the intervention ending|Baseline cardiorespiratory fitness, To record cardiorespiratory fitness, maximum heart rate and patients' perception of exertion, the Bruce incremental submaximal test (modified) was performed on a treadmill. During the test, the patients will wear a chest strap for heart rate monitoring. Thus, following the protocol created by Bruce, the treadmill will start with a 0% incline and a speed of 1.7 m/h which will be maintained for the first 3 minutes. Every 3 minutes, both the speed and the incline will be increased until the participants decide that their fatigue is too great to continue. At the end of the test, the recovery heart rate is recorded 1 minute after stopping the test to assess the recovery rate. Subsequently, the maximum oxygen consumption of each patient (VO2max = 2.282* (time) + 8.545) will be calculated from the formula proposed by the creators., At baseline|After intervention cardiorespiratory fitness, To record cardiorespiratory fitness after the intervention, maximum heart rate and patients' perception of exertion, the Bruce incremental submaximal test (modified) was performed on a treadmill. During the test, the patients will wear a chest strap for heart rate monitoring. Thus, following the protocol created by Bruce, the treadmill will start with a 0% incline and a speed of 1.7 m/h which will be maintained for the first 3 minutes. Every 3 minutes, both the speed and the incline will be increased until the participants decide that their fatigue is too great to continue. At the end of the test, the recovery heart rate is recorded 1 minute after stopping the test to assess the recovery rate. Subsequently, the maximum oxygen consumption of each patient (VO2max = 2.282* (time) + 8.545) will be calculated from the formula proposed by the creators., Immediately after the intervention.|3 months after intervention cardiorespiratory fitness, To record cardiorespiratory

fitness 3 months after the intervention, maximum heart rate and patients' perception of exertion, the Bruce incremental submaximal test (modified) was performed on a treadmill. During the test, the patients will wear a chest strap for heart rate monitoring. Thus, following the protocol created by Bruce, the treadmill will start with a 0% incline and a speed of 1.7 m/h which will be maintained for the first 3 minutes. Every 3 minutes, both the speed and the incline will be increased until the participants decide that their fatigue is too great to continue. At the end of the test, the recovery heart rate is recorded 1 minute after stopping the test to assess the recovery rate. Subsequently, the maximum oxygen consumption of each patient (VO2max = 2.282* (time) + 8.545) will be calculated from the formula proposed by the creators., 3 months after the intervention ending|6 months after intervention cardiorespiratory fitness, To record cardiorespiratory fitness 6 months after the intervention, maximum heart rate and patients' perception of exertion, the Bruce incremental submaximal test (modified) was performed on a treadmill. During the test, the patients will wear a chest strap for heart rate monitoring. Thus, following the protocol created by Bruce, the treadmill will start with a 0% incline and a speed of 1.7 m/h which will be maintained for the first 3 minutes. Every 3 minutes, both the speed and the incline will be increased until the participants decide that their fatigue is too great to continue. At the end of the test, the recovery heart rate is recorded 1 minute after stopping the test to assess the recovery rate. Subsequently, the maximum oxygen consumption of each patient (VO2max = 2.282* (time) + 8.545) will be calculated from the formula proposed by the creators., 6 months after the intervention ending|Baseline measurement of lower-body strength endurance, Functional strength will be measure by the 30 seconds chair stand test. The patient will stand up, position herself fully stretched, and perform as many repetitions as possible in 30 seconds., At baseline|After intervention measurement of lower-body strength endurance, Functional strength will be measure by the 30 seconds chair stand test. The patient will stand up, position herself fully stretched, and perform as many repetitions as possible in 30 seconds., Immediately after the intervention.|3 months after intervention measurement of lower-body strength endurance, Functional strength will be measure by the 30 seconds chair stand test. The patient will stand up, position herself fully stretched, and perform as many repetitions as possible in 30 seconds., 3 months after the intervention ending|6 months after intervention measurement of lower-body strength endurance, Functional strength will be measure by the 30 seconds chair stand test. The patient will stand up, positioning herself fully stretched, and perform as many repetitions as possible in 30 seconds., 6 months after the intervention ending|Baseline maximal strength, The evaluation of maximal strength will be performed by using an encoder for the correct calculation of the Maximum Repetition (RM) from the speed and power generated by moving the weight vertically. The participants will perform 4 tests to assess the different muscular groups' strength (Back Squat Test, Deadlift Test, Lunge Test, Barbell

Hip Thrust Test). Concretely, 4-5 repetitions will be performed with incremental weights where the speed of execution decreases., At baseline|After intervention maximal strength, The evaluation of maximal strength after the intervention will be performed by using an encoder for the correct calculation of the Maximum Repetition (RM) from the speed and power generated by moving the weight vertically. The participants will perform 4 tests to assess the different muscular groups' strength (Back Squat Test, Deadlift Test, Lunge Test, Barbell Hip Thrust Test). Concretely, 4-5 repetitions will be performed with incremental weights where the speed of execution decreases., Immediately after the intervention.|3 months after intervention maximal strength, The evaluation of maximal strength 3 months after the intervention will be performed by using an encoder for the correct calculation of the Maximum Repetition (RM) from the speed and power generated by moving the weight vertically. The participants will perform 4 tests to assess the different muscular groups' strength (Back Squat Test, Deadlift Test, Lunge Test, Barbell Hip Thrust Test). Concretely, 4-5 repetitions will be performed with incremental weights where the speed of execution decreases., 3 months after the intervention ending|6 months after intervention maximal strength, The evaluation of maximal strength 6 months after the intervention will be performed by using an encoder for the correct calculation of the Maximum Repetition (RM) from the speed and power generated by moving the weight vertically. The participants will perform 4 tests to assess the different muscular groups' strength (Back Squat Test, Deadlift Test, Lunge Test, Barbell Hip Thrust Test). Concretely, 4-5 repetitions will be performed with incremental weights where the speed of execution decreases., 6 months after the intervention ending| Baseline vertical applied force, The force-power will be measured using a countermovement jump test (CMJ) and squat jump test (SJ). From these tests, the maximum force (N) and power (P) exerted during impulse and landing, flight time (ms) and jump height (cm) will be obtained. For the evaluation of the different variables indicated, different technologies will be used such as a jump platform and/or the recording of each of the jumps for subsequent analysis with the validated application of My Jump and Kinovea., At baseline|After intervention vertical applied force, The after-intervention force-power will be measured using a countermovement jump test (CMJ) and squat jump test (SJ). From these tests, the maximum force (N) and power (P) exerted during impulse and landing, flight time (ms) and jump height (cm) will be obtained. For the evaluation of the different variables indicated, different technologies will be used such as a jump platform and/or the recording of each of the jumps for subsequent analysis with the validated application of My Jump and Kinovea., Immediately after the intervention.|3 months intervention vertical applied force, The force-power 3 months after the intervention will be measured using a countermovement jump test (CMJ) and squat jump test (SJ). From these tests, the maximum force (N) and power (P) exerted during impulse and landing, flight time (ms) and jump height (cm) will be obtained. For the evaluation of the different variables indicated,

different technologies will be used such as a jump platform and/or the recording of each of the jumps for subsequent analysis with the validated application of My Jump and Kinovea., 3 months after the intervention ending|6 months intervention vertical applied force, The force-power 6 months after the intervention will be measured using a countermovement jump test (CMJ) and squat jump test (SJ). From these tests, the maximum force (N) and power (P) exerted during impulse and landing, flight time (ms) and jump height (cm) will be obtained. For the evaluation of the different variables indicated, different technologies will be used such as a jump platform and/or the recording of each of the jumps for subsequent analysis with the validated application of My Jump and Kinovea., 6 months after the intervention ending|Baseline measurement of upper body strength endurance, The strength endurance of the patients will be measured utilizing the 30-second arm curl test reporting the maximum number of repetitions in 30 seconds., At baseline|After intervention measurement of upper body strength endurance, The strength endurance of the patients after the intervention will be measured employing the 30-second arm curl test reporting the maximum number of repetitions in 30 seconds., Immediately after the intervention.|3 months after intervention measurement of upper body strength endurance, The strength endurance of the patients 3 months after the intervention will be measured utilizing the 30-second arm curl test reporting the maximum number of repetitions in 30 seconds., 3 months after the intervention ending|6 months after intervention measurement of upper body strength endurance, The strength endurance of the patients 6 months after the intervention will be measured employing the 30-second arm curl test reporting the maximum number of repetitions in 30 seconds., 6 months after the intervention ending|Baseline maximal upper body strength, Maximal strength of different muscular group exercises will be assessed (chest press, shoulder press, bent over row, biceps curl with barbell, Triceps extension with barbell) based on the number of repetitions that the participants are able to perform. An encoder will be used to calculate the Maximum Repetition (RM) by the speed and power generated by moving the weight vertically., At baseline|After intervention maximal upper body strength, Maximal strength of different muscular group exercises after the intervention will be assessed (chest press, shoulder press, bent over row, biceps curl with barbell, Triceps extension with barbell) based on the number of repetitions that the participants are able to perform. An encoder will be used to calculate the Maximum Repetition (RM) by the speed and power generated by moving the weight vertically., Immediately after the intervention.|3 months after intervention maximal upper body strength, Maximal strength of different muscular group exercises 3 months after the intervention will be assessed (chest press, shoulder press, bent over row, biceps curl with barbell, Triceps extension with barbell) based on the number of repetitions that the participants are able to perform. An encoder will be used to calculate the Maximum Repetition (RM) by the speed and power generated by moving the weight vertically., 3 months after the intervention ending|6 months after

intervention maximal upper body strength, Maximal strength of different muscular group exercises 6 months after the intervention will be assessed (chest press, shoulder press, bent over row, biceps curl with barbell, Triceps extension with barbell) based on the number of repetitions that the participants are able to perform. An encoder will be used to calculate the Maximum Repetition (RM) by the speed and power generated by moving the weight vertically., 6 months after the intervention ending|Baseline measurement of agility and dynamic balance, The 8-foot up-and-go test will be employed to measure dynamic balance and agility, where the participants will get up from the chair and walk as fast as possible to the cone, placed 2,44 meters far away, and around the cone, back to the chair. The outcome measure will be the time spend in seconds., At baseline|After intervention measurement of agility and dynamic balance, The 8-foot up-and-go test will be employed to measure dynamic balance and agility after the intervention, where the participants will get up from the chair and walk as fast as possible to the cone, placed 2,44 meters far away, and around the cone, back to the chair. The outcome measure will be the time spend in seconds., Immediately after the intervention.|3 months after intervention measurement of agility and dynamic balance, The 8-foot up-and-go test will be employed to measure dynamic balance and agility 3 months after the intervention, where the participants will get up from the chair and walk as fast as possible to the cone, placed 2,44 meters far away, and around the cone, back to the chair. The outcome measure will be the time spend in seconds., 3 months after the intervention ending|6 months after intervention measurement of agility and dynamic balance, The 8-foot up-and-go test will be employed to measure dynamic balance and agility 6 months after the intervention, where the participants will get up from the chair and walk as fast as possible to the cone, placed 2,44 meters far away, and around the cone, back to the chair. The outcome measure will be the time spend in seconds., 6 months after the intervention ending|Baseline static monopodal balance, The one-leg stand test from the adults ALHPA battery will assess static balance. For this purpose, the patient will be placed in monopodal support, placing the sole on the inside of the knee. The time reached, in seconds, without touching the group with the other foot will be recorded., At baseline|After intervention static monopodal balance, The one-leg stand test from the adults ALHPA battery will assess static balance after the intervention. For this purpose, the patient will be placed in monopodal support, placing the sole of the foot on the inside of the knee. The time reached, in seconds, without touching the group with the other foot will be recorded., Immediately after the intervention.|3 months after intervention static monopodal balance, The one-leg stand test from the adults ALHPA battery will assess static balance 3 months after the intervention. For this purpose, the patient will be placed in monopodal support, placing the sole on the inside of the knee. The time reached, in seconds, without touching the group with the other foot will be recorded., 3 months after the intervention ending|6 months after intervention static monopodal balance, The one-leg stand

test from the adults ALHPA battery will assess static balance 6 months after the intervention. For this purpose, the patient will be placed in monopodal support, placing the sole of the foot on the inside of the knee. The time reached, in seconds, without touching the group with the other foot will be recorded, 6 months after the intervention ending|Baseline measurement of upper body flexibility, Flexibility will be assessed using the Back scratch test, previously used in breast cancer patients and belonging to the Senior Fitness Test battery. During the test, participants will stand upright and try to reach over their head, with their arm in flexion and external rotation, to touch their other hand, which will be placed on their back in a supine position with the arm flexed. The centimeters left or passed from one hand to the other will be noted., At baseline|After intervention measurement of upper body flexibility, Flexibility after the intervention will be assessed using the Back scratch test, previously used in breast cancer patients and belonging to the Senior Fitness Test battery. During the test, participants will stand upright and try to reach over their head, with their arm in flexion and external rotation, to touch their other hand, which will be placed on their back in a supine position with the arm flexed. The centimeters left or passed from one hand to the other will be noted., Immediately after the intervention.|3 months after intervention measurement of upper body flexibility, Flexibility 3 months after the intervention will be assessed using the Back scratch test, previously used in breast cancer patients and belonging to the Senior Fitness Test battery. During the test, participants will stand upright and try to reach over their head, with their arm in flexion and external rotation, to touch their other hand, which will be placed on their back in a supine position with the arm flexed. The centimeters left or passed from one hand to the other will be noted., 3 months after the intervention ending|6 months after intervention measurement of upper body flexibility, Flexibility 6 months after the intervention will be assessed using the Back scratch test, previously used in breast cancer patients and belonging to the Senior Fitness Test battery. During the test, participants will stand upright and try to reach over their head, with their arm in flexion and external rotation, to touch their other hand, which will be placed on their back in a supine position with the arm flexed. The centimeters left or passed from one hand to the other will be noted., 6 months after the intervention ending| Baseline measurement of lower body flexibility, Hamstring flexibility will be measured using the V Sit and Reach test where the participant will be seated on the floor with knees fully extended and feet 30 cm apart. A tape measure will be placed on the floor, equidistant between the feet, placing the 0 cm in line with the heels. Pressing the palms of the hands together and keeping the elbows fully extended, the participants shall bend their trunk as far as possible over the tape measure. The results will be expressed in centimeters reporting the distance left or passed from the feet., At baseline|After intervention measurement of lower body flexibility, Hamstring flexibility after the intervention will be measured using the V Sit and Reach test where the

participant will be seated on the floor with knees fully extended and feet 30 cm apart. A tape measure will be placed on the floor, equidistant between the feet, placing the 0 cm in line with the heels. Pressing the palms of the hands together and keeping the elbows fully extended, the participants shall bend their trunk as far as possible over the tape measure. The results will be expressed in centimeters reporting the distance left or passed from the feet., Immediately after the intervention.|3 months after intervention measurement of lower body flexibility, Hamstring flexibility 3 months after the intervention will be measured using the V Sit and Reach test where the participant will be seated on the floor with knees fully extended and feet 30 cm apart. A tape measure will be placed on the floor, equidistant between the feet, placing the 0 cm in line with the heels. Pressing the palms of the hands together and keeping the elbows fully extended, the participants shall bend their trunk as far as possible over the tape measure. The results will be expressed in centimeters reporting the distance left or passed from the feet., 3 months after the intervention ending|6 months after intervention measurement of lower body flexibility, Hamstring flexibility 6 months after the intervention will be measured using the V Sit and Reach test where the participant will be seated on the floor with knees fully extended and feet 30 cm apart. A tape measure will be placed on the floor, equidistant between the feet, placing the 0 cm in line with the heels. Pressing the palms of the hands together and keeping the elbows fully extended, the participants shall bend their trunk as far as possible over the tape measure. The results will be expressed in centimeters reporting the distance left or passed from the feet., 6 months after the intervention ending|Baseline health-related quality of life measure, Psychological variables will be assessed employing self-administered questionnaires specifically validated for cancer patients. Health-related quality of life will be assessed using the EORTC QLQ-C30 Quality of Life Questionnaire which includes functional and cancer-specific symptom assessment. Higher global scores will mean a higher quality of life., At baseline|After intervention health-related quality of life measure, Psychological variables will be assessed employing self-administered questionnaires specifically validated for cancer patients. Health-related quality of life will be assessed using the EORTC QLQ-C30 Quality of Life Questionnaire which includes functional and cancer-specific symptom assessment. Higher global scores will mean a higher quality of life., Immediately after the intervention.|3 months after intervention health-related quality of life measure, Psychological variables will be assessed utilizing self-administered questionnaires specifically validated for cancer patients. Health-related quality of life will be assessed 3 months after the intervention using the EORTC QLQ-C30 Quality of Life Questionnaire which includes functional and cancer-specific symptom assessment. Higher global scores will mean a higher quality of life., 3 months after the intervention ending|6 months after intervention health-related quality of life measure, Psychological variables will be assessed through self-administered questionnaires specifically

validated for cancer patients. Health-related quality of life 6 months after the intervention will be assessed using the EORTC QLQ-C30 Quality of Life Questionnaire which includes functional and cancer-specific symptom assessment. Higher global scores will mean a higher quality of life., 6 months after the intervention ending|Baseline cancer-related fatigue, To assess cancer-related fatigue, the FACT-F questionnaire will be employed. It includes 13 items where patients will select their fatigue perception with a Likert scale from 1 to 5 being 1 the lowest fatigue score and 5 the highest., At baseline|After intervention cancer-related fatigue, To assess cancer-related fatigue after the intervention, the FACT-F questionnaire will be employed. It includes 13 items where patients will select their fatigue perception with a Likert scale from 1 to 5 being 1 the lowest fatigue score and 5 the highest., Immediately after the intervention.|3 months after intervention cancer-related fatigue, To assess cancer-related fatigue 3 months after the intervention, the FACT-F questionnaire will be employed. It includes 13 items where patients will select their fatigue perception with a Likert scale from 1 to 5 being 1 the lowest fatigue score and 5 the highest., 3 months after the intervention ending|6 months after intervention cancer-related fatigue, To assess cancer-related fatigue 6 months after the intervention, the FACT-F questionnaire will be employed. It includes 13 items where patients will select their fatigue perception with a Likert scale from 1 to 5 being 1 the lowest fatigue score and 5 the highest., 6 months after the intervention ending|Baseline life satisfaction measure, Life satisfaction will be assessed using the Satisfaction With Life Scale (SWLS) questionnaire. The scale is composed of 5 items to score with a Likert scale from 1 (strongly disagree) to 5 (strongly agree)., At baseline|After intervention life satisfaction measure, Life satisfaction after the intervention will be assessed using the Satisfaction With Life Scale (SWLS) questionnaire. The scale is composed of 5 items to score with a Likert scale from 1 (strongly disagree) to 5 (strongly agree)., Immediately after the intervention.|3 months after intervention life satisfaction measure, Life satisfaction 3 months after the intervention will be assessed using the Satisfaction With Life Scale (SWLS) questionnaire. The scale is composed of 5 items to score with a Likert scale from 1 (strongly disagree) to 5 (strongly agree)., 3 months after the intervention ending|6 months after intervention life satisfaction measure, Life satisfaction 6 months after the intervention will be assessed using the Satisfaction With Life Scale (SWLS) questionnaire. The scale is composed of 5 items to score with a Likert scale from 1 (strongly disagree) to 5 (strongly agree)., 6 months after the intervention ending|Baseline self-esteem, Patients' level of self-esteem will be assessed using the Rosenberg Self-Esteem Scale which includes 10 items. Participants will have to score each item with a Likert scale from 1 (strongly disagree) to 4 (strongly agree)., At baseline|After intervention self-esteem, Patients' level of self-esteem will be assessed after intervention using the Rosenberg Self-Esteem Scale which includes 10 items. Participants will have to score each item

with a Likert scale from 1 (strongly disagree) to 4 (strongly agree)., Immediately after the intervention.|3 months after intervention self-esteem measure, Patients' level of self-esteem will be assessed 3 months after the intervention using the Rosenberg Self-Esteem Scale which includes 10 items. Participants will have to score each item with a Likert scale from 1 (strongly disagree) to 4 (strongly agree)., 3 months after the intervention ending|6 months after intervention self-esteem measure, Patients' level of self-esteem will be assessed 6 months after the intervention using the Rosenberg Self-Esteem Scale which includes 10 items. Participants will have to score each item with a Likert scale from 1 (strongly disagree) to 4 (strongly agree)., 6 months after the intervention ending|Baseline anxiety and depression perception measure, Anxiety and depression will be evaluated by the HAD Scale (Hospital Anxiety and Depression Scale). It is composed of 14 items and participants will have to choose one from 4 options to select the affirmation which better corresponds to their perception., At baseline|After intervention anxiety and depression perception measure, Anxiety and depression will be evaluated after intervention by the HAD Scale (Hospital Anxiety and Depression Scale). It is composed by 14 items and participants will have to choose one from 4 options to select the affirmation which better corresponds to their perception., Immediately after the intervention.|3 months after intervention anxiety and depression perception measure, Anxiety and depression will be evaluated 3 months after the intervention by the HAD Scale (Hospital Anxiety and Depression Scale). It is composed of 14 items and participants will have to choose one from 4 options to select the affirmation which better corresponds to their perception., 3 months after the intervention ending|6 months after intervention anxiety and depression perception measure, Anxiety and depression will be evaluated 6 months after the intervention by the HAD Scale (Hospital Anxiety and Depression Scale). It is composed of 14 items and participants will have to choose one from 4 options to select the affirmation which better corresponds to their perception., 6 months after the intervention ending|Baseline Shoulder disability perception measure, For the assessment of their perception of disability due to shoulder mobility, the Quick DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire will be used. It is an 11- item self-administered survey referenced over 7 days prior to administration., At baseline|After intervention shoulder disability perception measure, For the assessment of their perception of disability due to shoulder mobility, the Quick DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire will be used after the intervention. It is an 11- item self-administered survey referenced over 7 days prior to administration., Immediately after the intervention.|3 months after the intervention shoulder disability perception measure, For the assessment of their perception of disability due to shoulder mobility, the Quick DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire will be used 3 months after the intervention. It is an 11- item self-administered survey referenced over 7 days prior to administration., 3 months after the intervention ending|6 months after

the intervention shoulder disability perception measure, For the assessment of their perception of disability due to shoulder mobility, the Quick DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire will be used 6 months after the intervention. It is an 11- item self-administered survey referenced over 7 days prior to administration., 6 months after the intervention ending|Baseline physical activity level measure, The International Physical Activity Questionnaire will be administered to assess the physical activity level of patients before starting the exercise programme. Participants will report the activity performed during the prior 7 days specifying the time spent in each type of physical activity., At baseline|After intervention physical activity level measure, The International Physical Activity Questionnaire will be administered to assess the physical activity level of patients after the end of the programme. Participants will report the activity performed during the prior 7 days specifying the time spent in each type of physical activity., Immediately after the intervention.|3 months after intervention physical activity level measure, The International Physical Activity Questionnaire will be administered to assess the physical activity level of patients after 3 months of the end of the programme. Participants will report the activity performed during the prior 7 days specifying the time spent in each type of physical activity., 3 months after the intervention ending|6 months after intervention physical activity level measure, The International Physical Activity Questionnaire will be administered to assess the physical activity level of patients after 6 months of the end of the programme. Participants will report the activity performed during the prior 7 days specifying the time spent in each type of physical activity., 6 months after the intervention ending|Baseline exercise motivation, The existence or not of behavioural change/motivation towards exercise will be assessed before the intervention by using the Behaviour Regulation in Physical Exercise Scale (BREQ-2). The BREQ-2 is a 19 item questionnaire that measures the stages of the self-determination continuum concerning motivation to exercise with a 5 point Likert scale (0=not true for me, 4=very true for me)., At baseline|After intervention exercise motivation, The existence or not of behavioural change/motivation towards exercise will be assessed after the intervention by using the Behaviour Regulation in Physical Exercise Scale (BREQ-2). The BREQ-2 is a 19 item questionnaire that measures the stages of the self-determination continuum concerning motivation to exercise with a 5 point Likert scale (0=not true for me, 4=very true for me)., Immediately after the intervention.|3 months after intervention exercise motivation, The existence or not of behavioural change/motivation towards exercise will be assessed 3 months after the intervention by using the Behaviour Regulation in Physical Exercise Scale (BREQ-2). The BREQ-2 is a 19 item questionnaire that measures the stages of the self-determination continuum concerning motivation to exercise with a 5 point Likert scale (0=not true for me, 4=very true for me)., 3 months after the intervention ending|6 months after intervention exercise motivation, The existence or not of behavioural

change/motivation towards exercise will be assessed 6 months after the intervention by using the Behaviour Regulation in Physical Exercise Scale (BREQ-2). The BREQ-2 is a 19 item questionnaire that measures the stages of the self-determination continuum concerning motivation to exercise with a 5 point Likert scale (0=not true for me, 4=very true for me)., 6 months after the intervention ending|Baseline kinesiophobia, Fear of movement will be measured before intervention by using the Tampa Kinesiophobia Scale. The scale is composed by 17 items that include two subscales, one measures activity avoidance and the other one somatic focus. The total score of the scale range from 17- 68, where 17 means no kinesiophobia, 68 means severe kinesiophobia., At baseline|After intervention kinesiophobia, Fear of movement will be measured after the intervention by using the Tampa Kinesiophobia Scale. The scale is composed of 17 items that include two subscales, one measures activity avoidance and the other one somatic focus. The total score of the scale range from 17- 68, where 17 means no kinesiophobia, 68 means severe kinesiophobia., Immediately after the intervention.|3 months after intervention kinesiophobia, Fear of movement will be measured 3 months after the intervention by using the Tampa Kinesiophobia Scale. The scale is composed of 17 items that include two subscales, one measures activity avoidance and the other one somatic focus. The total score of the scale range from 17- 68, where 17 means no kinesiophobia, 68 means severe kinesiophobia., 3 months after the intervention ending|6 months after intervention kinesiophobia, Fear of movement will be measured 6 months after the intervention by using the Tampa Kinesiophobia Scale. The scale is composed of 17 items that include two subscales, one measures activity avoidance and the other one somatic focus. The total score of the scale range from 17- 68, where 17 means no kinesiophobia, 68 means severe kinesiophobia., 6 months after the intervention ending
Other Outcome Measures:
Sponsor: GO fit Lab- Ingesport
Collaborators: Marqués de Valdecilla University Hospital|Center for Sport Studies, Rey Juan Carlos University
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 90
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: CARDIEJERCAN
Start Date: 2021-09-13
Primary Completion Date: 2022-07-30
Completion Date: 2022-09-20
First Posted: 2021-09-10
Results First Posted:
Last Update Posted: 2021-09-10

Locations: GOfit, Santander, Cantabria, 39011, Spain
Study Documents:

NCT Number: NCT04892667
Study Title: Early Detection of Patients at Risk of Developing Anthracycline Cardiotoxicity With TEP/CT -FDG
Study URL: https://beta.clinicaltrials.gov/study/NCT04892667
Acronym: DETECT
Study Status: RECRUITING
Brief Summary: Management of patients with lymphoma is based on the administration of a chemotherapy containing anthracyclines (ATC), and allows cure rates of 65% to 80% at 5 years. The administration of ATCs can lead to an increase in the risk of the Left Ventricular Systolic dysfunction (LVSD) which ranges from 6 to 15% at 1 year, and of heart failure from which impact at 3.5 years can reach 5%. The major issue in the management of this toxicity is the early identification of this population for monitoring and prevention. No pharmacological intervention strategy is currently recommended.

According to the recommendations of the European Society of Cardiology, this identification is based on the measurement of the left ventricular ejection fraction (LVEF) and the overall longitudinal strain (SLG) before and after the last administration of ATC (at D84 or D126, depending on the duration of the chemotherapy protocol). Recent studies have evaluated the diagnostic performance of earlier strategies highlighting the benefit of SLG measured after 150 mg / m2 of ATC (D42). However, the tools are lacking to detect these patients as close as possible to the onset of ATC, a necessary condition for effective secondary prevention. The hypothesis is that an early assessment of myocardial binding of 18F-FDG, analyzed during the first routine PET / CT scan as part of the assessment of the response to chemotherapy (D42) should verify a population at risk of developing LVSD at 1 year.
Study Results: NO
Conditions: Lymphoma, Non-Hodgkin|Lymphoma, Hodgkin
Interventions: OTHER: intervention
Primary Outcome Measures: Evaluation of the cardiac uptake of 18F-FDG, Evaluation of the cardiac uptake of 18F-FDG measured on Day 42 of the administration of ATCs to identify at 1 year the patients at risk of occurrence of a LVSD defined by a drop of more than 10 units of the LVEF and LVEF \<53%., Day 42
Secondary Outcome Measures: Evaluate with the echocardiography performed at the end of chemotherapy the sensitivity, specificity, the negative predictive value and the positive predictive value of the SLG change (difference of, SLG change is defined as: difference in SLG measured prior to chemotherapy administration and at the end of chemotherapy (Day 84 or Day 126 depending on the chemotherapy protocol) ., Day 84 and Day 126|Compare PET/CT sensitivities at Day 42 and SLG variation between the start and the end of chemotherapy administration (Day 84 or Day 126 depending on the chemotherapy

protocol) to identify patients at risk of LVSD at 1 year., Day 42|Search for an intensity threshold in Standard Uptake Value (SUV)) of global 18F-FDG uptake to predict the occurrence of LVSD at 1 year., 1 year|Evaluate the concordance between the result of the 18F-FDG cardiac uptake performed at Day 42 assessed by the investigator and the result obtained at the centralized review., Day 42
Other Outcome Measures:
Sponsor: Assistance Publique - Hôpitaux de Paris
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 484
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: APHP191102|IDRCB 2020-A01971-38
Start Date: 2022-04-01
Primary Completion Date: 2023-12
Completion Date: 2024-10
First Posted: 2021-05-19
Results First Posted:
Last Update Posted: 2022-11-25
Locations: Cardiology department, Paris, 75012, France
Study Documents:

NCT Number: NCT01253590
Study Title: Cardiac Monitoring of Post-Operative Cancer Patients Experiencing Atrial Fibrillation
Study URL: https://beta.clinicaltrials.gov/study/NCT01253590
Acronym:
Study Status: TERMINATED
Brief Summary: The purpose of this study is to assess whether it is possible and acceptable to monitor patients at a distance who experience a condition called atrial fibrillation after their cancer surgery. Some patients have no other clinical reason for staying in the hospital after cancer surgery except in order to control their heart rhythm. Being able to send these patients home earlier and monitor them at a distance from their home can be good for their quick recovery. Studies have shown greater quality of life and patient satisfaction when patients are monitored at a distance for conditions like atrial fibrillation, however cancer patients have not been studied.
Study Results: NO
Conditions: Post-Operative Cancer Patients Experiencing Atrial|Fibrillation
Interventions: BEHAVIORAL: questionnaire about the use of ECG device
Primary Outcome Measures: Assess the feasibility and acceptance of continuous remote cardiac monitoring, In post-operative patients with

respect to recurrence of post-operative atrial fibrillation upon discharge., 4 to 6 weeks
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 5
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 10-213
Start Date: 2010-12
Primary Completion Date: 2011-11
Completion Date: 2011-11
First Posted: 2010-12-03
Results First Posted:
Last Update Posted: 2015-03-06
Locations: Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States
Study Documents:

NCT Number: NCT05110690
Study Title: Behavioral Activation and Medication Optimization for Perioperative Mental Health
Study URL: https://beta.clinicaltrials.gov/study/NCT05110690
Acronym:
Study Status: COMPLETED
Brief Summary: Inadequate management of preoperative mental health disorders often contributes to poor postoperative outcomes, including increased rates of readmission, delirium, falls, and mortality. However, very little work has been done to improve perioperative mental health. In particular, there have been limited systematic efforts that identify evidence-based behavioral and pharmacological strategies that were originally developed for depression and anxiety in otherwise medically well psychiatric patients. A mental health intervention bundle, composed of behavioral and pharmacological strategies, can mitigate anxiety and depression symptoms during the perioperative period. However, lacking is conclusive evidence on effectiveness of such an intervention bundle focused on the delivery of perioperative mental health care in older surgical patients. Towards this end, the investigators will develop and test an intervention bundle that encompasses: (1) behavioral activation, and (2) medication optimization.
Study Results: NO
Conditions: Older Adults|Anxiety|Depression|Cardiac Surgery|Orthopedic Surgery|Major Surgical Resection of a Thoracic Malignancy|Major Surgical Resection of an Abdominal Malignancy

Interventions: BEHAVIORAL: Behavioral Activation|OTHER: Medication Optimization
Primary Outcome Measures: Reach of the study as measured by the number of participants who agree to participate in the study out of the total eligible participants, Completion of the study (estimated to be 27 months)|Reach of the intervention bundle as measured by the number of participants who completed the interventions out of the participants who agreed to participate in the trial, Completion of the study (estimated to be 27 months)
Secondary Outcome Measures: Completeness of planned primary outcome data collection at specified timepoints, Completion of study (estimated to be 27 months)
Other Outcome Measures:
Sponsor: Washington University School of Medicine
Collaborators: National Institute of Mental Health (NIMH)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 29
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 202101103|1P50MH122351
Start Date: 2021-11-17
Primary Completion Date: 2023-01-06
Completion Date: 2023-01-06
First Posted: 2021-11-08
Results First Posted:
Last Update Posted: 2023-01-10
Locations: Washington University School of Medicine, Saint Louis, Missouri, 63110, United States
Study Documents:

NCT Number: NCT02971397
Study Title: Cytarabine and Daunorubicin Hydrochloride in Treating Patients With Newly Diagnosed Acute Myeloid Leukemia
Study URL: https://beta.clinicaltrials.gov/study/NCT02971397
Acronym:
Study Status: UNKNOWN
Brief Summary: This pilot clinical trial studies the side effects of cytarabine and daunorubicin hydrochloride and to see how well they work in treating patients with newly diagnosed acute myeloid leukemia. Drugs used in chemotherapy, such as cytarabine and daunorubicin hydrochloride, work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading, and may be safer for the heart.
Study Results: NO
Conditions: Acute Myeloid Leukemia
Interventions: PROCEDURE: Bone Marrow Aspiration and Biopsy|DRUG:

Cytarabine|DRUG: Daunorubicin Hydrochloride|OTHER: Laboratory Biomarker Analysis
Primary Outcome Measures: Change in incidence of cardiac toxicity, defined as reduction in LVEF of >= 10% compared to baseline LVEF and EF =< 50% on the follow-up scan, assessed using MRI, In addition to point estimates of these rates, 95% confidence intervals will be calculated., Baseline up to 3 months after last dose of study drug|Incidence of other unexpected toxicities, measured by Common Terminology Criteria for Adverse Events version 4.0, In addition to point estimates of these rates, 95% confidence intervals will be calculated., Up to 6 months after last dose of study drug|Proportion of patients who complete the infusion therapy, Will report these proportions with 95% confidence intervals., Up to 4 months|Proportion of patients with study-related deviations, Will report these proportions with 95% confidence intervals., Up to 2 years|Change in incidence of cardiac toxicity, defined as reduction in LVEF of >= 10% compared to baseline LVEF and EF =< 50% on the follow-up scan, assessed using ECHO, In addition to point estimates of these rates, 95% confidence intervals will be calculated., Baseline up to 3 months after last dose of study drug
Secondary Outcome Measures: Change in EF, assessed by MRI and ECHO, Will determine the correlation between ECHO and MRI assessments performed pre-chemotherapy. Will assess correlations between post-chemotherapy ECHO and MRI assessments. Will assess correlations between each of the time points. Paired t-tests will be performed to compare the actual values of each ECHO/MRI measurement to each other at each time point. Bland-Altman plots will be generated at baseline, follow-up and using the change in measure for each of the MRI/ECHO derived measures., Baseline up to 6 months after last dose of study drug|Change in incidence of cardiac toxicity, defined as reduction in LVEF of >= 10% compared to baseline LVEF and EF =< 50% on the follow-up scan, assessed using MRI and ECHO, Will determine the correlation between ECHO and MRI assessments performed pre-chemotherapy. Will assess correlations between post-chemotherapy ECHO and MRI assessments. Will assess correlations between each of the time points. Paired t-tests will be performed to compare the actual values of each ECHO/MRI measurement to each other at each time point. Bland-Altman plots will be generated at baseline, follow-up and using the change in measure for each of the MRI/ECHO derived measures., Baseline up to 6 months after last dose of study drug|Change in left ventricular end diastolic volume, assessed by MRI and ECHO, Will determine the correlation between ECHO and MRI assessments performed pre-chemotherapy. Will assess correlations between post-chemotherapy ECHO and MRI assessments. Will assess correlations between each of the time points. Paired t-tests will be performed to compare the actual values of each ECHO/MRI measurement to each other at each time point. Bland-Altman plots will be generated at baseline, follow-up and using the change in measure for each of the MRI/ECHO derived measures., Baseline up to 6 months after last dose of study drug|Change in left ventricular end systolic volume, assessed by MRI and ECHO, Will

determine the correlation between ECHO and MRI assessments performed pre-chemotherapy. Will assess correlations between post-chemotherapy ECHO and MRI assessments. Will assess correlations between each of the time points. Paired t-tests will be performed to compare the actual values of each ECHO/MRI measurement to each other at each time point. Bland-Altman plots will be generated at baseline, follow-up and using the change in measure for each of the MRI/ECHO derived measures., Baseline up to 6 months after last dose of study drug|Change in myocardial strain, assessed by MRI and ECHO, Will determine the correlation between ECHO and MRI assessments performed pre-chemotherapy. Will assess correlations between post-chemotherapy ECHO and MRI assessments. Will assess correlations between each of the time points. Paired t-tests will be performed to compare the actual values of each ECHO/MRI measurement to each other at each time point. Bland-Altman plots will be generated at baseline, follow-up and using the change in measure for each of the MRI/ECHO derived measures., Baseline up to 6 months after last dose of study drug|Disease-free survival for those patients who achieve remission, From the date of CR until relapse from CR or death, assessed for up to 2 years|Induction death rate, Up to 28 days|Overall response rate, defined as CR + CRi, Up to 2 years
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: IRB00040792|NCI-2016-01464|CCCWFU 22616|P30CA012197
Start Date: 2016-11
Primary Completion Date: 2018-03
Completion Date: 2020-03
First Posted: 2016-11-23
Results First Posted:
Last Update Posted: 2018-11-02
Locations: Comprehensive Cancer Center of Wake Forest University, Winston-Salem, North Carolina, 27157, United States
Study Documents:

NCT Number: NCT04630743
Study Title: Cognitive and Behavioral Intervention for the Management of Episodic Breathlessness in Patients With Advanced Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT04630743
Acronym: CoBeMEB
Study Status: COMPLETED
Brief Summary: Episodic breathlessness is a common and distressing

symptom in patients with advanced disease such as cancer, chronic obstructive pulmonary disease (COPD) and chronic heart failure. Since the short duration of the majority of breathless episodes limits the effectiveness of pharmacological interventions (e.g. opioids), non-pharmacological management strategies play a major role. As non-pharmacological strategies patients use, for example, cognitive and behavioural methods such as breathing or relaxation techniques.

The aim of the study is to test a brief cognitive and behavioural intervention for an improved management of episodic breathlessness. Initially, a Delphi procedure with international experts has been used to develop the brief intervention consisting of various non-pharmacological strategies to enhance the management of breathless episodes.

In the single-arm therapeutic exploratory trial (phase II), the feasibility and potential effects of the brief intervention, such as patient-reported breathlessness mastery, episodic breathlessness characteristics, quality of life, symptom burden, caregivers' burden, and breathlessness in general will be examined. The results of the study form the basis for planning and implementing a subsequent confirmatory randomized control trial (phase III).
Study Results: NO
Conditions: Dyspnea|Respiratory Insufficiency|Neoplasms|Pulmonary Disease, Chronic Obstructive|Lung Diseases|Heart Failure|Lung Diseases, Interstitial|Palliative Care|Palliative Medicine|Breathlessness
Interventions: BEHAVIORAL: Cognitive and Behavioral intervention for the Management of Episodic Breathlessness
Primary Outcome Measures: Enrollment rate (Feasibility), Ratio of patients screened and patients that signed informed consent, week 6|Study completion rate (Feasibility), Ratio of patients who signed the informed consent and filled out the final assessment, week 6|Drop Outs (Feasibility), Withdrawal from the study at specific date (e.g. Intervention, refresher, Outcome at week 2/4/6), week 6
Secondary Outcome Measures: Occurence of side-effects due to the brief cognitive and behavioral Intervention (Safety), closed-ended question (yes/no), week 6|Occurence of adverse events due to the brief cognitive and behavioral Intervention (Safety), closed-ended Question (yes/no), week 6|Occurence of adverse events due to the study procedure (Safety), closed-ended Question (yes/no), week 6|Satisfaction with the brief cognitive and behavioral intervention (Acceptability), closed-ended Questions, week 6|Patients' experience with the Intervention and study procedure, qualitative interview, week 6|Potential effects of the brief cognitive and behavioral Intervention on Depression, Hospital Anxiety and Depression Scale: the Depression Subscale (the higher the score, the worse the outcome), week 2, 4 and 6|Potential effects of the brief cognitive and behavioral Intervention on Anxiety, Hospital Anxiety and Depression Scale: the Anxiety Subscale (the higher the score, the worse the outcome), week 2, 4 and

6|Potential effects of the brief cognitive and behavioral Intervention on breathlessness mastery, Mastery Domain of the Chronic Respiratory Questionnaire (the higher the score, the better the outcome), week 2, 4 and 6|Potential effects of the brief cognitive and behavioral Intervention on Quality of Life, Chronic Respiratory Questionnaire (the higher the score, the better the outcome), week 2, 4 and 6| Potential effects of the brief cognitive and behavioral Intervention on Palliative Care needs, Integrated Palliative Care Outcome Scale (the higher the score, the worse the outcome), week 2, 4 and 6| Potential effects of the brief cognitive and behavioral Intervention on catastrophizing thoughts concerning dyspnea, Dyspnea catastrophizing scale (the higher the score, the worse the outcome), week 2, 4 and 6|Informal caregivers' burdens while caring for breathlessness patients, Zarid Burden Interview (the higher the score, the worse the Outcome), week 2, 4 and 6|Informal caregivers' experience with Intervention and study procedure, qualitative interview, week 6
Other Outcome Measures:
Sponsor: University of Cologne
Collaborators: University Hospital of Cologne|Bethanien Krankenhaus gGmbH
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 49
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: OTHER
Other IDs: Uni-Koeln-0917
Start Date: 2019-02-09
Primary Completion Date: 2020-03-01
Completion Date: 2020-03-15
First Posted: 2020-11-16
Results First Posted:
Last Update Posted: 2020-11-16
Locations: University Hospital of Cologne, Cologne, NRW, 50937, Germany
Study Documents:

NCT Number: NCT02275143
Study Title: Computed Tomography (CT) Coronary Angiogram Evaluation in Cancer Patients Having CT Thorax, Abdomen and Pelvis
Study URL: https://beta.clinicaltrials.gov/study/NCT02275143
Acronym:
Study Status: COMPLETED
Brief Summary: Currently patients with certain cancer usually have routine follow up (Computed Tomography of Thorax, Abdomen and Pelvis) CT TAP scans to see response to treatment or relapse. The study proposal allows the evaluation of the coronary arteries by modifying

the current CT TAP technique without significant additional procedures, intravenous contrast or radiation - i.e. an opportunistic Computed Tomography Coronary Angiogram (CTCA) without any penalty. The question is does performing Computed Tomography (CT) of the thorax in such a way confer important additional information about cardiac risk? At the same time the investigators need to ensure that doing scan as per CTCA protocol produces equivalent image quality to evaluate other structures in the chest. A recent small retrospective study has using a similar technique suggests that it may in fact improve image quality due to less cardiac related motion artefact.
Study Results: NO
Conditions: Coronary Stenosis
Interventions: RADIATION: CT TAP Scan
Primary Outcome Measures: Objective Image quality analysis, Calculating image noise as measured by standard deviation (SD) in a region of interest., 20 minutes|Objective Image quality analysis, Calculating contrast-to-noise ratio (CNR), 20 minutes|Subjective Image quality analysis, All image data sets will be presented in blinded and randomized manner to two experienced consultant radiologists. Subjective image quality will be assessed in terms of subjective image noise, subjective image contrast, lesion conspicuity, diagnostic confidence and artefacts. The image quality attributes are taken from the European Guidelines on Quality Criteria for Computerized Tomography document and have been proven to be robust in comparing subjective image quality., 20 minutes
Secondary Outcome Measures: Dose estimation, The total exam dose-length product (DLP) displayed by the CT scanner at the end of each CTPA is recorded. The effective dose in mSv is calculated by multiplying the total DLP for each exam by the conversion coefficient for the chest of 0.014 (as taken from National Radiological Protection Board Document)., 20 minutes|Coronary segments analysis, Image quality of the 4 main coronary arteries (left main, left anterior descending, left circumflex, and right coronary artery) was determined based on a 4-point grading system - Non-diagnostic; Adequate; Good; Excellent., 20minutes
Other Outcome Measures:
Sponsor: University Hospital Plymouth NHS Trust
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 80
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 14/P/152
Start Date: 2015-10
Primary Completion Date: 2016-02
Completion Date: 2016-02
First Posted: 2014-10-27

Results First Posted:
Last Update Posted: 2016-05-24
Locations: Plymouth Hospitals NHS Trust (PHNT), Plymouth, Devon, PL6 8DH, United Kingdom
Study Documents:

NCT Number: NCT02696707
Study Title: An Integrated Consent Model Study to Compare Two Standard of Care Schedules for Monitoring Cardiac Function in Patients Receiving Trastuzumab for Early Stage Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02696707
Acronym: OTT 15-05
Study Status: COMPLETED
Brief Summary: Several large adjuvant trastuzumab trials have demonstrated improved overall survival, in participants with early stage breast cancer, with a 33% decrease in risk of death. However, retrospective analyses of participant outcomes in these trials have demonstrated increased risk of cardiotoxicity (i.e damage to the heart) in a small number of patients (4-8%).

At this time, investigators are unable to predict which participants are at increased risk of cardiac-related treatment complications. Currently all patients receive regular cardiac imaging throughout their one year of trastuzumab treatment.

At this time, the optimal monitoring schedule for trastuzumab-related cardiotoxicity remains unknown, and several published consensus guidelines are currently in use as "standard of care.
Study Results: NO
Conditions: Breast Cancer
Interventions: PROCEDURE: LVEF 3 month|PROCEDURE: LVEF 4 month
Primary Outcome Measures: LVEF results, Changes in LVEF results compared to baseline (by echocardiography or MUGA) throughout the course of trastuzumab based therapy, at year one
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Ottawa Hospital Research Institute
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: 20150777-01H
Start Date: 2016-06
Primary Completion Date: 2020-05
Completion Date: 2020-07

First Posted: 2016-03-02
Results First Posted:
Last Update Posted: 2021-03-03
Locations: The Ottawa Hospital, Ottawa, Ontario, K1H 8L6, Canada|The Ottawa Hospital Cancer Centre, Ottawa, Ontario, K2H 8L6, Canada
Study Documents:

NCT Number: NCT05094843
Study Title: The Cardiac Stress and Electrocardiographic Changes Caused by Lung Cancer Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT05094843
Acronym:
Study Status: RECRUITING
Brief Summary: Lung cancer surgery causes significant changes in the small circulation as well as changes in the intrathoracic anatomy. The effects of lung cancer surgery on electrocardiography and the cardiac stress associated with the procedures have not been previously extensively studied. The aim of the present study is to ascertain whether modern mini-invasive lung cancer surgery causes changes in the electrocardiogram, and whether these changes are transitory during short-term follow-up. Furthermore, the study aims to describe whether lung cancer surgery causes significant cardiac stress detectable by intraoperative electrocardiography.
Study Results: NO
Conditions: Lung Cancer|Surgery|Arrhythmia|Myocardial Ischemia
Interventions:
Primary Outcome Measures: Postoperative electrocardiographic p-, R-, and T-wave amplitude changes, Amplitude changes in the 12-lead rest electrocardiography in millimeters, analyzed daily postoperatively., 2 weeks|Postoperative QRS-duration, The duration of the QRS-complex in milliseconds in the electrocardiogram, measured daily postoperatively using 12-lead rest electrocardiogram., 2 weeks|Postoperative PQ-delay, Changes in the PQ-delay in milliseconds in the 12-lead rest electrocardiogram measured daily postoperatively., 2 weeks|Postoperative QT-interval, The duration of QT-interval in milliseconds in the 12-lead rest electrocardiogram measured daily postoperatively., 2 weeks|The postoperative incidence of new bundle branch blocks, New complete or partial bundle branch blocks, such as RBBB, in the 12-lead rest electrocardiogram., 2 weeks|Postoperative ST-level changes, ST-level changes in millimeters in the 12-lead rest electrocardiogram, 3 days|Postoperative P-wave, QRS-complex, and T-wave axle changes, The occurrence and type of P-wave, QRS-complex, and T-wave axle changes in the postoperative 12-lead rest electrocardiogram, 2 weeks|Postoperative heart rate, Postoperative heart rate variability in continuous electrocardiographic monitoring, 1 week|Postoperative arrhythmias, Arrhythmia rate as well as their type during the early postoperative period detected by continuous electrocardiogram monitoring, 1 week|Perioperative ST-level changes, The occurrence, duration (in minutes) as well as the magnitude (in millimeters) of perioperative ST-elevation or depression in the continuous

perioperative electrocardiographic monitoring., 1 day|Perioperative heart rate variability, Heart rate levels perioperatively in the continuous perioperative electrocardiographic monitoring., 1 day| Perioperative arrhythmias, The occurrence and type of perioperative arrhythmias, such as atrial fibrillation or flutter, or ventricular tachycardia in the perioperative electrocardiographic monitoring., 1 day|Perioperative R- and T-wave amplitude changes, The amplitude (in millimeters) of possible R- and T-wave amplitude changes in the perioperative electrocardiographic monitoring., 1 day
Secondary Outcome Measures: Postoperative air leak, The presence and duration of (in days) postoperative air leak, 1 week|Need for reoperation, Need for reoperation due to for example bleeding., 1 week
Other Outcome Measures:
Sponsor: Tampere University Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: R21087
Start Date: 2022-02-01
Primary Completion Date: 2028-12-31
Completion Date: 2028-12-31
First Posted: 2021-10-26
Results First Posted:
Last Update Posted: 2022-05-02
Locations: Heart Hospita, Tampere University Hospital, Tampere, Pirkanmaa, 33580, Finland
Study Documents:

NCT Number: NCT01554943
Study Title: Late Cardiac Evaluation of the Three Arm Belgian Trial Involving Node-positive Early Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT01554943
Acronym:
Study Status: COMPLETED
Brief Summary: Late Cardiac Evaluation of the Three Arm Belgian Trial
A phase III randomized trial involving node-positive early breast cancer patients with a long median follow-up (\~ 15 years)

OBJECTIFS

Primary:

• To compare the incidence of late cardiac events between anthracycline and non-anthracycline chemotherapy given to node-positive breast cancer patients in the Belgian three arm randomized

clinical trial

Secondary:

* To compare the late incidence of cardiac events between higher and lower dose anthracycline treated node-positive breast cancer patients;
* To compare anthracyclines (higher and lower doses) and non-anthracycline chemotherapy for:
* left ventricular diastolic function assessed by Echo
* exercise capacity assessed by 6-minute walk test (6MWT)
* cardiac morphology (myocardial inflammation or injury, fibrosis, LVEF) assessed by MRI
* serum cardiac biomarkers (BNP and TNT)
* patient-reported cardiac symptoms
* patient-reported cardiac symptoms assessed by QOL questionnaires are associated with subclinical findings on LVEF assessment
* cognitive function, functional autonomy, and psychological distress
Study Results: NO
Conditions: Breast Cancer
Interventions: OTHER: cardiac MRI
Primary Outcome Measures: Late cardiac toxicity, The primary objective of this study is to compare the incidence of cardiac events \[(defined as asymptomatic systolic dysfunction (LVEF \< 50%, asymptomatic NYHA I) or symptomatic heart failure NYHA class II-IV either by Echo and/or by clinical exam (LVEF \< 50% and heart failure symptoms)\] between anthracycline and non-anthracycline chemotherapy. Analysis of the primary endpoint will involve a comparison of the CMF-treated patients versus the pooled anthracycline treated patients (EC and HEC)., Exams will be performed only once, which will take place several years after the completion of chemotherapy (up to 15 years)
Secondary Outcome Measures: Late cardiac and cognitive toxicity, * To compare the late incidence of cardiac events between higher and lower dose anthracycline treated node-positive breast cancer patients;
* To compare anthracyclines (higher and lower doses) and non-anthracycline chemotherapy for: LVEF assessed by Echo; exercise capacity assessed by 6-minute walk test; cardiac morphology assessed by MRI; serum cardiac biomarkers; patient-reported cardiac symptoms assessed by QOL questionnaires; cognitive function, functional autonomy, and psychological distress, Exams will be performed only once, which will take place several years after the completion of chemotherapy (up to 15 years)
Other Outcome Measures:
Sponsor: Jules Bordet Institute
Collaborators: Centre Hospitalier Universitaire de Tivoli|Clinique Sainte Elisabeth|Centre Hospitalier Jolimont-Lobbes|Réseau Hospitalier Médecine Sociale d'Ath|Hôpital de Braine-l'Alleud
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 73

Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: CE1740
Start Date: 2010-07
Primary Completion Date: 2013-08
Completion Date: 2013-08
First Posted: 2012-03-15
Results First Posted:
Last Update Posted: 2013-08-30
Locations: Jules Bordet Institute, Brussels, 1000, Belgium
Study Documents:

NCT Number: NCT01044290
Study Title: Outlook Quality of Life Intervention Study
Study URL: https://beta.clinicaltrials.gov/study/NCT01044290
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine whether discussions of life story, forgiveness, and future goals improve quality of life for patients with serious illness.
Study Results: YES
Conditions: Cancer|Congestive Heart Failure (CHF)|Chronic Obstructive Pulmonary Disease (COPD)|End Stage Renal Disease (ESRD)
Interventions: OTHER: Life Completion|OTHER: Attention Control
Primary Outcome Measures: QUAL-E - Preparation Sub-scale, Quality Of Life At The End Of Life (the QUAL-E 2009) is a 31 item measure of quality of life at the end of life assessing five domains: life completion, relationship with health care providers, preparation for death, physical symptoms and affective social support. We include the 4-item preparation sub-scale as a primary outcomes measure. Individual items used a 5 point likert scale. The sub-scale minimum score was 5 and maximum was 20 with higher numbers indicating higher preparation., Baseline (n=75, 74, 72), 5 weeks (n=61, 59, 60) and 7 weeks (n=64, 56, 64)|QUAL-E Life Completion Sub-scale, Quality Of Life At The End Of Life (the QUAL-E 2009) is a 31 item measure of quality of life at the end of life assessing five domains: life completion, relationship with health care providers, preparation for death, physical symptoms and affective social support. We include the 7-item life completion sub-scale as a primary outcomes measure. Individual items used a 5 point likert scale. The sub-scale minimum score was 7 and maximum was 35 with higher scores indicating greater completion., Baseline (n=75, 74, 72), 5 weeks (n=61, 59, 60) and 7 weeks (n=64, 55, 64)
Secondary Outcome Measures: POMS Anxiety Sub-scale, The anxiety sub-scale from the modified Brief Profile of Mood States (POMS) is a 5-item measure of psychological distress.Items are on a 5-point likert scale with scoring ranging from 0-20. Higher scores indicate greater anxiety., Baseline (n=75, 74, 72), 5 weeks (n=61, 60, 60), 7 weeks (n=64, 57, 64)|CES-D, Center for Epidemiology Studies - Depression

Scale (CES-D) is a 10-item measure of depression. Items are rated on a 4 point likert scale with total scores ranging from 0-30. Higher scores indicate greater depressive symptoms., Baseline (n=75, 74, 72), 5 weeks (n=61, 60, 61) and 7 weeks (n=64, 57, 64)|FACIT-SP, The Functional Assessment of Chronic Illness Therapy- Spiritual Well-being Scale (Facit-SP) is a 12-item measure of faith, meaning and purpose, with a range of 0 to 48. Higher scores indicate greater spiritual well-being., Baseline (n=75, 74, 72), 5 weeks (61, 59, 60) and 7 weeks (64, 56, 63)|FACT-G - Social Sub-scale, Functional assessment of Cancer Therapy-General) is a 27 item survey which assesses physical, social/family, emotional, and functional well being. This sub-scale assesses social well-being. We omitted an item assessing satisfaction with sex life, due to high missing data. Items are rated on a 5 point likert scale, with 0 indicating "not at all" and 4 indicating, "very much" in response to item questions. Total sub-scale range is 0 to 30, with higher scores indicating better well-being., Baseline (n=75, 74, 72), 5 weeks (n=61, 60, 61) and 7 weeks (64, 57, 64)
Other Outcome Measures:
Sponsor: VA Office of Research and Development
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 221
Funder Type: FED
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IIR 10-050
Start Date: 2011-01
Primary Completion Date: 2014-02
Completion Date: 2014-04
First Posted: 2010-01-07
Results First Posted: 2015-02-23
Last Update Posted: 2015-11-20
Locations: Durham VA Medical Center HSR&D COE, Durham, North Carolina, 27705, United States
Study Documents:

NCT Number: NCT00955890
Study Title: Dexrazoxane as a Protective Agent in Anthracycline Treated Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00955890
Acronym: cardioprotec
Study Status: TERMINATED
Brief Summary: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Chemoprotective drugs, such as dexrazoxane, may protect normal cells from the side effects of chemotherapy. Monoclonal antibodies such as trastuzumab can locate tumor cells and either kill them or deliver tumor-killing

substances to them without harming normal cells. Radiation therapy uses high-energy x-rays to damage tumor cells. CTnT/cTnI/ANP/BNP were proved to be used as a biomarker of drug related cardiotoxicity. There are excellent correlations between the total cumulative dose of doxorubicin, the severity of the resulting cardiomyopathy, and the level of serum troponin-T.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Dexrazoxane hydrochloride|DRUG: Dexrazoxane hydrochloride
Primary Outcome Measures: Occurence of cardiac toxicity in patients with breast cancer receiving anthracycline chemotherapy, 1 year
Secondary Outcome Measures: Relationship between serum level of cTnT/cTnI/ANP/BNP and cardiac toxicity, 1 year
Other Outcome Measures:
Sponsor: Fudan University
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 12
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: MBC0901 FUCH
Start Date: 2009-06
Primary Completion Date: 2012-02
Completion Date: 2012-02
First Posted: 2009-08-10
Results First Posted:
Last Update Posted: 2012-02-28
Locations: Fudan University Cancer Hospital, Shanghai, Shanghai, 200032, China
Study Documents:

NCT Number: NCT00710697
Study Title: Cardiac Safety Assessment Study of Picoplatin in Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT00710697
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to investigate what effects, if any, picoplatin has on the heart rhythm.
Study Results: NO
Conditions: Solid Tumors
Interventions: DRUG: Picoplatin
Primary Outcome Measures: ECG interval change, 24 hours
Secondary Outcome Measures: Safety/Efficacy, 24 hours
Other Outcome Measures:

Sponsor: Poniard Pharmaceuticals
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 40
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 0701
Start Date: 2008-06
Primary Completion Date: 2009-03
Completion Date: 2009-07
First Posted: 2008-07-04
Results First Posted:
Last Update Posted: 2009-09-24
Locations: Premiere Oncology of Arizona, Scottsdale, Arizona, 85258, United States|Moores UCSD Cancer Center, La Jolla, California, 92093, United States|Premiere Oncology, Santa Monica, California, 90404, United States|Georgia Cancer Specialists, Atlanta, Georgia, 30341, United States|UNM Cancer Center, Albuquerque, New Mexico, 87131, United States|Swedish Cancer Institute, Seattle, Washington, 98104, United States|Northwest Medical Specialities, Tacoma, Washington, 98405, United States
Study Documents:

NCT Number: NCT03450590
Study Title: Heart Rate Variability and Cardiorespiratory Complications During Ophthalmic Arterial Chemotherapy for Retinoblastoma
Study URL: https://beta.clinicaltrials.gov/study/NCT03450590
Acronym:
Study Status: COMPLETED
Brief Summary: A patient undergoing ophthalmic arterial chemosurgery may experience a sudden, profound decrease in lung compliance when the microcatheter is in the ICA or ophthalmic artery. However, underlying pathophysiology of the respiratory complication is unknown. In this study, the investigators are going to investigate the relation between underlying balance of parasympathetic and sympathetic tone and the respiratory complications by analyzing heart rate beat-to-beat variability.
Study Results: NO
Conditions: Parasympathetic Cardiovascular Function Disorder
Interventions:
Primary Outcome Measures: Heart rate variability, Heart rate variability, 5 min after microcatheter enters ophthalmic artery
Secondary Outcome Measures: Heart rate variability, Heart rate variability, 5 min after anesthesia induction|Heart rate variability, Heart rate variability, 5 min before end of anesthesia

Other Outcome Measures:
Sponsor: Seoul National University Hospital
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 38
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IAchemo_HRV
Start Date: 2018-04-09
Primary Completion Date: 2019-09-09
Completion Date: 2019-09-09
First Posted: 2018-03-01
Results First Posted:
Last Update Posted: 2021-10-04
Locations: Seoul National University Hospital, Seoul, 03080, Korea, Republic of
Study Documents:

NCT Number: NCT05078190
Study Title: Mechanisms, Predictors, and Social Determinants of Cardiotoxicity in Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05078190
Acronym: CCT2
Study Status: RECRUITING
Brief Summary: This is an observational study for patients with breast cancer that will be treated with doxorubicin (Adriamycin) and/or trastuzumab (Herceptin). The study will help the investigators learn more about how these medications affect the heart and how those effects relate to patients' medical history and social determinants of health (such as race, gender identity, education, occupation, access to health services and economic resources). Patients on this study will have echocardiograms, blood draws, and answer questions about their symptoms and activity level. Patients will be followed on this study for up to 15 years.
Study Results: NO
Conditions: Breast Cancer|Cardiotoxicity|Drug-Related Side Effects and Adverse Reactions|Cardiovascular Diseases
Interventions: OTHER: Social Determinants of Health
Primary Outcome Measures: Change in Left Ventricular Ejection Fraction (LVEF), Absolute change in LVEF by echocardiogram at follow-up, through study completion (expected to be 15 years)
Secondary Outcome Measures: Cancer therapy-related cardiac dysfunction (CTRCD), Incidence of CTRCD defined as at least a 10% absolute change in LVEF by echocardiogram at follow-up relative to baseline to a value \< 50%, through study completion (expected to be 15 years)|Symptomatic Heart Failure (HF), Incidence of symptomatic heart failure (centrally adjudicated), through study completion (expected to be 15 years)|

Change in Longitudinal Strain, Change in longitudinal strain by echo from baseline, through study completion (expected to be 15 years)| Change in Circumferential Strain, Change in circumferential strain by echo from baseline, through study completion (expected to be 15 years)|Change in Diastolic function, Change in diastolic function defined as E/e' by echo from baseline, through study completion (expected to be 15 years)|Change in Left Ventricular (LV) Mass, Change in LV Mass by echo from baseline, through study completion (expected to be 15 years)|Change in Relative LV Wall Thickness, Change in relative LV wall thickness from baseline, through study completion (expected to be 15 years)|Change in Ventricular-Arterial Coupling, Change in Ventricular-Arterial Coupling defined as Ea/Ees by echo from baseline, through study completion (expected to be 15 years)|Change in LV Twist, Change in LV Twist measured by 3D echo from baseline, through study completion (expected to be 15 years)|Change in LV Torsion, Change in LV Torsion measured by 3D echo from baseline, through study completion (expected to be 15 years)|Change in NTproBNP, Change in NTproBNP measured in batches from banked samples from baseline., through study completion (expected to be 15 years)|Change in high-sensitivity troponin (hsTnT), Change in hs-TnT measured in batches from banked samples from baseline., through study completion (expected to be 15 years)|Change in patient reported fatigue, Change in Patient Reported Outcomes Information System (PROMIS) Fatigue Score from baseline. A higher score corresponds to higher reported levels of fatigue., through study completion (expected to be 15 years)|Change in patient reported quality of life, Change in Patient Reported Outcomes Information System (PROMIS) Global Health score from baseline. Higher scores indicate a healthier patient., through study completion (expected to be 15 years)|Change in patient reported activity level, Change in total weekly leisure activity in METS assessed by Godin Leisure Time Exercise Questionnaire from baseline., through study completion (expected to be 15 years)
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators: American Heart Association
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 200
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 11121
Start Date: 2021-10-21
Primary Completion Date: 2039-10
Completion Date: 2039-10
First Posted: 2021-10-14
Results First Posted:
Last Update Posted: 2023-01-20
Locations: University of Pennsylvania, Philadelphia, Pennsylvania,

19104, United States
Study Documents:

NCT Number: NCT03181997
Study Title: Outcomes of Transcatheter Aortic Valve Implantation in Oncology Patients With Severe Aortic Stenosis
Study URL: https://beta.clinicaltrials.gov/study/NCT03181997
Acronym: TOP-AS
Study Status: COMPLETED
Brief Summary: As for today, transcatheter aortic valve implantation (TAVI) is indicated only in symptomatic patients with severe aortic stenosis (AS) at high surgical risk. As cancer therapy improves, some AS patients suffering active malignancy (including advanced metastatic diseases) may be more endangered by their untreated valvular disease than their oncological disease. Among these patients, TAVI may be indicated before cancer related surgery or cardiotoxic anti-cancer therapy in order to achieve better anti-cancer therapy outcomes. Individualized life expectancy assumptions should be evaluated by the heart team in the clinical decision-making process as an essential factor in weighing the risk-benefit ratio for oncologic patients undergoing TAVI. A multicenter, international TAVI in Oncology Patients with AS (TOP-AS) registry was designed to collect data on patients with an active malignancy and severe AS undergoing TAVI. The aim of the study is to evaluate the outcomes, benefits and risks of oncology patients undergoing TAVI, mainly the patients' survival and cause of death and also the interactions between the valvular and the oncologic conditions.
Study Results: NO
Conditions: Aortic Valve Stenosis|Malignancy
Interventions: DEVICE: Native aortic valve|PROCEDURE: Transcatheter aortic valve implantation (TAVI)
Primary Outcome Measures: Patients survival, Patients survival in days, 2 years
Secondary Outcome Measures: New York Heart Association Functional Classification (NYHA FC), Provides information regarding patients functional status on scale of 1-4., 2 years|Cause of death, Whether the cause of death is cardiovascular or non-cardiovascular., 2 years
Other Outcome Measures:
Sponsor: Rabin Medical Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 168
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 0136-17-RMC
Start Date: 2017-01-01
Primary Completion Date: 2019-03-01

Completion Date: 2019-03-01
First Posted: 2017-06-09
Results First Posted:
Last Update Posted: 2019-03-28
Locations: Rabin Medical Center,, Petaḥ Tiqwa, Israel
Study Documents:

NCT Number: NCT02018497
Study Title: Essential Hypotension and Allostasis Registry
Study URL: https://beta.clinicaltrials.gov/study/NCT02018497
Acronym: ESSENTIAL
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The essential arterial hypotension and allostasis registry is a prospective, observational research that has the purpose of demonstrating that essential blood pressure (BP) disorders and the associated comorbidities are a result of the inappropriate allostatic response to daily life stress. This required a functioning brain orchestrating the evaluation of the threat and choosing the response, this is a mind-mediated phenomenon. If the response is excessive it contributes to high BP, if deficient to low BP, and the BP itself will identify the allostatic pattern, which in turn will play an important role in the development of the comorbidities.

To do so, consecutive patients of any age and gender that visit a cardiologist's office in Medellin, Colombia, are recruited. Individuals are classified according to their arterial BP and allostasis and follow them in time to see what kind of diseases develops the most (including BP) in the follow up according to the categorization of the characteristic chosen and after adjustment for confounder's variables. In addition, stress events with their date are registered.

HYPOTHESIS

The causes of the diseases are multifactorial.

Physical, biochemical, psychological, social, and cultural dimensions of development dynamically interact to shape the health development process.

A person´s health depends on their:

1. Biological and physiologic systems
2. External and internal environment (a) physical, b) internal behavioural and arousal state as registered by the brain.
3. Their interaction.

The allostatic mechanisms to the internal and external stressors (allostatic load) involves a network composed by:

1. Functional systems; mediated by:

   1. The Autonomic Nervous System
   2. The endocrine system
   3. The immune system
2. Structural changes: whenever the internal and/or external stressors are long lasting and/or strength enough, they may induce changes in:

   1. Epigenetic, endophenotypes, polyphenism.
   2. Plasticity
3. The interaction between a) and b).

The network response do not affect exclusively the BP, propitiating the development of comorbidities, which may prompt strategies for prevention, recognition and ultimately, treatment.

The allostatic model defines health as a state of responsiveness.

The concept of psycho-biotype: The allostasis is the result of both: biological (allostasis) and psychological (psychostasis) abilities. It is proposed that both components behave in similar direction and magnitude.

Immune disorders may be associated with the development of cancer. High BP population has a higher sympathetic and lower vagal tone, this has been associated with a decrease in the immune´s system function.

Resources and energy depletion: Terms like weathering have been used to describe how exposures to different allostatic loads gradually scrape away at the protective coating that keeps people healthy. It is postulated that High BP individuals have more resources and energy.
Study Results: NO
Conditions: Blood Pressure|Depression|Panic Attack|Fibromyalgia|POTS|Inappropriate Sinus Tachycardia|Coronary Heart Disease|Acute Coronary Syndrome (ACS)|Acute Myocardial Infarction (AMI)|Cerebrovascular Disease (CVD)|Transient Ischemic Attack (TIA)|Atrial Fibrillation|Diabetes Mellitus|Cancer|Systolic Heart Failure|Diastolic Heart Failure|Chronic Fatigue Syndrome|Syncope|Vasovagal Syncope
Interventions:
Primary Outcome Measures: Relationship between Blood pressure group and comorbidities, Blood pressure group: 1) Essential arterial hypotension, 2) normotension and 3) Essential arterial hypertension.

Comorbidities: As describe in the protocol, as a summary: 1) cardiovascular, 2) metabolic, 3) Endocrine, 4) psychiatric disorders: depression and panic disorder, 5) orthostatic intolerance: neurally mediated syncope, vasovagal syncope, inappropriate sinus tachycardia, Postural orthostatic syndrome, carotid sinus hypersensitivity; 6) others: chronic fatigue syndrome, fibromyalgia, arthritis, autoimmune diseases, pulmonary thromboembolism, OSA (obstructive sleep apnea),

Alzheimer disease, Parkinson disease, others dementias, epilepsia, nephropathies, and others.

Cardiovascular mortality Total mortality, A 7-year prospective study| Relationship between adaptability group and comorbidities, Adaptability group: Hyper adaptable, normal adaptability, hypo adaptable. Comorbidities: As describe in the protocol, as a summary: 1) cardiovascular, 2) metabolic, 3) Endocrine, 4) psychiatric disorders: depression and panic disorder, 5) orthostatic intolerance: neurally mediated syncope, vasovagal syncope, inappropriate sinus tachycardia, Postural orthostatic syndrome, carotid sinus hypersensitivity; 6) others: chronic fatigue syndrome, fibromyalgia, arthritis, autoimmune diseases, pulmonary thromboembolism, OSA (obstructive sleep apnea), Alzheimer disease, Parkinson disease, others dementias, epilepsia, nephropathies, and others.

Cardiovascular mortality Total mortality, A 7-year prospective study| Relationship between blood pressure group, adaptability group and comorbidities, Blood pressure group: 1) Essential arterial hypotension, 2) normotension and 3) Essential arterial hypertension.

Adaptability group: Hyper adaptable, normal adaptability, hypo adaptable. Comorbidities: As describe in the protocol, as a summary: 1) cardiovascular, 2) metabolic, 3) Endocrine, 4) psychiatric disorders: depression and panic disorder, 5) orthostatic intolerance: neurally mediated syncope, vasovagal syncope, inappropriate sinus tachycardia, Postural orthostatic syndrome, carotid sinus hypersensitivity; 6) others: chronic fatigue syndrome, fibromyalgia, arthritis, autoimmune diseases, pulmonary thromboembolism, OSA (obstructive sleep apnea), Alzheimer disease, Parkinson disease, others dementias, epilepsia, nephropathies, and others.

Cardiovascular mortality Total mortality, A 7-year prospective study Secondary Outcome Measures: Relationship between blood pressure group, habits and anthropometric, metabolic, endocrine, Electrocardiogram, Holter, ambulatory blood pressure monitoring (ABPM), Blood pressure group: 1) Essential arterial hypotension, 2) normotension and 3) Essential arterial hypertension.

Habits: smoke and drink

Anthropometric variables: Body mass index, waist, hip

Metabolic variables: Fasting glucose, 2 hs postprandial plasma glucose, insulin plasma levels, homoeostasis model assessment (HOMA), total cholesterol, LDL, HDL, triglycerides.

Endocrine variables: plasma cortisol, free cortisol in 24 hs. urine, epinephrine, norepinephrine, metanephrines, vanilmandelic acid, ACTH, aldosterone, renin, thyrotropine, free thyroxine, triiodothyronine,

testosterone

Electrocardiogram: HR; PR interval, QRS complex, cQT interval

Holter variables: HR, standard deviation of NN intervals (SDNN) and sympathovagal balance, at day, night and 24 hs.

ABPM: Systolic, diastolic, and heart rate, at day, night and 24 hs., BP matinal surge., A 7-year prospective study|Relationship between blood pressure group, adaptability group, habits anthropometric, metabolic, endocrine, electrocardiographic, Holter, ambulatory arterial blood pressure monitoring., Blood pressure group: 1) Essential arterial hypotension, 2) normotension and 3) Essential arterial hypertension.

Adaptability group: Hyper adaptable, normal adaptability, hypo adaptable.

Habits: smoke and drink

Anthropometric variables: Body mass index, waist, hip

Metabolic variables: Fasting glucose, 2 hs postprandial plasma glucose, insulin plasma levels, HOMA, total cholesterol, LDL, HDL, triglycerides.

Endocrine variables: plasma cortisol, free cortisol in 24 hs. urine, epinephrine, norepinephrine, metanephrines, vanilmandelic acid, ACTH, aldosterone, renin, thyrotropine, free thyroxine, triiodothyronine, testosterone

Electrocardiogram: PR interval, QRS complex, Heart rate, cQT interval

Holter variables: HR, SDNN and sympathovagal balance, at day, night and 24 hs.

ABPM: Systolic, diastolic, and heart rate, at day, night and 24 hs., BP matinal surge., A 7-year prospective study|For metabolic disorders what it matters the most: the anthropometric variables vs blood pressure group vs adaptability group, Blood pressure group: 1) Essential arterial hypotension, 2) normotension and 3) Essential arterial hypertension.

Adaptability group: 1) Hyper adaptable, 2) normal adaptability and 3) hypo adaptable.

Habits: smoke and drink, exercise

Anthropometric variables: Body mass index, waist, hip

Metabolic and other variables: Fasting glucose, 2 hs postprandial plasma glucose, insulin plasma levels, HOMA, total cholesterol, LDL, HDL, triglycerides; thyrotropine,

Holter variables: HR, standard deviation of NN intervals (SDNN) and sympathovagal balance, at day, night and 24 hs.

ABPM: Systolic, diastolic, and heart rate, at day, night and 24 hs., BP matinal surge., A 7-year prospective study|Relationship between adaptability group, habits and anthropometric, metabolic, endocrine, Electrocardiogram, Holter, ambulatory blood pressure monitoring (ABPM), Adaptability group: Hyper adaptable, normal adaptability, hypo adaptable.

Habits: smoke and drink Anthropometric variables: Body mass index, waist, hip

Metabolic variables: Fasting glucose, 2 hs postprandial plasma glucose, insulin plasma levels, HOMA, total cholesterol, LDL, HDL, triglycerides.

Endocrine variables: plasma cortisol, free cortisol in 24 hs. urine, epinephrine, norepinephrine, metanephrines, vanilmandelic acid, ACTH, aldosterone, renin, thyrotropine, free thyroxine, triiodothyronine, testosterone

Electrocardiogram: PR interval, QRS complex, Heart rate, cQT interval

Holter variables: HR, SDNN and sympathovagal balance, at day, night and 24 hs.

ABPM: Systolic, diastolic, and heart rate, at day, night and 24 hs., BP matinal surge., A 7-year prospective study
Other Outcome Measures: Syncope Registry, Clinical syncope characteristics (age of first syncope, number of syncope episodes, trauma, duration, clinical score, convulse, sphincter relaxation, etc.) Syncope cause Blood pressure group Adaptability group Prognosis, Up 100 weeks|Tilt table testing (TTT) registry, TTT protocol: describe the protocol, the time at positive response, nitroglycerine use, autonomic and hemodynamic variables.

TTT outcome for syncope: positive or negative TTT other outcomes: 1) Chronotropic incompetence, 2) arterial orthostatic hypotension, 3) carotid hypersensitivity, 4) POTS, 5) IST The relationship between TTT results and Clinical score for syncope in regard to: syncope behaviour and other orthostatic intolerance entities, symptoms and comorbidities.

The relationship between neurally mediated syncope response at the TTT and comorbidities., Up to 100 weeks|Sinus node function at the

electrophysiological study (EPS), EPS variables: AH, AV, CL, sino atrial conduction time (SACT), sinus node recovery time (SNRT), corrected sinus node recovery time (CSNRT), response to Isoproterenol, intrinsic heart rate Diagnosis: control, sick sinus syndrome, IST, chronotropic incompetence at the TTT HR at the ECG HR at the Holter monitoring HR at the TTT HRV at the Holter monitoring Syncope, cardiac or neurally mediated HR at the physical treadmill test Relationship with the blood pressure group Relationship with the adaptability group, Up to 100 weeks|Score for coronary artery disease, Define how the blood pressure group and/or the adaptability group may add to the already known and include in this registry, in the diagnosis of cardiovascular complications as coronary artery disease, cerebrovascular disease, peripheral artery disease, nephropathy., Up to 200 weeks|Neurally Mediated Syncope: further of the transient lost of consciousness (TLC), Blood pressure group: 1) Essential arterial hypotension, 2) normotension and 3) Essential arterial hypertension.

Adaptability group: Hyper adaptable, normal adaptability, hypo adaptable. Comorbidities: As describe in the protocol, as a summary: 1) cardiovascular, 2) metabolic, 3) Endocrine, 4) psychiatric disorders: depression and panic disorder, 5) orthostatic intolerance: neurally mediated syncope, vasovagal syncope, inappropriate sinus tachycardia, Postural orthostatic syndrome, carotid sinus hypersensitivity; 6) others: chronic fatigue syndrome, fibromyalgia, arthritis, autoimmune diseases, pulmonary thromboembolism, OSA (obstructive sleep apnea), Alzheimer disease, Parkinson disease, others dementias, epilepsia, nephropathies, COPD, and others.

Mortality, A 7-year prospective study|Psychobiotype: relationship between biological and psychological variables, Blood pressure group: 1) Essential arterial hypotension, 2) normotension and 3) Essential arterial hypertension.

Adaptability group: Hyper adaptable, normal adaptability, hypo adaptable.

Psychiatric variables:

1. Big Five Questionary (BFQ) for personality.
2. Modify of the Coping Scale (Scale of modified coping strategies)
3. Zung questionary for depression and anxiety
4. MINI in those patients with moderate or severe depression and/or anxiety at the Zung questionary, Up to 100 weeks|The role of high sodium intake in the development of essential hypertension. Comparison between essential hypotension (high sodium intake) vs normotension population (normal or low sodium intake) in the follow-up., High sodium intake in the diet is recognized as a risk factor for hypertension development.

Essential hypotension population is advised to increase the sodium (at

least 10 grams a day) and water intake (at least 2 liters a day), or as much as possible, several have taken Fludrocortisone (is not a exclusion criteria). Normal blood pressure population are advised to have a normal or low sodium intake. Physical exercise is recommended in both groups.

This registry is a good opportunity to test how important sodium diet is to induce hypertension, or if by the contrary adaptability could prevail over high sodium intake in this registry.

Blood pressure groups: essential hypotension and normotension and those with new essential hypertension. Adaptability groups.

The results will be adjusted for age, gender and BMI., 4 years|White coat effect in the heart rate or masked bradycardia., Consistent bradycardia in the ECG at the office and normal HR in the holter monitoring or the contrary.

There are patients with complaints that may be attributed to bradycardia, low blood pressure, hypothyroidism, or other entities.

Some patients very often have bradycardia in the ECG taken in the office and normal HR in the 24 Holter monitoring, the opposite is also possible.

Patients with bradycardia (without medication or physiological condition as exersice affecting heart rate) in at least 2 ECG (less 60 bpm) and at least 2 Holter monitoring will be analyzed,

Other variables to consider are:

Age, gender, blood pressure group, adaptability group, maximum HR in the treadmill test, white coat or masked hypertension, Tilt-Table-test result or syncope cause, Electrophysiological study if available.

The acknowledge of this phenomenon could have clinical implications in the diagnosis of sick sinus syndrome and physiopathological ones., 1 year|Reversible Bradycardia Mimicking Sinus Node Dysfunction as a Manifestation of Subacute Autonomic Nervous System Dysfunction (ANSD)., Bradycardia is the classical presentation form for sinus node dysfunction, mainly when associated with symptoms. Chronotropic incompetence is also a manifestation. Absence of medications with effects on the heart rate (HR) must be ruled out.

Variables

1. HR at the ECG, Holter monitoring, stress text, and at the physical examination previous to pacemaker implantation,
2. Electrophysiological study (EPS): Basic cycle length, Sino-atrial conduction time, Sinus node recovery time, Corrected sinus node

recovery time, Intrinsic HR when available 3. Pacemaker variables: HR at day and night or rest time Percentage of stimulation in A and V chambers 4. Syncope: Clinical characteriscs and clinical score Tilt table test results Trans Thoracic Echocardiogram in rest and or stress text Hypothesis: patients with ANSD will start to decrease the percentage atrial stimulation., 2 years|Description of the blood pressure hemodynamic profile at a medical office and their prognostic implications., A non invasive, beat to beat BP monitoring, with the ability to measure BP, HR, Cardiac Output and Systemic Vascular Resistance (SVR) was started to use in the EHAR registry since May 2017. A description of this variables in the three BP groups will be collected in the data base (DB).

This will allow to characterize whether SVR and/or CO maintain BP. Until now BP levels are related with prognosis. In the prognosis model SVR and CO will be add them to know what matter the most: BP levels, SVR and/or CO? In the EHAR registry a collection of the variables recognized as a risk factor for several comorbidities are available to adjust in multivariable analysis., Three years
Sponsor: CES University
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 5000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: LEMD001
Start Date: 1995-01
Primary Completion Date: 2022-12-30
Completion Date: 2022-12-30
First Posted: 2013-12-23
Results First Posted:
Last Update Posted: 2022-03-10
Locations: CES University, Medellín, Antioquia, 00, Colombia
Study Documents:

NCT Number: NCT02943590
Study Title: STOP-CA (Statins TO Prevent the Cardiotoxicity From Anthracyclines)
Study URL: https://beta.clinicaltrials.gov/study/NCT02943590
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This research study will test whether atorvastatin, a drug commonly prescribed for reducing cholesterol levels, can protect the heart during chemotherapy with doxorubicin. Atorvastatin is from a family of medications that are commonly called "statins"
Study Results: NO
Conditions: Heart Failure

Interventions: DRUG: Placebo|DRUG: Atorvastatin
Primary Outcome Measures: Left ventricular Ejection Fraction (LVEF), To determine if statins preserve the LVEF at 12 months, 12 months
Secondary Outcome Measures: Number of Cardiac Events, To determine whether statins reduce cardiac events (new onset heart failure), 2 years|Myocardial Fibrosis, To determine The Effect Of Statins On Myocardial Fibrosis, 6 months|Troponin T and Global Longitudinal Strain, To determine whether changes in troponin T or global longitudinal strain by echocardiography at 3 months predict the reduction in LVEF at 12 months on MRI., 3 months
Other Outcome Measures:
Sponsor: Massachusetts General Hospital
Collaborators: Dana-Farber Cancer Institute|Brigham and Women's Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 300
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: TREATMENT
Other IDs: 16-440
Start Date: 2017-01-13
Primary Completion Date: 2022-09-16
Completion Date: 2023-10-11
First Posted: 2016-10-24
Results First Posted:
Last Update Posted: 2022-11-15
Locations: Massachusetts general Hospital, Boston, Massachusetts, 02114, United States|Dana Farber Cancer Institute, Boston, Massachusetts, 02115, United States|University of Pennsylvania Medical System, Philadelphia, Pennsylvania, 19104, United States|McGill University Health Center, Toronto, Canada
Study Documents:

NCT Number: NCT03038997
Study Title: Early Detection of Cardiac Toxicity in Childhood Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT03038997
Acronym:
Study Status: TERMINATED
Brief Summary: To evaluate cardiac MRI and/or serum biomarkers for detecting cardiac cardiac toxicity in children who received anthracycline based chemotherapy (ABC).
Study Results: NO
Conditions: Heart Failure|Cardiotoxicity
Interventions:
Primary Outcome Measures: Echocardiogram marker measurements pre ABC chemo and post ABC, •Measure echocardiogram markers on pre

anthracycline based chemotherapy (ABC) and post ABC echocardiograms, using standard echocardiogram measurements and speckle tracking., At the end of each cardiac MRI exam through study completion, up to 5 years
Secondary Outcome Measures: Detection of cardiac toxicity on MRI and echocardiogram, •Measure sensitivity of detecting cardiac toxicity between standard echocardiogram, speckle tracking on echo, and MRI, At the end of each cardiac MRI exam through study completion, up to 5 years|Serum biomarkers correlation, •Correlate measurement of serum biomarkers with prevalence of cardiac changes measured on echocardiograms and MRI imaging., At the end of the study, up to 10 years
Other Outcome Measures:
Sponsor: Niti Dham
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 42
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 5405
Start Date: 2014-11
Primary Completion Date: 2018-03-11
Completion Date: 2018-03-11
First Posted: 2017-02-01
Results First Posted:
Last Update Posted: 2018-12-04
Locations: Children's National Health System, Washington, District of Columbia, 20010, United States
Study Documents:

NCT Number: NCT02010190
Study Title: Vascular Assessment in Adult Survivors of Childhood Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02010190
Acronym:
Study Status: COMPLETED
Brief Summary: This is an observational study that will collect data from adult survivors of childhood cancer and compare it to data collected from age- and gender-matched controls for the purpose of assessing vascular risk among cancer survivors.

Advances in cancer therapies have led to increasing numbers of adults previously treated for a pediatric malignancy, many of whom experience late adverse health-related sequelae and are at risk for developing chronic conditions related to their prior therapy. The epidemiology of many end-organ toxicities has been described, yet the pathophysiologic mechanisms of injury are incompletely understood. One mechanism may be

damage to the circulatory system, in particular the endothelial layer, initiating an inflammatory state leading to dysfunction and premature atherosclerotic disease. This process may begin and significantly progress in a sub-clinical nature for many years prior to manifesting as a cardio- or cerebrovascular event. Using established and novel biomarkers predictive of atherosclerotic disease combined with unique measurements of vascular function, this study will assess pre-clinical vascular disease in a population of childhood and adolescent cancer survivors. The goals of this project are to investigate the effects of cancer therapy on the vascular system and acquire new knowledge with which to risk-stratify survivors and plan interventional studies to prevent or reduce premature vascular morbidity and mortality.
Study Results: NO
Conditions: Cardiovascular Risk|Pediatric Cancer
Interventions:
Primary Outcome Measures: Mean high sensitivity C-reactive protein (hsCRP), Once, at first clinic visit|Mean fibrinogen, Once, at first clinic visit|Mean CEC surface expression of vascular cell adhesion molecule-1 (VCAM-1), Once, at first clinic visit|Mean larger artery elasticity, Once, at first clinic visit
Secondary Outcome Measures: Mean number of circulating endothelial cells (CECs), Once, at first clinic visit|Mean CEC surface expression of P-selectin, Once, at first clinic visit|Mean soluble vascular cell adhesion molecule-1 (VCAM-1), Once, at first clinic visit|Mean soluble P-selectin, Once, at first clinic visit|Mean von Willebrand factor (vWF), Once, at first clinic visit|Mean D-dimer, Once, at first clinic visit|Mean plasminogen activator inhibitor-1 (PAI-1), Once, at first clinic visit|Mean tissue-type plasminogen activator (tPA), Once, at first clinic visit|Mean lipoprotein(a), Once, at first clinic visit|Mean small artery elasticity (SAE), Once, at first clinic visit|Mean reactive hyperemia peripheral arterial tonometry (RH-PAT) ratio, Once, at first clinic visit|Mean carotid-femoral pulse wave velocity, Once, at first clinic visit
Other Outcome Measures:
Sponsor: St. Jude Children's Research Hospital
Collaborators: University of Minnesota
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 394
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: VASCC
Start Date: 2013-12
Primary Completion Date: 2016-07
Completion Date: 2016-07
First Posted: 2013-12-12
Results First Posted:
Last Update Posted: 2016-07-27

Locations: St. Jude Children's Research Hospital, Memphis, Tennessee, 38105, United States
Study Documents:

NCT Number: NCT04242667
Study Title: Penn Biobank Return of Research Results Program
Study URL: https://beta.clinicaltrials.gov/study/NCT04242667
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: The overall goal of the proposed research is to assess the feasibility of a randomized study evaluating the non-inferiority of an electronic Health (e-Health) delivery alternative (e.g. private web portal) as compared to return of actionable genetic research results with a genetic counselor.
Study Results: NO
Conditions: Cancer|Cardiovascular Diseases|Hereditary Cancer|Hereditary Cardiac Amyloidosis
Interventions: BEHAVIORAL: e-Health (web-based) disclosure portal|BEHAVIORAL: Provider mediated disclosure
Primary Outcome Measures: Completion of surveys, Participant will self-complete surveys to collect psychological and knowledge outcomes, Baseline survey prior to disclosure of results, and then two post-disclosure surveys at 2-7 days and 6 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Pennsylvania
Collaborators: Fox Chase Cancer Center
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: 833373
Start Date: 2020-03-01
Primary Completion Date: 2023-06
Completion Date: 2023-08
First Posted: 2020-01-27
Results First Posted:
Last Update Posted: 2023-02-02
Locations: University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT00563407
Study Title: Novel Surrogate Markers as Predictors of Radiation Toxicity in Breast Cancer Patients Undergoing Helical Tomotherapy Compared to Standard Radiation Therapy

Study URL: https://beta.clinicaltrials.gov/study/NCT00563407
Acronym:
Study Status: TERMINATED
Brief Summary: Radiotherapy is standard treatment for breast cancer after lumpectomy. Although this treatment showed substantial patient benefits and decrease of local recurrence and deaths from breast cancer, it also results in some severe late side-effects, such as skin fibrosis and cardiac failure. It's possible to offer breast irradiation (RT) and minimizing toxicities radiation dose to skin, lung and heart. This will be achieved with highly conformal RT delivery using Tomotherapy. We plan to evaluate this approach in clinical study. We plan also to evaluate the value of genomic, cellular and functional imaging endpoints as predictive markers of toxicity in our breast cancer population. This program is expected to prospectively validate that Tomotherapy for breast RT can decrease skin, lung and heart toxicities and maintaining excellent cancer control after lumpectomy.
Study Results: NO
Conditions: Genetic Markers|Cardiac Toxicity|Breast and Skin Motion
Interventions:
Primary Outcome Measures: skin and cardiac toxicity, 24 months post RT
Secondary Outcome Measures: prediction, 24 months post RT
Other Outcome Measures:
Sponsor: AHS Cancer Control Alberta
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 16
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: BR-1-0090
Start Date: 2006-07
Primary Completion Date: 2011-03
Completion Date: 2011-03
First Posted: 2007-11-26
Results First Posted:
Last Update Posted: 2016-02-24
Locations: Alberta Cancer Board, Edmonton, Alberta, Canada
Study Documents:

NCT Number: NCT00806507
Study Title: Early Detection and Prediction of Chemotherapy Induced Cardiac Toxicity in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT00806507
Acronym:
Study Status: COMPLETED
Brief Summary: The goal of this clinical research study is to learn whether different ways of viewing echocardiogram pictures along with

blood tests can help to see heart-related side effects of chemotherapy and trastuzumab earlier than the usual tests.
Study Results: NO
Conditions: Breast Cancer
Interventions: PROCEDURE: Echocardiograms|PROCEDURE: Blood Test
Primary Outcome Measures: Predictors of cardio-toxicity in female patients with breast cancer exposed to trastuzumab +/- previous anthracycline agents, Identification of heart-related side effects of chemotherapy and trastuzumab using echocardiogram pictures plus blood tests., Baseline to 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators: Massachusetts General Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 45
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2007-0339
Start Date: 2008-11
Primary Completion Date: 2011-08
Completion Date: 2011-08
First Posted: 2008-12-10
Results First Posted:
Last Update Posted: 2012-07-23
Locations: Partners Healthcare Systems, Boston, Massachusetts, 02199, United States|UT MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT03790943
Study Title: Cardiac Dysfunction in Childhood Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT03790943
Acronym: Cardio-Onco
Study Status: RECRUITING
Brief Summary: This multicenter, prospective cohort study evaluates early cardiac dysfunction in adult survivors of childhood cancer. The hypothesis of this study is that cardiac dysfunction can be detected earlier when using speckle tracking echocardiography as novel echocardiographic technique compared to conventional echocardiography.
Study Results: NO
Conditions: Cardiac Dysfunction|Cardiovascular Diseases|Childhood Cancer
Interventions: DIAGNOSTIC_TEST: cardiac assessment
Primary Outcome Measures: Prevalence of cardiac dysfunction, Conventional echocardiography: left ventricular ejection fraction (%), Baseline and longitudinal follow-up where clinically indicated|

Prevalence of cardiac dysfunction, Speckle tracking echocardiography: longitudinal (LS), circumferential (CS), and radial strain (RS), Baseline and longitudinal follow-up where clinically indicated| Prevalence of impaired exercise capacity, Cardiopulmonary exercise testing: peak oxygen consumption, percent-predicted carbon dioxide production, Baseline|Treatment-related risk factors, Cumulative doses of anthracyclines, steroids, and alkylating agents (mg/m2), Baseline| Treatment-related risk factors, Dose of chest radiation (Gray), Baseline
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Bern
Collaborators: University Hospital, Basel, Switzerland|University Children's Hospital Basel|Insel Gruppe AG, University Hospital Bern| Cantonal Hospital of St. Gallen|Luzerner Kantonsspital|University Hospital, Geneva
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 500
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SCCSS_cardiac_FU
Start Date: 2018-02-13
Primary Completion Date: 2023-12-31
Completion Date: 2024-01-01
First Posted: 2019-01-02
Results First Posted:
Last Update Posted: 2023-03-14
Locations: Department of Cardiology, University Hospital Basel, Basel, Basel-City, 4031, Switzerland|Institute of Social and Preventive Medicine, University of Bern, Bern, BE, 3012, Switzerland|Department of Cardiology, Inselspital Bern, Bern, 3010, Switzerland|Department of Cardiology, University Hospitals of Geneva, Geneva, 1205, Switzerland| Department of Cardiology, Lucerne Cantonal Hospital, Lucerne, 6000, Switzerland|Department of Cardiology, Cantonal Hospital of St. Gallen, Saint Gallen, 9007, Switzerland
Study Documents:

NCT Number: NCT02922543
Study Title: A Safety and Efficacy Study of Revlimid® 5 mg Capsules in Patients With Relapsed or Refractory Multiple Myeloma Who Have Received Long-term Treatment With it Under the Actual Condition of Use
Study URL: https://beta.clinicaltrials.gov/study/NCT02922543
Acronym:
Study Status: COMPLETED
Brief Summary: To understand the safety and efficacy of Revlimid® 5 mg Capsules (hereinafter referred to as Revlimid) in patients with "relapsed or refractory multiple myeloma" (hereinafter referred to as

"relapsed or refractory MM") who have received long-term treatment with it under the actual condition of use.

1. Planned registration period This period started on the date of initial marketing of Revlimid and will end at the time when the planned number of patients to be enrolled, 300, is reached (estimated to be approximately 1 year and 3 moths).
2. Planned surveillance period This period started on the date of initial marketing of Revlimid and will end 3 years after the last enrolled patient begins receiving Revlimid (estimated to be approximately 4 years and 3 months).
Study Results: NO
Conditions: Multiple Myeloma
Interventions:
Primary Outcome Measures: Adverse Events (AEs), Number of participants with adverse events, 3 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Celgene
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 361
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NIS-Celgene-JP-PMS-001b
Start Date: 2011-02-18
Primary Completion Date: 2014-10-11
Completion Date: 2014-10-11
First Posted: 2016-10-04
Results First Posted:
Last Update Posted: 2022-06-14
Locations: Shinko Hospital, Kobe, Hyogo, 651-0072, Japan
Study Documents:

NCT Number: NCT02772367
Study Title: Generation of Heart Muscle Cells From Blood or Skin Cells of Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02772367
Acronym:
Study Status: RECRUITING
Brief Summary: The purpose of this study is to investigate whether cells from a biopsy taken from the patient skin can be transformed into cardiomyocytes the changes in cardiomyocyte (heart muscle cells) when grown in a special culture medium outside of the body. The structure and function of these cells will then be studied to determine why some patients with breast cancer who are treated with chemotherapy including anthracycline (e.g. Doxorubicin) and anti-HER2

therapy (e.g. Herceptin) develop decreased heart function.
Study Results: NO
Conditions: Breast Cancer
Interventions: PROCEDURE: skin punch biopsy
Primary Outcome Measures: derive iPSs from skin fibroblasts, described by Yamanaka et al with modification using the Millipore STEMCCA excisable polycystronic lentivirus reprogramming kit.2, 1 day
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators: Icahn School of Medicine at Mount Sinai
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 70
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 16-025
Start Date: 2016-05-11
Primary Completion Date: 2026-05
Completion Date: 2026-05
First Posted: 2016-05-13
Results First Posted:
Last Update Posted: 2023-06-02
Locations: Memorial Sloan-Kettering Cancer Center, New York, New York, 10065, United States
Study Documents:

NCT Number: NCT05063643
Study Title: Cardiotoxicity of Targeted Therapy for HER-2 Positive Breast Cancer Patients at High Altitude
Study URL: https://beta.clinicaltrials.gov/study/NCT05063643
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: This is a prospective, multicenter, cohort study aiming to explore the cardiotoxicity of targeted therapy for HER-2 positive breast cancer patients who lives in high altitude area. One hundred and thirty two HER-2 positive breast cancer patients who will receive neoadjuvant, adjuvant, or palliative targeted therapy will be enrolled. The cardiotoxicity of targeted therapy will be observed and recorded during the treatment and one year after the end of treatment. The subjects will be stratified by age, baseline cardiac risk factors, and anthracyclines.
Study Results: NO
Conditions: HER2-positive Breast Cancer|Targeted Therapy|Cardiac Toxicity|High Altitude
Interventions: OTHER: High altitude
Primary Outcome Measures: Incidence rate of cardiotoxicity, Cardiotoxicity includes death from cardiac cause, severe congestive

heart failure (New York Heart Association Class III or IV), more than 10% decrease of left ventricular ejection fraction (LVEF) and to below 50%, and an asymptomatic or mildly symptomatic (NYHA class II) substantial decrease in LVEF., 5 years
Secondary Outcome Measures: pCR rate, Pathologic complete response (pCR) rate in patients received neoadjuvant therapy, 4 years|ORR, Objective remission rate in patients received neoadjuvant and palliative therapy, 4 years|DCR, Disease control rate in patients received neoadjuvant and palliative therapy, 4 years|OS, Overall survival of the enrolled patients, 5 years|the incidence of treatment-related adverse events, Incidence and Severity of adverse events according to the CTC AE V4.03 Incidence and Severity of adverse events according to the CTC AE V4.03 Incidence and severity of adverse events according to the CTC AE V4.03, 5 years
Other Outcome Measures:
Sponsor: Affiliated Hospital of Qinghai University
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 132
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SL-2020076
Start Date: 2021-10
Primary Completion Date: 2024-12
Completion Date: 2024-12
First Posted: 2021-10-01
Results First Posted:
Last Update Posted: 2021-10-01
Locations: Affiliated Hospital of Qinghai University, Xining, Qinghai, 810000, China
Study Documents:

NCT Number: NCT05867667
Study Title: Cardiac Rehabilitation to Improve Breast Cancer Outcomes
Study URL: https://beta.clinicaltrials.gov/study/NCT05867667
Acronym: CRIBCO
Study Status: NOT_YET_RECRUITING
Brief Summary: To develop a novel, proactive cardiac rehabilitation program for breast cancer survivors at enhanced risk of cardiovascular disease. Considering this program is secondary to the Michigan Medicine Cardiac Rehabilitation program's goal to manage cardiac patients, the hybrid program has been designed that limits utilization of cardiac rehabilitation to 12 visits over the first eight weeks of the intervention compared to 32 visits for cardiovascular patients.
Study Results: NO
Conditions: Breast Cancer|Cardiovascular Diseases
Interventions: OTHER: Cardiac Rehab

Primary Outcome Measures: Change in cardiovascular fitness (as assessed using VO2max) between baseline and after 12 weeks of participation in a tapered 12-week cardiac rehabilitation program., Change in cardiovascular fitness will be based on endpoints related to aerobic and anaerobic thresholds, including an increase in post maximal oxygen consumption (VO2max). VO2max will be assessed by indirect calorimetry (COSMED) during a graded exercise stress test using the Bruce protocol., up to 12 weeks after enrollment
Secondary Outcome Measures: changes in upper body strength between baseline and after a 12-week hybrid cardiac rehabilitation program., Change in muscular strength will be assessed using 5-RM tests. The tests will be performed for leg extension, leg flexion, chest press, lat pull down, and bicep curl., up to 12 weeks after enrollment| changes in lower body strength between baseline and after a 12-week hybrid cardiac rehabilitation program., Change in muscular strength will be assessed using 5-RM tests. The tests will be performed for leg extension, leg flexion, chest press, lat pull down, and bicep curl., up to 12 weeks after enrollment
Other Outcome Measures:
Sponsor: University of Michigan Rogel Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 30
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: UMCC 2023.010|HUM00230386
Start Date: 2023-07
Primary Completion Date: 2025-01
Completion Date: 2025-01
First Posted: 2023-05-22
Results First Posted:
Last Update Posted: 2023-05-22
Locations: University of Michigan Rogel Cancer Center, Ann Arbor, Michigan, 48109, United States
Study Documents:

NCT Number: NCT05010109
Study Title: Cardiovascular Injury and Cardiac Fitness in Locally Advanced Non-Small Cell Lung Cancer Patients Receiving Model Based Personalized Chemoradiation
Study URL: https://beta.clinicaltrials.gov/study/NCT05010109
Acronym:
Study Status: RECRUITING
Brief Summary: This study assesses cardiovascular injury and cardiac fitness in patients with non-small cell lung cancer that has spread to nearby tissue or lymph nodes (locally advanced) receiving model based

personalized chemoradiation. The goal of this study is to learn more about the risk of developing heart disease as a result of chemoradiation treatment for lung cancer. Researchers also want to learn if the risk can be reduced by using a patient's individual risk profile to guide cancer treatment and help protect the heart.
Study Results: NO
Conditions: Locally Advanced Lung Non-Small Cell Carcinoma|Stage III Lung Cancer AJCC v8|Stage IIIA Lung Cancer AJCC v8|Stage IIIB Lung Cancer AJCC v8|Stage IIIC Lung Cancer AJCC v8
Interventions: PROCEDURE: 6 Minute Walk Functional Test|PROCEDURE: Biospecimen Collection|PROCEDURE: Computed Tomography|PROCEDURE: Echocardiography|PROCEDURE: Exercise Cardiac Stress Test|OTHER: Questionnaire Administration|PROCEDURE: Single Photon Emission Computed Tomography
Primary Outcome Measures: Increase in level of hs-TnT >= 5ng/L, Baseline up to end or chemoradiation (CRT), up to 24 months|Incidence of grade >= 2 cardiovascular events, Defined by Common Terminology Criteria for Adverse Events version 5.0., Within 12-month of completion of CRT]
Secondary Outcome Measures: Overall cardiac fitness, Assessed using 6 minute walk test., Up to 24 months after CRT|EuroQol 5 Dimension 5 Level: Patient reported outcomes, Score Range 0-100 (0) Worst health and (100) best health Level 1- No complaints Level 5- Worst, Up to 24 months after CRT|MD Anderson Symptom Inventory-Lung Cancer: Patient Report outcomes, Score Range 0-10 (0) No symptom and (10) worst symptoms, Up to 24 months after CRT|Overall survival, Up to 10 years
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators: National Heart, Lung, and Blood Institute (NHLBI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SEQUENTIAL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 2021-0071|NCI-2021-02280|2021-0071|1R01HL157273-01
Start Date: 2021-07-05
Primary Completion Date: 2026-02-23
Completion Date: 2026-02-23
First Posted: 2021-08-18
Results First Posted:
Last Update Posted: 2023-02-13
Locations: M D Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT05315908
Study Title: COVID-19 Testing in Underserved and Vulnerable

Populations
Study URL: https://beta.clinicaltrials.gov/study/NCT05315908
Acronym:
Study Status: TERMINATED
Brief Summary: As part of National Institutes of Health Rapid Acceleration of Diagnostics-Underserved Populations (RADx-UP) program, the goal of the RADxUP study is to develop, test, and evaluate a rapid, scalable capacity building project to enhance COVID-19 testing in three regional community health centers (CHCs) in San Diego County, California. In collaboration with CHC partners, their consortium organization, Health Quality Partners (HQP), investigators are pursuing the following Specific Aims: 1) Compare the effectiveness of automated calls vs text messaging for uptake of COVID-19 testing among asymptomatic adult patients with select medical conditions and those 65 years of age and older receiving care at participating CHCs. Secondarily, investigators will invite all study participants to receive flu vaccination and will assess feasibility and acceptability of study participants to refer adult family household members who are essential workers for COVID-19 testing. 2) Gather patient, provider, CHC leadership, and community stakeholder insights to establish best practices for future scale-up of COVID-19 testing sustainability and vaccination.
Study Results: NO
Conditions: Heart Failure|Coronary Artery Disease|Cancer|Chronic Kidney Diseases|COPD|Obesity|Sickle Cell Disease|Diabetes Mellitus, Type 2
Interventions: OTHER: Community outreach method
Primary Outcome Measures: Proportion of tested patients, The proportion of patients who undergo testing within one month of initial contact (automated call vs text messaging) and by the end of the study period (to consider individuals who could not come to the clinic within one month), 1 year|Number (%) tested (total and by clinic), Number (%) of patients who complete COVID-19 test (total and by clinic), 1 year|Number (%) infected (total and by clinic), Number (%) of patients with positive COVID-19 test (total and by clinic), 1 year|Timeliness of testing, From time of contact to testing, 1 year
Secondary Outcome Measures: Number vaccinated with flu vaccine, Number of patients who receive flu vaccine, 1 year|Proportion of patients who refer for testing, The proportion of study participants with eligible household members who refer household member(s) for COVID-19 testing, 1 year|Number of household members referred for testing, The number of household members referred for COVID-19 testing, 1 year
Other Outcome Measures:
Sponsor: Jesse Nodora
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 37
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: OTHER
Other IDs: 201505
Start Date: 2020-11-01
Primary Completion Date: 2021-11-15
Completion Date: 2021-11-15
First Posted: 2022-04-07
Results First Posted:
Last Update Posted: 2022-04-07
Locations: University of California, San Diego, La Jolla, California, 92093, United States
Study Documents:

NCT Number: NCT05617391
Study Title: An Evaluation of Concordance of Smartwatch ECG and One Clinical ECG and Comparison of The Two ECGS in Terms of Predictive Risks
Study URL: https://beta.clinicaltrials.gov/study/NCT05617391
Acronym:
Study Status: RECRUITING
Brief Summary: The participant is being asked to take part in this trial, because the participant is a survivor of childhood cancer.

Primary Objective

To evaluate remote cardiomyopathy prediction via smartwatch and one clinical ECG and assess the concordance of the two ECGs in terms of predicted risk.

Secondary Objective

To build a novel predictive model solely on smartwatch ECG to predict risk for cardiomyopathy.
Study Results: NO
Conditions: Childhood Cancer|Cardiomyopathy, Primary
Interventions:
Primary Outcome Measures: Standard 12-lead ECG, To be obtained during SLIFE Human Performance Lab appointment. Participant will receive a resting (supine) 12-lead ECG using a GE Mac 2000 Resting ECG System (General Electric Healthcare, Milwaukee, WI, USA). This will be assessed with the Apple Smartwatch ECG recording to determine concordance of the two ECGs., Baseline|Apple Smartwatch ECG 30-second recording, To be obtained during the SLIFE Human Performance Lab appointment, collected immediately after recording of the standard 12-lead ECG. A study team member will place an Apple Smartwatch Series 7 on the participant's wrist. The participant will be instructed to start the ECG, which will be a 30-second recording process. Once captured, the data will be automatically transferred to the IOS application on the study iPhone. This will be assessed with the

standard 12-lead ECG recording to determine concordance of the two ECGs., Baseline
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: St. Jude Children's Research Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1300
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: WATCH4ECG
Start Date: 2022-12-13
Primary Completion Date: 2024-01
Completion Date: 2025-06
First Posted: 2022-11-15
Results First Posted:
Last Update Posted: 2023-01-10
Locations: St. Jude Children's Research Hospital, Memphis, Tennessee, 38105, United States
Study Documents:

NCT Number: NCT05001009
Study Title: Goals of Care Conversations Study
Study URL: https://beta.clinicaltrials.gov/study/NCT05001009
Acronym: LSTDI
Study Status: ENROLLING_BY_INVITATION
Brief Summary: The long term goal is to improve quality of care in Veterans with serious illnesses by aligning medical care with Veterans' goals and values. The objective of this study is to use a sequentially randomized trial to determine what implementation strategies are effective to increase early, outpatient goals of care conversations. The study will use interviews with and surveys of medical providers, patients, and caregivers, along with medical record data. This work is significant because it tests ways Veterans can express their goals and preferences for life sustaining treatments and have them honored.
Study Results: NO
Conditions: Seriously Ill Patients|Cancer|Heart Failure|Interstitial Lung Disease|Chronic Obstructive Pulmonary Disease|End-stage Renal Disease|End-stage Liver Disease|Dementia
Interventions: BEHAVIORAL: Clinician Implementation Strategy Stage 1|BEHAVIORAL: Clinician Implementation Strategy Stage 2|BEHAVIORAL: Low patient engagement|BEHAVIORAL: High patient engagement
Primary Outcome Measures: Number of goals of care conversation notes completed among clinicians, Number of goals of care conversation notes completed among clinicians in both stages of the SMART., 6 months in Stage 1, 9 months in Stage 2

Secondary Outcome Measures: Percent of eligible patients sent a letter, Percent of eligible patients sent a letter about goals of care conversations in both stages of the SMART., 3 months|Percent of eligible patients that view the PREPARE website, Percent of eligible patients that view the PREPARE website in both stages of the SMART., 6 months in Stage 1, 9 months in Stage 2|Percent of eligible patients spoken to by telephone during stage 2 of the SMART, Percent of eligible patients spoken to by telephone during stage 2 of the SMART., 9 months
Other Outcome Measures:
Sponsor: VA Office of Research and Development
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 72
Funder Type: FED
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SEQUENTIAL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: IIR 19-018|HX002935
Start Date: 2022-09-13
Primary Completion Date: 2024-09-30
Completion Date: 2025-09-30
First Posted: 2021-08-11
Results First Posted:
Last Update Posted: 2022-10-10
Locations: VA Palo Alto Health Care System, Palo Alto, CA, Palo Alto, California, 94304-1290, United States|VA Greater Los Angeles Healthcare System, West Los Angeles, CA, West Los Angeles, California, 90073, United States|Rocky Mountain Regional VA Medical Center, Aurora, CO, Aurora, Colorado, 80045, United States
Study Documents:

NCT Number: NCT04222608
Study Title: The BRAvAdO Registry
Study URL: https://beta.clinicaltrials.gov/study/NCT04222608
Acronym: BRAvAdO
Study Status: UNKNOWN
Brief Summary: The BRAVADO Registry pretends to identify stratification, diagnosis, total atherosclerotic burden and treatment approaches in oncologic patients with Acute Coronary Syndrome (ACS) and identify strategies to improve health care quality
Study Results: NO
Conditions: ACS - Acute Coronary Syndrome|Oncology
Interventions:
Primary Outcome Measures: Major adverse cardiovascular events, Composite endpoint of All-cause Death, Myocardial Infarction, Stroke and Myocardial Revascularization, 30 days|Total Atherosclerotic burden

and lesion complexity on angiography, The number and location of coronary lesions with obstructions greater than 50% were recorded. Each lesion was classified based on Ambrose's, Goldstein complexity, Leaman and SYNTAX scores., 30 days|Incidence of Major Bleeding, Requiring a transfusion of ≥2 U PRBCs Resulting in a decrease in hematocrit of ≥10% Occurring intracerebrally Resulting in stroke or death, 30 days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Sao Paulo General Hospital
Collaborators: Instituto do Cancer do Estado de São Paulo|Beneficência Portuguesa de São Paulo|Instituto de Cardiologia do Rio Grande do Sul|InCor Heart Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 600
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: BRAvAdO
Start Date: 2016-09-01
Primary Completion Date: 2021-09-01
Completion Date: 2021-09-01
First Posted: 2020-01-10
Results First Posted:
Last Update Posted: 2020-01-10
Locations: Carlos M Campos, São Paulo, 05403-900, Brazil
Study Documents:

NCT Number: NCT04896242
Study Title: Multimodal Assesment of Acute Cardiac Toxicity Induced by Thoracic Radiotherapy in Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04896242
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The purpose of this study is to evaluate and compare the changes by two modalities: Imaging by Strain by Speckle Tracking and Magnetic Resonance versus soluble markers of cardiac dysfunction as early predictors of cardio-toxicity in cancer patients receiving low or high doses of radiotherapy.
Study Results: NO
Conditions: Radiotherapy; Complications|Cardiotoxicity|Cancer|Lung Cancer|Breast Cancer|Esophageal Cancer
Interventions:
Primary Outcome Measures: Global Longitudinal Strain (Left Ventricle), \>5 Absolute drop or 12% Relative reduction from baseline, Baseline, 1 and 12 weeks after Treatment
Secondary Outcome Measures: Cardiac Magnetic Resonance Cinema Imaging, Cinema imaging: Long axis balance, Balance 4 cameras, Short shaft full

balance, Right ventricular balance, Baseline, 1 and 12 weeks after treatment|Cardiac Magnetic Resonance Anatomical Image, Inversion recovery single shot balance 3D short axis covering the entire heart and aorta with free respiratory trigger, Baseline, 1 and 12 weeks after treatment|Cardiac Magnetic Resonance Flow Image, 2D outflow tract of the aorta 2D pulmonary artery outflow tract, Baseline, 1 and 12 weeks after treatment|Cardiac Magnetic Resonance Quantitative Image, T1 map short axis apical section T1 map short axis medial section T1 map short axis basal section

T2 map short axis apical section T2 map short axis medial section T2 map short axis basal section, Baseline, 1 and 12 weeks after treatment
Other Outcome Measures: High-sensitivity Cardiac Troponin-T, Troponin rises \>99%th percentile of the upper reference limit, Baseline, 1 and 12 weeks after treatment|N-Terminal pro-Brain Natriuretic Peptide, N-Terminal pro-Brain Natriuretic Peptide, rises \>99%th percentile of the upper reference limit, Baseline, 1 and 12 weeks after treatment|Circulating Endothelial Cells, Number of Circulating Endothelial Cells, Baseline, 1 and 12 weeks after treatment
Sponsor: Pontificia Universidad Catolica de Chile
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 60
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 11190071
Start Date: 2020-01-09
Primary Completion Date: 2022-10-31
Completion Date: 2023-10-31
First Posted: 2021-05-21
Results First Posted:
Last Update Posted: 2023-03-30
Locations: Pontificia Universidad Catolica de Chile, Santiago, Metropolitana, Chile
Study Documents:

NCT Number: NCT05252065
Study Title: Cardiac Substructure Radiation Dose and Early Clinical Monitoring of Stage N2-3 Non-Small Cell Lung Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05252065
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: Calculating which cardiac substructure accepting with the highest radiation dose by conventional radiotherapy, then to investigate the relationship between the changes of global longitudinal strain or cardiac magnetic resonance imaging and cardiac biomarkers and the certain cardiac substructure for stage N2-3 non-

small cell lung cancer
Study Results: NO
Conditions: Non-small Cell Lung Cancer
Interventions: OTHER: Cardiac biomarkers, Echocardiography,Cardiac magnetic resonance imaging
Primary Outcome Measures: Concentration of Troponin I, troponin T, hypersensitive troponin, brain natriuretic peptide and NT-proBNP, These levels are measured with the Siemens ADVIA Centaur XP Immunoassay System, normal ranges of Troponin I, troponin T, hypersensitive troponin, brain natriuretic peptide and NT-proBNP are 0-0.03 ng/mL, 0-0.01 ng/mL, 0-0.04 ng/mL, 0-100 pg/mL, and 0-125pg/mL respectively, through study completion, an average of 1 year|Global longitudinal strain value, global longitudinal strain value is obtained by offline analysis of 2-dimensional Echocardiography, reduction of more than 15% in left ventricular systole suggests some degree of cardiotoxicity by European Society of Cardiology 2016, through study completion, an average of 1 year|The average flow velocity of the anterior descending coronary artery, obtained by phase contrast magnetic resonance arteriography of cardiac magnetic resonance imaging, through study completion, an average of 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Guizhou Medical University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 40
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: GuizhouMuu
Start Date: 2022-02-28
Primary Completion Date: 2022-12-30
Completion Date: 2022-12-30
First Posted: 2022-02-23
Results First Posted:
Last Update Posted: 2022-02-23
Locations:
Study Documents:

NCT Number: NCT03492242
Study Title: Immune CHeckpoint Inhibitors Monitoring of Adverse Drug ReAction
Study URL: https://beta.clinicaltrials.gov/study/NCT03492242
Acronym: CHIMeRA
Study Status: COMPLETED
Brief Summary: Immune checkpoint inhibitors (ICIs) might have high grade immune-related adverse events (irAEs) from rhumatologic, endocrinologic, cardiac or other system origin. This study

investigates reports of drug induced irAEs with treatment including anti-PD1, Anti-PDL-1, and Anti-CTLA4 classes using the World Health Organization (WHO) database VigiBase and the french database Base Nationale de PharmacoVigilance (BNPV).
Study Results: NO
Conditions: Arthritis|Cancer|Cardiac Disease|Endocrine System Diseases|Autoimmune Diseases|Ophthalmopathy|Myositis|Neuropathy
Interventions: DRUG: Immune checkpoint inhibitor
Primary Outcome Measures: Adverse drug reactions induced by ICIs and reported in the World Health Organization (WHO) or the Base Nationale de Pharmacovigilance (BNPV), Identification and report of cases of adverse events associated with ICIs. Drugs investigated are ICIs: Ipilimumab (L01XC11), Nivolumab (L01XC17), Pembrolizumab (L01XC18), Durvalumab (L01XC28), Avelumab (L01XC31), Atezolizumab (L01XC32)., Case reported in the World Health Organization (WHO) or BNPV database of individual safety case reports to May 2018
Secondary Outcome Measures: Causality assessment of reported adverse drug reaction according to the WHO system, Case reported in the World Health Organization (WHO) or BNPV database of individual safety case reports to May 2018|Description of the type of adverse drug reaction depending on the category of ICIs, Case reported in the World Health Organization (WHO) or BNPV database of individual safety case reports to May 2018|Description of the other immune related adverse events concomitant to the adverse drug reaction induced by ICIs, Case reported in the World Health Organization (WHO) or BNPV database of individual safety case reports to May 2018|Description of the duration of treatment when the toxicity happens (role of cumulative dose), Case reported in the World Health Organization (WHO) or BNPV database of individual safety case reports to May 2018|Description of the drug-drug interactions associated with adverse events, Case reported in the World Health Organization (WHO) or BNPV database of individual safety case reports to May 2018|Description of the pathologies (cancer) for which the incriminated drugs have been prescribed, Case reported in the World Health Organization (WHO) or BNPV database of individual safety case reports to May 2018|Description of the population of patients having adverse event, Case reported in the World Health Organization (WHO) or BNPV database of individual safety case reports to May 2018
Other Outcome Measures:
Sponsor: Groupe Hospitalier Pitie-Salpetriere
Collaborators: Institut National de la Santé Et de la Recherche Médicale, France
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CIC1421-18-06

Start Date: 2018-02-01
Primary Completion Date: 2018-09-30
Completion Date: 2018-09-30
First Posted: 2018-04-10
Results First Posted:
Last Update Posted: 2019-09-26
Locations: AP-HP, Pitié-Salpêtrière Hospital, Department of Pharmacology, CIC-1421, Pharmacovigilance Unit, INSERM., Paris, 75013, France
Study Documents:

NCT Number: NCT01014065
Study Title: A Prospective Study of Acute Cardiovascular Effects of First-line Sunitinib in Metastatic Renal Cell Carcinoma Patients (SUnitinib Prospective CardiovasculaR Effect)
Study URL: https://beta.clinicaltrials.gov/study/NCT01014065
Acronym: SUPER
Study Status: COMPLETED
Brief Summary: While sunitinib can be very helpful to treat kidney cancer, these medications can also cause side effects, including heart damage. Studies performed in the past did not look at heart function in detail, so the investigators do not know what happens to the heart when people start sunitinib treatment. The aim of the study is to prospectively study acute effects of sunitinib on heart function, overall fitness and blood markers of heart disease.
Study Results: NO
Conditions: Renal Cell Carcinoma|Cardiotoxicity|Heart Failure|Hypertension
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: AHS Cancer Control Alberta
Collaborators: Cross Cancer Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 42
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 00028 / 24942
Start Date: 2011-07
Primary Completion Date: 2012-11
Completion Date: 2013-01
First Posted: 2009-11-16
Results First Posted:
Last Update Posted: 2016-02-25
Locations: University of Alberta/ Cross Cancer Institute, Edmonton, Alberta, Canada

Study Documents:

NCT Number: NCT05019365
Study Title: Investigating the Long-term Cardiac Sequelae of Trastuzumab Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT05019365
Acronym:
Study Status: RECRUITING
Brief Summary: The introduction of trastuzumab for the treatment of patients with human epidermal growth factor receptor 2 (HER2) positive breast cancer has had a major impact upon cancer outcomes. However, cardiac toxicity remains a substantial concern. Conventionally, this toxicity has been considered as a transient and reversible phenomenon occurring in the immediate peri-treatment period in around 20% of patients. Current guidelines recommend monitoring heart function during treatment and at completion. Recent registry data suggest that trastuzumab-related cardiotoxicity may also manifest in the longer-term. The nature and longer-term prevalence of left ventricular dysfunction with HER2 positive breast cancer treated with trastuzumab is unclear. The aim of this project is to define the prevalence of left ventricular dysfunction late after completion of trastuzumab therapy.
Study Results: NO
Conditions: Breast Cancer|HER2-positive Breast Cancer|Cardiotoxicity
Interventions:
Primary Outcome Measures: Left Ventricular Systolic Dysfunction, To define the prevalence of left ventricular dysfunction in patients who received trastuzumab chemotherapy at least 5 years previously, Through study completion, on average <2years.|Reduced Global Longitudinal Strain (global and segmental), GLS less than 2 standard deviations from normal reference range, using Displacement Encoding with Stimulated Echoes (DENSE) MRI., Through study completion, on average <2years.|Reduced Circumferential Strain (global and segmental), GCS less than 2 standard deviations from normal reference range, using Displacement Encoding with Stimulated Echoes (DENSE) MRI., Through study completion, on average <2years.
Secondary Outcome Measures:
Other Outcome Measures: T1 relaxation times (global and segmental), Left ventricular (LV) Parametric maps (T1, T2, Extracellular volume) will be assessed using a 16 segment model with bespoke MRI analysis software., Through study completion, on average <2years.|T2 decay time (global and segmental), Left ventricular (LV) Parametric maps (T1, T2, Extracellular volume) will be assessed using a 16 segment model with bespoke MRI analysis software., Through study completion, on average <2years.|Extracellular volume fraction (ECV) (global and segmental), Left ventricular (LV) Parametric maps (T1, T2, Extracellular volume) will be assessed using a 16 segment model with bespoke MRI analysis software., Through study completion, on average <2years.|Presence of scar by late gadolinium enhancement (LGE), Late gadolinium enhancement will be assessed using a 16 segment model with bespoke MRI analysis

software., Through study completion, on average <2years.|Aortic Stiffness, Aortic stiffness will be assessed using MRI sequences., Through study completion, on average <2years.|ECG abnormalities, Rhythm and heart rate will be recorded. Evidence of LVH, ST segment deviations and T wave flattening/inversion, and conduction abnormalities including QRS and QT interval will be recorded., Through study completion, on average <2years.|Computational Modelling, To identify novel biomarkers of heart pump function through the generation of computational models in patients who received trastuzumab and age matched healthy volunteers., Through study completion, on average <2years.
Sponsor: University of Glasgow
Collaborators: NHS Greater Glasgow and Clyde|Tenovus Scotland
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 60
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: GN19ON381
Start Date: 2021-03-15
Primary Completion Date: 2022-05-25
Completion Date: 2022-11-25
First Posted: 2021-08-24
Results First Posted:
Last Update Posted: 2021-08-24
Locations: Beatson West of Scotland Cancer Centre, Glasgow, United Kingdom
Study Documents:

NCT Number: NCT04065165
Study Title: Lanreotide Combined With Telotristat Ethyl or Placebo for the First-line Treatment in Patients With Advanced Well Differentiated Small Intestinal Neuroendocrine Tumours (siNET) With Highly-functioning Carcinoid Syndrome
Study URL: https://beta.clinicaltrials.gov/study/NCT04065165
Acronym: TELEFIRST
Study Status: WITHDRAWN
Brief Summary: This is a randomized phase III clinical trial of Lanreotide combined with Telotristat ethyl or placebo for the first-line treatment in patients with advanced well differentiated small intestinal neuroendocrine tumours (siNET) with highly-functioning carcinoid syndrome to test whether telotristat ethyl plus lanreotide is more effective than placebo plus lanreotide in reducing the number of daily bowel movements.

In addition, the study allows evaluation of the biochemical response (5-HIAA and chromogranin-A), the reduction in the number of daily cutaneous flushing episodes, the improvement in abdominal pain/

discomfort, health-related quality of life, improvement in gastro-intestinal and endocrine symptoms, changes in emotional functioning, the impact of discontinuation of telotristat ethyl/placebo on HRQOL and symptoms, and the safety and toxicity of the treatment.

Patients will enter into a screening/run-in period of 1 week to establish baseline characteristics and symptomatology. The baseline assessment of daily bowel movement, as assessed in an electronic diary, will be averaged over the run-in period.

Following the screening/run-in period, patients will be randomly assigned (1:1) to either the control arm or the experimental arm for 12 months. Randomization will be stratified according to the grade of tumour differentiation (grade 1 vs. grade 2) and by baseline number of bowel movements per day (4-6 versus \>6). A total of 94 patients will be randomly assigned (1:1) to either arm.

Upon randomization, all patients will enter the 12-month treatment period with lanreotide + telotristat ethyl/placebo (blinded). In the experimental arm, patients will receive the deep subcutaneous injection of lanreotide (120 mg) every 28 days and 250 mg orally three times daily (TID) of telotristat ethyl for 12 months. In the control arm, patients will receive the deep subcutaneous injection of lanreotide every 28 days (120 mg) and placebo orally TID for 12 months.

After completion of a minimum of 6 months on randomized blinded-treatment, the protocol allows for patients on treatment with telotristat ethyl/placebo to be unblinded in the event of "lack of symptom control". Unblinding due to "lack of symptom control" can happen at any time between 6 and 12 months of the blinded-treatment period. After unblinding, patient will interrupt protocol treatment and will be further treated as per clinician discretion.

All patients will be unblinded after a maximum of 12 months on randomized blinded-treatment.

After a follow-up of 12 months, patients will go off study except patients with carcinoid heart disease. Patients off study will be further treated as per clinician discretion.

Patients with carcinoid heart disease will continue open-label treatment on study (lanreotide + telotristat ethyl or lanreotide alone according to what they were receiving at unblinding at 12 months) for 4 additional years (open-label extension period). Patients with carcinoid heart disease who discontinue protocol treatment before 12 months will also enter the extension period for additional follow-up. Additional follow-up will last 4 years for these patients and will include 6-monthly cardiological assessments.

All efficacy analyses will be conducted in the Intention-to-treat population as primary analyses i.e. all 94 randomized patients will be analyzed in the arm they were allocated by randomization. Safety analyses will be performed on the Safety population i.e. on all patients who have received at least one dose of the study drugs.

The translational research projects include blood metabolite discovery and targeted assays to find new biomarker candidates of response to Telotristat.

Human biological material that will be collected for translational research purpose:

* whole blood, plasma and serum at baseline, 4 hours after first dose, 4 weeks, 12 weeks and at end of treatment visit with telotristat/ placebo (due to end of study, disease progression or lack of benefit)
* archival tissue samples (formalin-fixed paraffin-embedded) will be retrieved for all patients at study entry. In addition, one EDTA blood tube of whole blood (10 ml) at baseline, 12 weeks and end of treatment (EOT visit) might be also collected for not yet pre-defined and further translational research.

Quality of life will be assessed with the EORTC Quality of Life Questionnaire (QLQ-C30) version 3, together with the QLQ-GI.NET21 specific module designed for Neuroendocrine Tumours. The computer-adaptive testing (CAT) diarrhea scale will also be used. The baseline questionnaires must be completed during the screening period and before randomization. Subsequent questionnaires are completed at 4 weeks, 12 weeks, 24 weeks, 36 weeks and 52 weeks. Once a patient has stopped treatment, HRQoL data collection for that patient is required 1 month (28-35 days) after protocol treatment discontinuation.
Study Results: NO
Conditions: Small Intestinal NET|Carcinoid Heart Disease
Interventions: DRUG: Telotristat Ethyl|DRUG: Lanreotide
Primary Outcome Measures: Number of bowel movements (BMs), The change from baseline in the number of bowel movements (BMs) per day, 43 months after first patient in
Secondary Outcome Measures: Urine/serum/plasma 5-HIAA and chromogranin-A, Intrapatient change from baseline in urine/serum/ plasma 5-HIAA and chromogranin-A, 43 months after first patient in|Number of daily cutaneous flushing episodes, Change from baseline in the number of daily cutaneous flushing episodes., 43 months after first patient in|Health Related Quality of Life (HRQoL), Quality of life will be assessed with the EORTC Quality of Life Questionnaire (QLQ-C30) version 3. Scale measures are: not at all; a little; quite a bit; very much., 43 months after first patient in
Other Outcome Measures:
Sponsor: European Organisation for Research and Treatment of Cancer - EORTC
Collaborators: Ipsen

Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 0
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR,
OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: EORTC-1715-GITCG
Start Date: 2020-04
Primary Completion Date: 2023-07
Completion Date: 2027-10
First Posted: 2019-08-22
Results First Posted:
Last Update Posted: 2020-02-05
Locations:
Study Documents:

NCT Number: NCT04547465
Study Title: 2D Speckle-tracking Echocardiography in Chemotherapy-induced Cardiomyopathy With Cardiovascular Risk Factors
Study URL: https://beta.clinicaltrials.gov/study/NCT04547465
Acronym:
Study Status: RECRUITING
Brief Summary: The aims of this study is to evaluate the role of 2D speckle-tracking echocardiography in diagnosis chemotherapy related left ventricular dysfunction in breast cancer patients with cardiovascular risks
Study Results: NO
Conditions: Cardiomyopathy Due to Drug|Breast Cancer|Cardiovascular Risk Factor
Interventions: DIAGNOSTIC_TEST: Echocardiography
Primary Outcome Measures: The incidence of chemotherapy induced cardiomyopathy in breast cancer patients with cardiovascular risk, the incidence, two year follow-up|The kinetics of global longitudinal strain (GLS) in breast cancer patients treated by anthracycline and/or trastuzumab, global longitudinal strain (percentage), two year follow-up|The cut-off value of global longitudinal strain (GLS) to predict chemotherapy induced cardiomyopathy in breast cancer patients treated by anthracycline and/or trastuzumab, global longitudinal strain (percentage), two year follow-up
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Gia Dinh People Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 300

Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 230/HĐĐĐ-ĐHYD
Start Date: 2020-09-15
Primary Completion Date: 2023-05-30
Completion Date: 2023-06-30
First Posted: 2020-09-14
Results First Posted:
Last Update Posted: 2022-08-10
Locations: Nguyen Hoang Hai, Ho Chi Minh, Vietnam
Study Documents:

NCT Number: NCT04118530
Study Title: Long Term Arrhythmia Risk and Cardiovascular Events in Hematopoietic Stem Cell Transplant
Study URL: https://beta.clinicaltrials.gov/study/NCT04118530
Acronym: ARCHER
Study Status: RECRUITING
Brief Summary: The purpose of this study is to better understand the following aims:

1. Aim 1: To evaluate the rate of recurrent Atrial Fibrillation (AF)/ Atrial Flutter (AFL) in hematopoietic stem call transplant (HCST) patients with incident AF/AFL identified during the initial 30 days of the transplant
2. Aim 2: To evaluate incident episodes of 1) stroke/TIA; 2) other thromboembolic events (not stroke/TIA); 3) Heart failure events; 4) Ischemic heart events
3. Aim 3: To evaluate overall implantation safety in this population
Study Results: NO
Conditions: Hematopoietic Stem Cell Transplant|Atrial Fibrillation|Atrial Flutter
Interventions: OTHER: HSCT Patients
Primary Outcome Measures: Recurrent AF/AFL episodes, Any recurrent episodes of AF/AFL lasting ≥2 minutes identified in ICM monitoring, 1 year
Secondary Outcome Measures: Incident Episodes of Interest, Incident episodes of: stroke/TIA; other thromboembolic events (not stroke/TIA); Heart failure events; ischemic heart events. Overall device implantation safety., 1 year
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators: Medtronic
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 70
Funder Type: OTHER
Study Type: OBSERVATIONAL

Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC35420
Start Date: 2021-04-21
Primary Completion Date: 2023-04
Completion Date: 2023-04
First Posted: 2019-10-08
Results First Posted:
Last Update Posted: 2022-06-02
Locations: Abramson Cancer Center at University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT02220231
Study Title: Echocardiographic Evaluation of the Change on Pulmonary Blood Flow and Cardiac Function Induced by Capnothorax During One Lung Ventilation
Study URL: https://beta.clinicaltrials.gov/study/NCT02220231
Acronym:
Study Status: COMPLETED
Brief Summary: Video-assisted thoracoscopic extended thymectomy (VATET) is a minimally-invasive method for excision of mediastinal mass instead of open thymectomy. The iatrogenic capnothorax with one-lung ventilation during VATET may cause hemodynamic instability due to the compression of intrathoracic structures. The purpose of this study is to evaluate the effects of capnothorax on the pulmonary blood flow and cardiac function during the VATET by using the transesophageal echocardiography.
Study Results: NO
Conditions: Mediastinal Tumors
Interventions: PROCEDURE: capnothorax
Primary Outcome Measures: The changes of the echocardiographic indices, pulmonary blood flow = PVA(cross sectional area of LUPV) x VTI(velocity time integral) x HR , Fractional area change = \[(LVAd-LVAs)/LVAd\] × 100 Ejection fraction = \[(LVEDV(LV end-diastolic volume) -LVESV(LV end-systolic volume)/LVEDV\] × 100, four time points during the operation. (1)10 min after induction (baseline); (2) 1 min after CO2 insufflation; (3)10 min after of CO2 insufflation; and (4)20 min after CO2 insufflation
Secondary Outcome Measures: The changes of the oxygenation and respiratory dynamic parameters, shunt fraction Qs/Qt = (CcO2- CaO2)/(CcO2- CvO2) CcO2 = Hgb x 1.34 x ScO2 + PcO2 x 0.003, lung compliance : Compliance= Vt / Pplat, physiologic dead space : Vd/Vt = 1.14 x (PaCO2 - PETCO2)/PaCO2- 0.005, four time points during the operation, an expected average of 3 hours. (1)10 min after induction (baseline); (2) 1 min after CO2 insufflation; (3)10 min after of CO2 insufflation; and (4)20 min after CO2 insufflation
Other Outcome Measures:
Sponsor: Yonsei University
Collaborators:
Sex: ALL

Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 25
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose:
Other IDs: 4-2014-0492
Start Date: 2014-08
Primary Completion Date: 2015-03
Completion Date: 2015-03
First Posted: 2014-08-19
Results First Posted:
Last Update Posted: 2015-04-17
Locations:
Study Documents:

NCT Number: NCT03673631
Study Title: Oxygenation Methods and Non-invasive Ventilation in Patients With Acute Respiratory Failure and a do Not Intubate Order
Study URL: https://beta.clinicaltrials.gov/study/NCT03673631
Acronym: OXYPAL
Study Status: UNKNOWN
Brief Summary: ICU care of patients considered "palliative" but without contraindications to admission to intensive care, for whom a do-not intubate order decision was made upon admission represents a particular target for non-invasive oxygenation techniques. The benefits of non invasive ventilation (NIV) in this population are debated especially in cancer patients. The more recently used nasal humidified high flux canula oxygenation (HFNC) therapy may have benefits over NIV in these patients. It is supposed to have better tolerance and could allow better compliance and thus higher efficiency. These potential benefits are major for such a population for which tolerance and symptomatic relief are priority goals
Study Results: NO
Conditions: Acute Respiratory Failure|Cancer|Hematologic Malignancy|Cardiac Insufficiency|Chronic Respiratory Insufficiency
Interventions: DEVICE: NIV|DEVICE: NFHC-O2
Primary Outcome Measures: Survival at day 14, Survival at day 14 in patients weaned from NIV and or HNFC-O2, day 14
Secondary Outcome Measures: Clinical respiratory parameters evolution, respiratory rate improvement will be assessed by a decrease of respiratory rate below 20/min, day 1, day 2, day 3|Oxygenation parameters evolution, sPO2 (oxygen saturation) expressed in % improvement will be assessed by an increase above 92%, day 1, day 2, day 3|tolerance of technique of oxygenation, tolerance will be assessed by comfort visual analogic scale from 1 worse tolerance to 10 very good tolerance; improvement defined as a 20% decrease of the value, day 1, day 2, day 3|evolution of quality of life, quality of life will be measured by the EuroQuality of life 5D score (EQ5D)

recording 5 subscore (mobility, autonomy, ability to perform current activities, pain, anxety/depression); the value of each is from 1 to 3 points; total score is the sum of the 5 subscores with a minimal score of 5 and a maximal score of 15. The baseline score will be recorded after admission in the ICU and reflects the patient's quality of life just before his or her admission. After 3 and 6 months, a higher value of the score will represent a worse outcome., on admission and after 3 and 6 months after ICU stay|Acceptation of the non invasive technique, tolerance defined by the absence of refusal to continue the technique (NIV or HNFC O2) by the patient, day 14|mortality day 28, percentage of patients deceased at day 28 whatever the cause of death, day 28
Other Outcome Measures:
Sponsor: Poitiers University Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 330
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: OXY-PAL
Start Date: 2018-08-07
Primary Completion Date: 2020-01
Completion Date: 2020-01
First Posted: 2018-09-17
Results First Posted:
Last Update Posted: 2018-09-28
Locations: Chu de Poitiers, Poitiers, 86000, France
Study Documents:

NCT Number: NCT04014231
Study Title: Novel Single Wave Assessment in Measuring Cardiac Dysfunction and Metabolic Syndrome in Patients With Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT04014231
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This clinical trial studies a novel single wave assessment in measuring cardiac dysfunction and metabolic syndrome in patients with cancer. The novel single wave assessment is a hand held device that can report left ventricular ejection fraction, which measures how well the heart is pumping blood (by giving a percentage) and measures how stiff the arteries are in the heart (pulse wave velocity). A novel single wave assessment may help identify patients at increased risk for type II diabetes and metabolic syndrome (disease where patients have increased blood pressure and high blood sugar level and excess body fat around the waist and abnormal cholesterol levels).
Study Results: NO
Conditions: Malignant Neoplasm

Interventions: PROCEDURE: Diagnostic Imaging|OTHER: Laboratory Biomarker Analysis
Primary Outcome Measures: Single wave measure of insulin resistance (delta omega) and markers of inflammation, The agreement of the single wave-based ejection fraction (EF) to EF measured by 2-dimensional (2D) echocardiography will be estimated in this study. Generalized linear models will be fitted to insulin resistance as the dependent variable and the inflammation markers as independent variables, adjusted for sex, age, and other clinical factors, along with an indicator of MetS (1 if present; 0 if absent) and the interactions of MetS and the inflammation markers to examine their association with insulin resistance., Up to end of single wave assessment|Difference in left ventricular ejection fraction (LVEF) measured by the single wave application and 2D echocardiography, Initially, the measurements from the two methods will be plotted to visualize their agreement. The Bland-Altman plot will then be used to assess the degree of agreement. The difference in LVEF measured by the two methods will be plotted against the mean of the measurements from the two methods. The 95% confidence interval for the mean difference will be determined. Sensitivity and specificity of the single wave-based LVEF measure for various cutpoints of LVEF from 2D echocardiography (as the gold standard) will also be computed. Pearson correlation coefficient will be calculated., Up to end of single wave assessment
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: City of Hope Medical Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 160
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 15317|NCI-2015-01612|15317
Start Date: 2017-07-21
Primary Completion Date: 2023-12-31
Completion Date: 2023-12-31
First Posted: 2019-07-10
Results First Posted:
Last Update Posted: 2023-03-30
Locations: City of Hope Medical Center, Duarte, California, 91010, United States
Study Documents:

NCT Number: NCT03862131
Study Title: PROactive Evaluation of Function to Avoid CardioToxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT03862131
Acronym: PROACT
Study Status: TERMINATED

Brief Summary: This study is intended to evaluate the ability of an intramyocardial strain analysis package with cardiac MRI to assist in the early detection and management of cardiotoxicity from therapeutics used to treat cancer.
Study Results: NO
Conditions: Cardiotoxicity|Breast Cancer|Lymphoma|Sarcoma|Leukemia|Myeloma|Lung Cancer
Interventions: DEVICE: MyoStrain®
Primary Outcome Measures: Sensitivity and accuracy of detection of patients with myocardial dysfunction who necessitate cardioprotection during cancer treatment using MyoStrain compared to standard of care (SOC) as measured by left ventricular ejection fraction, -Receiver operating characteristic curves will be used to identify criteria for standard of care and MyoStrain cardiac features to detect subclinical cardiotoxicity.

-. Considering many patients will have a complex management of cardioactive medications as well as cancer treatment regimen, the classification of cardiotoxicity status will be based on a clinical committee to designate whether the patient experienced no cardiotoxicity, functional decline without cardiotoxicity, subclinical cardiotoxicity, or clinical cardiac dysfunction at each exam time point, Through 36 months|Sensitivity & accuracy of detection of patients requiring cardioprotection therapy for cardiotoxicity during cancer treatment who demonstrate an improvement in myocardial function using MyoStrain compared to SOC as measured by LVEF, -Receiver operating characteristic curves will be used to identify criteria for standard of care and MyoStrain cardiac features to detect improvement in cardiac function due to cardioprotective therapy in patients exhibiting cardiotoxicity

-. Considering many patients will have a complex management of cardioactive medications as well as cancer treatment regimen, the classification of cardiotoxicity status will be based on a clinical committee to designate whether the patient experienced no cardiotoxicity, functional decline without cardiotoxicity, subclinical cardiotoxicity, or clinical cardiac dysfunction at each exam time point, Through 36 months|Sensitivity and accuracy of detection of patients at risk of developing cardiotoxicity using MyoStrain compared to standard of care as measured by left ventricular ejection fraction, -Receiver operating characteristic curves will be used to identify criteria for standard of care and MyoStrain cardiac features to predict risk of developing cardiotoxicity.

-. Considering many patients will have a complex management of cardioactive medications as well as cancer treatment regimen, the classification of cardiotoxicity status will be based on a clinical committee to designate whether the patient experienced no cardiotoxicity, functional decline without cardiotoxicity, subclinical cardiotoxicity, or clinical cardiac dysfunction at each exam time

point, Through 36 months|Ability of MyoStrain testing to detect subclinical cardiac dysfunction compared to standard cardiac imaging as measured by left ventricular ejection fraction, Multivariate regression and logistic regression will be used with "stepwise" option to identify significant predictors for standard of care and MyoStrain cardiac features for predicting cardiotoxicity. Furthermore, the investigators will use decision trees for identifying the importance of MyoStrain cardiac features in cardiotoxicity risk prediction based on standard assessment of variables, Through 36 months|Impact of MyoStrain imaging on medical management of cardiotoxicity through early detection of at risk patients compared to standard cardiac imaging as measured by left ventricular ejection fraction, Multivariate regression and logistic regression will be used with "stepwise" option to identify significant predictors at standard of care and MyoStrain cardiac features for detecting improvement in cardiac function due to cardioprotective therapy in patients exhibiting cardiotoxicity. Furthermore, the investigators will use decision trees for identifying the importance of MyoStrain cardiac features in cardioprotection risk prediction based on standard assessment of variables, Through 36 months|Ability of MyoStrain testing to detect risk of developing cardiotoxicity compared to standard cardiac imaging as measured by left ventricular ejection fraction, Multivariate regression and logistic regression will be used with "stepwise" option to identify significant predictors at standard of care and MyoStrain cardiac features for predicting risk of developing cardiotoxicity. Furthermore, the investigators will use decision trees for identifying the importance of MyoStrain segmental intramyocardial strain in cardiotoxicity risk prediction based on standard assessment of variables, Through 36 months|Sensitivity and accuracy of detection of patients with myocardial dysfunction who necessitate cardioprotection during cancer treatment using MyoStrain compared to standard of care (SOC) as measured by stroke (LVSV) volumes indexed to body surface area, Receiver operating characteristic curves will be used to identify criteria for standard of care and MyoStrain cardiac features to detect subclinical cardiotoxicity.

-. Considering many patients will have a complex management of cardioactive medications as well as cancer treatment regimen, the classification of cardiotoxicity status will be based on a clinical committee to designate whether the patient experienced no cardiotoxicity, functional decline without cardiotoxicity, subclinical cardiotoxicity, or clinical cardiac dysfunction at each exam time point, Through 36 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Washington University School of Medicine
Collaborators: Myocardial Solutions
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: PHASE2
Enrollment: 49
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, CARE_PROVIDER)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 201809177
Start Date: 2019-03-13
Primary Completion Date: 2023-03-02
Completion Date: 2023-03-02
First Posted: 2019-03-05
Results First Posted:
Last Update Posted: 2023-03-06
Locations: Washington University School of Medicine, Saint Louis, Missouri, 63110, United States
Study Documents:

NCT Number: NCT03964142
Study Title: Exercise-based Cardiac Rehabilitation for the Prevention of Breast Cancer Chemotherapy-induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT03964142
Acronym: ONCORE
Study Status: COMPLETED
Brief Summary: This project aims to determine whether a comprehensive cardiac rehabilitation program including supervised exercise training is able to prevent cardiotoxicity during treatment with anthracyclines and / or anti-HER-2 antibodies in women with breast cancer. Participants will be randomly allocated to cardiac rehabilitation (intervention group) or conventional management with physical exercise recommendation (control group).
Study Results: NO
Conditions: Cardiotoxicity|Cardiac Rehabilitation
Interventions: OTHER: Cardiac rehabilitation
Primary Outcome Measures: Change in left ventricular systolic function quantified by left ventricular ejection fraction and global longitudinal strain by transthoracic echocardiography, Fall of 10 absolute percentage points of left ventricular ejection fraction with final value below 53% or global longitudinal strain fall \>15% with respect to baseline, Baseline to every 3 months through study completion, at the end of the study at an average of 18 months, and every year after study completion up to a maximum of 5 years
Secondary Outcome Measures: Change in health-related quality of life assessed by the Functional Assessment of Cancer Therapy - Breast plus Arm Morbidity (FACT-B+4) questionnaire, Score achieved in the Functional Assessment of Cancer Therapy - Breast plus Arm Morbidity (FACT-B+4) questionnaire, a specific validated scale to assess quality of life of women with breast cancer. It comprises 27 items within 5 areas of assessment: physical well-being (7 items), social and family environment (7 items), emotional well-being (7 items), functional

well-being (6 items) and worries related to the diagnosis and treatment of the disease (9 items). Each item is scored by means of a Likert scale from 0 to 5, with higher scores representing better results. The total score is obtained by adding the scores for each item, and ranges from a minimum of 0 (worst posible result) to a maximum of 146 (best possible result)., Baseline and at the end of the study at an average of 18 months|Change in tolerance to chemotherapy: number of participants with significant cardiovascular and non-cardiovascular adverse effects throughout the study, Significant cardiovascular and non-cardiovascular adverse effects during treatment, threatening life, requiring admission, prolonging hospitalization, being clinically relevant or causing chemotherapy interruptions, Every 3 months during study completion and at the end of the study at an average of 18 months|Change in global functional capacity assessed by conventional ergometry, cardiopulmonary exercise testing (CPET) or the 6-minute walking test (6MWT)., Change in functional capacity assessed by conventional ergometry, cardiopulmonary exercise test or the 6-minute walking test (6MWT) (metabolic equivalents: METs or peak oxygen consumption: VO2) * .

*Due to COVID-19 pandemic, participants' assessment with CPET had to be stopped for safety concerns. In such cases, functional capacity was estimated from the maximum work rate in the 6-minute walking test (6MWT). This test measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes, which is well correlated with VO2. The 6MWT has been proved to be valid and reliable for functional capacity assessment in the study population., Baseline and at the end of the study at an average of 18 months|Change in localized lower limb functional capacity assessed by number of repetitions performed within 30 seconds in the sit-to-stand test, Number of repetitions in the sit-to-stand test within 30 seconds, Baseline and at the end of the study at an average of 18 months|Change in shoulder functional capacity assessed by range of degrees in shoulder movement by goniometry, Range of degrees in shoulder movement measured by goniometry, Baseline and at the end of the study at an average of 18 months|Change in upper limb strength measured by dynamometry (kg), Kilograms by dynamometry of right and left upper limbs, Baseline and at the end of the study at an average of 18 months|Change in shoulder pain and disability assessed by the SPADI (shoulder pain and disability index (SPADI) questionnaire, Score achieved in the SPADI (shoulder pain and disability index) questionnaire. The pain dimension consists of five questions regarding the severity of an individual's pain, functional activities are assessed with eight questions. Each question may be scored from 0 to 10. Verbal anchors for the pain dimension are 'no pain at all' (0) and 'worst pain imaginable' (10) ,and those for the functional activities are 'no difficulty' (0) and 'so difficult it required help' (10). The scores from both dimensions are averaged to produce a total score ranging from 0 (best) to 100 (worst)., Baseline and at the end of the study at an average of 18 months|Change in cardiovascular risk profile

as assessed by the presence or absence of classic cardiovascular risk factors, Dyslipidemia, Diabetes mellitus, Arterial Hypertension, Smoking status, Baseline and at the end of the study at an average of 18 months|Change in anthropometric parameters: height in cm, Height measured in cm, Baseline and at the end of the study at an average of 18 months|Change in anthropometric parameters: weight in kg, Weight measured in kg, Baseline and at the end of the study at an average of 18 months|Change in anthropometric parameters: body mass index (BMI) in kg/m^2, Weight and height will be combined to report BMI in kg/m\^2, Baseline and at the end of the study at an average of 18 months|Change in anthropometric parameters: abdominal circumference in cm, Abdominal perimeter measured with a tape measure in cm, Baseline and at the end of the study at an average of 18 months|Change in resting heart rate measured by pulse oximetry (beats per min), Resting heart rate by pulse oximetry (beats per min), Baseline and at the end of the study at an average of 18 months|Change in resting blood pressure (mmHg) measured by sphygmomanometer, Resting blood pressure by sphyngomanometer in mmHg, Baseline and at the end of the study at an average of 18 months|Change in biomarkers NT-ProBNP, Value of NT-ProBNP(pg/mL) in blood tests, Baseline and at the end of the study at an average of 18 months|Change in biomarkers: troponin, Value of troponin I (ng/mL) in blood tests, Baseline and at the end of the study at an average of 18 months|Change in biomarkers: haemoglobin, Value of haemoglobin (g/dL) in blood tests, Baseline and at the end of the study at an average of 18 months|Change in dietary pattern as assessed by the PREDIMED (PREvención con DIeta MEDiterránea) questionnaire, Validated questionnaire to assess adherence to Mediterranean diet, including 14 questions regarding dietary habits, rated with 0 or +1 points. Global score is calculated by summing points and ranges from 0 to 14, with higher score representing higher adherence., Baseline and at the end of the study at an average of 18 months|Change in the score for depression assessed by Zigmond and Snaith questionnaire to rate anxiety and depression, Score achieved in the depression subscale of the Zigmond and Snaith test for anxiety or depression, a self-applied questionnaire. Depression scale includes 7 items each, scored on Likert scale from 0 to 3. Global score ranges from 0 to 21, with higher scores representing greater depression. The authors suggest that scores higher than eleven would indicate "case" and more than eight would be considered "probable case" (Zigmond and Snaith, 1983)., Baseline and at study completion at an average of 18 months, plus at the end of training (at an average of 12 to 15 months) in the intervention group|Change in the score for anxiety assessed by the Zigmond and Snaith questionnaire to rate depression and anxiety, Score achieved in the anxiety subscale of the Zigmond and Snaith test for anxiety or depression, a self-applied questionnaire. Anxiety scale includes 7 items each, scored on Likert scale from 0 to 3. Global score ranges from 0 to 21, with higher scores representing greater anxiety. The authors suggest that scores higher than eleven would indicate "case" and more than eight would be considered "probable case" (Zigmond and Snaith, 1983)., Baseline and at study completion,

plus at the end of training (at an average of 12 to 15 months) in the intervention group|Change in physical activity (minutes of dedicated physical activity), Minutes of In- and out-of-hospital dedicated physical activity, Baseline and at study completion at an average of 18 months|Change in physical activity assessed by the score in the Godin Leisure Test Exercise Questionnaire (GLTEQ), Score achieved in the Godin Leisure Test Exercise Questionnaire (GLTEQ) for quantification of physical activity. Activities are classified into three subgroups: "strenuous," "moderate," and "light." The scores corresponding to the energy expenditure (metabolic equivalent (MET)) are obtained by multiplying activities performed for more than 15 min in a week with their coefficients. The numbers represent the MET intensity values (strenuous/ exhausting exercises: 9 METs, moderate exercises: 5 METs, and light exercises: 3 METs).The increasing scores are associated with the increasing number of exercise behaviors, providing references about the contribution of physical activity to health: the activity score of 24 units and more as active (substantial benefits); the activity score of 14-23 units as moderately active (some benefits); and the activity score of 13 units and less as inactive (less substantial or low benefits)., Baseline and at study completion at an average of 18 months|Change in lymphedema assessed by perimeter of the upper limb by cirtometry (cm), stage and grade, Perimeter of the upper limb by cirtometry (cm), stage and grade as defined by the Spanish Society of Rehabilitation and Physical Medicine, Baseline after surgery and 2-4 weeks after the end of chemotherapy (at an average of 12 to 15 months)
Other Outcome Measures: Adherence and compliance to cardiac rehabilitation program (intervention group) assessed by number of training sessions attended/ number of sessions planned, Number of training sessions attended / number of sessions planned, At the end of the cardiac rehabilitation program at an average of 12 to 15 months| Security of the cardiac rehabilitation program assessed by number of adverse events during training (intervention group), Adverse events during training, At the end of the cardiac rehabilitation program at an average of 12 to 15 months|Changes in expectations regarding the cardiac rehabilitation program assessed by a questionnaire (intervention group), Program-related expectations at baseline and at the end of the program' are collected through an open question "What do you expect to achieve by participating in the program?" Responses regarding expectations will be categorized by the evaluator within the following areas: psychological sphere and/or social sphere and/or physical sphere. Global expectations of benefit are scored from 0 (no benefit) to 10 (highest benefit)., Baseline and at the end of the cardiac rehabilitation program at an average of 12 to 15 months| Satisfaction with the cardiac rehabilitation program assessed by a questionnaire (intervention group), Satisfaction at the end of the program is assessed by a questionnaire including 9 questions concerning comfort with training sessions, training spaces and development of the program, which are scored from 0 (worse posible result) to 10 (best posible result). Total score is calculated by

adding for each question, and ranges from 0 to 90.

* Due to the introduction of telematic exercise training during COVID-19 pandemic, questions were slightly modified to include assessment of satisfaction with this training modality., At the end of the cardiac rehabilitation program at an average of 12 to 15 months
Sponsor: Hospital Clinico Universitario de Santiago
Collaborators: Instituto de Salud Carlos III
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 122
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: PI17/01687
Start Date: 2018-08-01
Primary Completion Date: 2022-03-30
Completion Date: 2023-01-01
First Posted: 2019-05-28
Results First Posted:
Last Update Posted: 2023-05-12
Locations: Hospital Clínico Universitario de Santiago, Santiago de Compostela, A Coruña, 15706, Spain
Study Documents:

NCT Number: NCT03437642
Study Title: Psyhosomatic Medicine in Oncologic and Cardiac Disease Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03437642
Acronym: PSYCHONIC
Study Status: UNKNOWN
Brief Summary: Psychological processes play a complex role in the pathophysiology of many diseases. However, the body and emotional perception of patients and the relationship between dreams and disease still need to be investigated.

The investigators planned an observational and controlled research aimed at assessing some previously unaddressed baseline psychological characteristics and their changes at 1 and 5 years after a short-term psychotherapy in carefully characterised patients with heart or oncologic diseases .

The patients that will be enrolled are:

* 50 patients ≤ 75 year old with acute myocardial infarction;
* 30 patients ≤ 75 year old with Tako-Tsubo syndrome;
* 50 women ≤ 75 year old, recently operated on breast cancer:
* 90 control subjects of the same age and gender of the enrolled

patients, without relevant pathologies during the last 10 years. Relevant pathologies are defined as those that required a hospitalisation or a long-lasting medical therapy.

At the enrolment all the subjects will undergo a complete medical evaluation, and the following psychometric tests: Self-evaluation test, Social Support Questionnaire, Beck Depression Inventory II (BDI II), MacNew Heart Disease Health-Related Quality of Life Questionnaire, State-Trait Anxiety Inventory (STAI), State-Trait Anger Expression Inventory (STAXI 2).

In two distinct following meetings, an open questionnaire exploring the body and emotional perception, and another exploring past and recent dreams, will be administered.

The same evaluation will be done for the healthy subjects.

After the initial evaluation, all the patients will be given the choice to start a short-term psychotherapy lasting 6 months on top of medical therapy or to continue classic medical therapy only. Healthy subjects will be not offered the possibility to follow psychotherapy.

At first year of follow-up, the battery of psychometric test, and the two questionnaires exploring the body and emotional perception, and changes and characteristics of dreams during the psychotherapy, will be re-administered.

The following data will be evaluated:

Psychological characteristics at follow-up. Incidence of new relevant medical events Quality of life Relationship between psychological characteristics and health status, and quality of life

At 5 year follow-up psychometric tests and the clinical data will be evaluated in all the groups.
Study Results: NO
Conditions: Acute Myocardial Infarction|Tako Tsubo Cardiomyopathy|Breast Cancer
Interventions: BEHAVIORAL: Short Term Psychotherapy
Primary Outcome Measures: Cumulative incidence of new relevant medical events, Relevant medical events are defined as any new medical condition significantly impairing normal daily activities or requiring hospitalization or needing specific and permanent drug treatment., at 1 year
Secondary Outcome Measures: Cumulative incidence of new relevant medical events, Relevant medical events are defined as any new medical condition significantly impairing normal daily activities or requiring hospitalization or needing specific and permanent drug treatment., at 5 years|Changes in body perception and dreams, These changes will be evaluated with dedicated qualitative questionnaires formulated with

open questions., at 1 year|Incidence of rehospitalisations, Number of rehospitalisations during the first year of follow-up, at 1 year|Incidence of rehospitalisations, Number of rehospitalisations during 5 years follow-up, at 5 years|Distress grade, Self-evaluation test (score range 1-10, higher stress for higher values), at 1 year|Distress grade, Self-evaluation test (score range 1-10, higher stress for higher values), at 5 years|Depression symptoms, Beck depression inventory II (score range 0-63, more severe depression symptoms for higher values), at 1 year|Depression symptoms, Beck depression inventory II (score range 0-63, more severe depression symptoms for higher values), at 5 years|Social support, Social support questionnaire (score range 12-72, the higher the score the lower the support), at 1 year|Social support, Social support questionnaire (score range 12-72, the higher the score the lower the support), at 5 year|Quality of life, Mac New Health-related quality of life questionnaire (score range 1-7, the higher the score the higher the quality of life, 4 subscales not merged), at 1 year|Quality of life, Mac New Health-related quality of life questionnaire (score range 1-7, the higher the score the higher the quality of life, 4 subscales not merged), at 5 years|Anxiety grade, State-Trait Anxiety inventory (score range 20-80, the higher the score the more anxiety the patients has, 2 subscales), At 1 year|Anxiety grade, State-Trait Anxiety inventory (score range 20-80, the higher the score the more anxiety the patients has, 2 subscales), At 5 years|Anger level, State-Trait Anger Expression inventory (score range 0%-100%, the higher the score the higher the anger, two subscales), at 1 year|Anger level, State-Trait Anger Expression inventory (score range 0%-100%, the higher the score the higher the anger, two subscales), at 5 years
Other Outcome Measures:
Sponsor: San Filippo Neri General Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 220
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: v24-9-2017
Start Date: 2018-03-27
Primary Completion Date: 2022-12
Completion Date: 2022-12
First Posted: 2018-02-19
Results First Posted:
Last Update Posted: 2019-09-18
Locations: San Filippo Neri General Hospital, Roma, 00135, Italy
Study Documents:

NCT Number: NCT02796365
Study Title: Prevention Using Exercise Rehabilitation to Offset

Cardiac Toxicities Induced Via Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT02796365
Acronym: HF-PROACTIVE
Study Status: COMPLETED
Brief Summary: The purpose of this study is to identify patients at risk for future heart failure using novel markers of early cardiac damage and determine if exercise training can improve these emerging markers as well as overall fitness and quality of life.
Study Results: NO
Conditions: Doxorubicin Induced Cardiomyopathy|Breast Cancer|Gastric Cancer|Leukemia
Interventions: OTHER: Exercise
Primary Outcome Measures: Left ventricular strain, Spectral Doppler measure with General Electric software analysis of global longitudinal strain., 12 weeks
Secondary Outcome Measures: Peak VO2, During a graded treadmill test, breath-by-breath sampling of expired air will be measured using a MGC Diagnostics gas exchange analysis system., 12 weeks|Percent body fat, Body fat will be analyzed using air displacement plethysmography (BodPod/Cosmed), 12 weeks|Isokinetic strength, Peak torque will be measured using the Biodex Isokinetic dynamometer., 12 weeks|Quality of life, Quality of life will be assessed using the Functional Assessment of Cancer Therapy (FACT-G)., 12 weeks|Cardiac Troponin, High sensitivity cardiac troponin will be analyzed using a commercial immunoassay., 12 weeks
Other Outcome Measures:
Sponsor: Henry Ford Health System
Collaborators: Helen L. Kay Charitable Trust
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 29
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: HFHS-HF_PROACTIVE
Start Date: 2016-06
Primary Completion Date: 2018-12
Completion Date: 2018-12
First Posted: 2016-06-10
Results First Posted:
Last Update Posted: 2018-12-13
Locations: William Clay Ford Center for Athletic Medicine, Detroit, Michigan, 48202, United States
Study Documents:

NCT Number: NCT03394365
Study Title: Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Participants With Epstein-Barr Virus-Associated Post-

Transplant Lymphoproliferative Disease (EBV+ PTLD) After Failure of Rituximab or Rituximab and Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT03394365
Acronym: ALLELE
Study Status: RECRUITING
Brief Summary: The purpose of this study is to determine the clinical benefit and characterize the safety profile of tabelecleucel for the treatment of Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) in the setting of (1) solid organ transplant (SOT) after failure of rituximab and rituximab plus chemotherapy or (2) allogeneic hematopoietic cell transplant (HCT) after failure of rituximab.
Study Results: NO
Conditions: Epstein-Barr Virus+ Associated Post-transplant Lymphoproliferative Disease (EBV+ PTLD)|Solid Organ Transplant Complications|Lymphoproliferative Disorders|Allogeneic Hematopoietic Cell Transplant|Stem Cell Transplant Complications
Interventions: BIOLOGICAL: tabelecleucel
Primary Outcome Measures: Objective response rate (ORR) in the SOT or HCT cohort, 2 years
Secondary Outcome Measures: Duration of response (DOR) in SOT and HCT cohorts separately, 2 years|ORR and DOR in SOT and HCT cohorts combined, 2 years|Rates of complete response (CR) and partial response (PR), 2 years|Time to response, 2 years|Time to best response, 2 years|Overall survival (OS), 2 years|Rates of allograft loss or rejection episodes (SOT cohort), 2 years
Other Outcome Measures:
Sponsor: Atara Biotherapeutics
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 66
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: ATA129-EBV-302
Start Date: 2017-12-29
Primary Completion Date: 2022-06
Completion Date: 2027-06
First Posted: 2018-01-09
Results First Posted:
Last Update Posted: 2022-06-24
Locations: City of Hope (Adults and Pediatrics), Duarte, California, 91010, United States|University of California San Diego Moores Cancer Center (Adults only), La Jolla, California, 92093, United States|Loma Linda University Cancer Center (Adults only), Loma Linda, California, 92354, United States|Children's Hospital Los Angeles, Div. of Research Immunology/BMT (Adults and Pediatrics), Los Angeles, California,

90027, United States|UCLA Medical Center (Adults and Pediatrics), Los Angeles, California, 90095, United States|University of California Davis Comprehensive Cancer Center (Adults only), Sacramento, California, 95817, United States|Yale University (Adults and Pediatrics), New Haven, Connecticut, 06519, United States|MedStar Georgetown University Hospital (Adults and Pediatrics), Washington, District of Columbia, 20007, United States|University of Florida (Adults and Pediatrics), Gainesville, Florida, 32610, United States|University of Miami/Jackson Memorial Hospital (Adults only), Miami, Florida, 33136, United States|Children's Healthcare of Atlanta at Egleston (Pediatrics), Atlanta, Georgia, 30322-1060, United States|Winship Cancer Institute of Emory University (Adults only), Atlanta, Georgia, 30322, United States|Ann & Robert H. Lurie Children's Hospital of Chicago (Adults and Pediatrics), Chicago, Illinois, 60611, United States|University of Chicago Medical Center - Duchossois Center for Advanced Medicine (Adults only), Chicago, Illinois, 60637, United States|Loyola University Medical Center (Adults and Pediatrics), Maywood, Illinois, 60153, United States|University of Maryland School of Medicine (Adults only), Baltimore, Maryland, 21201, United States|Dana Farber Cancer Institute, Brigham and Women's Hospital (Adults and Pediatrics), Boston, Massachusetts, 02215, United States|Washington University School of Medicine (Adults only), Saint Louis, Missouri, 63110, United States|Montefiore Medical Center (Adults only), Bronx, New York, 10467, United States|Montefiore Medical Center (Pediatrics only), Bronx, New York, 10467, United States|Weill Cornell Medicine (Adults only), New York, New York, 10021, United States|Columbia University Medical Center (Adults and Pediatrics), New York, New York, 10032, United States|Memorial Sloan Kettering Cancer Center (Adults and Pediatrics), New York, New York, 10065, United States|University of North Carolina at Chapel Hill, Lineberger Comprehensive Cancer Center (Adults and Pediatrics), Chapel Hill, North Carolina, 27599, United States|Carolinas Medical Center/Levine Children's Hospital (Adults and Pediatrics), Charlotte, North Carolina, 28204, United States|Duke Cancer Institute (Adults only), Durham, North Carolina, 27710, United States|Cleveland Clinic Foundation (Adults and Pediatrics), Cleveland, Ohio, 44195, United States|Nationwide Children's Hospital (Pediatrics only), Columbus, Ohio, 43205, United States|The Ohio State University - Arthur G. James Cancer Center Hospital (Adults and Pediatrics), Columbus, Ohio, 43210, United States|Oregon Health and Science University Physicians Pavilion (Adults and Pediatrics), Portland, Oregon, 97239, United States|Children's Hospital of Philadelphia (Pediatrics only), Philadelphia, Pennsylvania, 19104, United States|University of Pennsylvania (Adults only), Philadelphia, Pennsylvania, 19104, United States|University of Pittsburgh Medical Center (Adults only), Pittsburgh, Pennsylvania, 15232, United States|Medical University of South Carolina (Adults and Pediatrics), Charleston, South Carolina, 29425, United States|Saint Jude Children's Research Hospital (Pediatrics only), Memphis, Tennessee, 38105, United States|Vanderbilt University Medical Center Henry-Joyce Cancer Clinic (Adults and Pediatrics), Nashville,

Tennessee, 37232, United States|Baylor Scott and White Research Institute (Adults only), Dallas, Texas, 75246, United States| University of Texas Southwestern Medical Center – Children's Medical Center (Pediatrics only), Dallas, Texas, 75390, United States|MD Anderson Cancer Center (Adults and Pediatrics), Houston, Texas, 77030, United States|Froedtert Hospital & the Medical College of Wisconsin (Adults only), Milwaukee, Wisconsin, 53226, United States|The Children's Hospital at Westmead (Pediatrics only), Westmead, New South Wales, 2145, Australia|Westmead Hospital (Adults only), Westmead, New South Wales, 2145, Australia|The Prince Charles Hospital (Adults only), Chermside, Queensland, 4032, Australia|Royal Adelaide Hospital (Adults only), Adelaide, South Australia, 5000, Australia|The Royal Children's Hospital Melbourne (Pediatrics only), Melbourne, Victoria, 3052, Australia|Fiona Stanley Hospital (Adults only), Murdoch, Western Australia, 6150, Australia|Medizinische Universitat Wien (Adults only), Wien, 1090, Austria|Centre Hospitalier Universitaire de Liège Site Sart Tilman (Adults and Pediatrics), Liège, Brussels, 4000, Belgium|Universitair Ziekenhuis Leuven (Adults and Pediatrics), Leuven, Flemish Brabant, 3000, Belgium|Alberta Children's Hospital (Adults and Pediatrics), Calgary, Alberta, T3B 6A8, Canada|Sick Kids (Pediatrics only), Toronto, Ontario, M5G 1X8, Canada|Princess Margaret Cancer Centre (Adults only), Toronto, Ontario, M5G 2M9, Canada|Groupe Hospitalier du Haut Leveque (Adults only), Pessac, Aquitaine, 33600, France|Hôpital Saint Antoine (Adults only), Paris, Ile-de-France, 75571, France|Centre Hospitalier Régional Universitaire de Lille (Adults and Pediatrics), Lille cedex, Nord-Pas-de-Calais, 59037, France|Hôpital Necker-Enfants Malades (Pediatrics only), Paris 15, Île-de-France, 75015, France|Hôpital Universitaire Pitié Salpêtrière (Adults only), Paris Cedex 13, Île-de-France, 75651, France|Azienda Socio Sanitaria Territoriale Grande Ospedale Metropolitano Niguarda (Adults only), Milano, 20162, Italy|Fondazione IRCCS Policlinico San Matteo (Adults and Pediatrics), Pavia, 27100, Italy|Fondazione Policlinico Universitario Agostino Gemelli (Adults only), Roma, 00168, Italy|Ospedale Pediatrico Bambino Gesu (Pediatrics only), Roma, 165, Italy|Azienda Ospedaliera – Universitaria Città della Salute e della Scienza di Torino (Adults only), Torino, 10126, Italy|Hospital Duran i Reynals, Badalona, Barcelona, 8908, Spain|Hospital Universitario Marqués de Valdecilla (Adults and Pediatrics), Santander, Cantabria, 39008, Spain|Hospital Universitari Vall d'Hebrón – Institut de Recerca (Adults and Pediatrics), Barcelona, 08035, Spain|Hospital General Universitario Gregorio Marañón (Adults and Pediatrics), Madrid, 28009, Spain|University Hospital Virgen del Rocio (Adults and Pediatrics), Sevilla, 41013, Spain|Hospital Universitario La Fe (Adults and Pediatrics), Valencia, 46009, Spain|University Hospitals Birmingham NHS Foundation Trust (Adults only), Birmingham, England, B15 2GW, United Kingdom|King's College Hospital NHS Foundation Trust (Adults only), London, England, SE5 9RS, United Kingdom|Imperial College Healthcare NHS Trust (Adults only), London, England, W12 0HS, United Kingdom

Study Documents:

NCT Number: NCT00547365
Study Title: Human Immune Globulin in Treating Patients With Primary Amyloidosis That is Causing Heart Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT00547365
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Antibodies, such as human immune globulin, can block the growth of abnormal cells in different ways. Some block the ability of abnormal cells to grow and spread. Others find abnormal cells and help kill them or carry cell-killing substances to them. Giving human immune globulin may be effective in treating patients with primary amyloidosis that is causing heart dysfunction.

PURPOSE: This phase I/II trial is studying the side effects and best dose of human immune globulin and to see how well it works in treating patients with primary amyloidosis that is causing heart dysfunction.
Study Results: YES
Conditions: Multiple Myeloma|Plasma Cell Neoplasm
Interventions: BIOLOGICAL: Human immune globulin intravenous (IGIV)
Primary Outcome Measures: Tolerance for Human Immune Globulin Intravenous (IGIV), as Reflected by the Number and Severity of Toxicity Incidents Occurring in Ten Patients Receiving at Least One Infusion of IGIV., Up to 1 year|Clinical Response of Patients With Cardiac-dominant AL Amyloidosis Given Human Immune Globulin Intravenous (IGIV), Positive clinical response was defined by improvement in heart function in participating patients with cardiac-dominant AL amyloidosis, as demonstrated by increased serum anti-fibril immunoglobulin G (IgG) antibody levels and reduction (or no evident progression) in amyloid burden., Up to 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Tennessee
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1|PHASE2
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CDR0000572104|BRCC-BHS-06127|UTCI-2645
Start Date: 2007-10
Primary Completion Date: 2011-07
Completion Date: 2011-07
First Posted: 2007-10-22
Results First Posted: 2013-02-04
Last Update Posted: 2013-09-19
Locations: Baptist Regional Cancer Center at Baptist Riverside,

Knoxville, Tennessee, 37901, United States|St. Mary's Medical Center, Powell, Tennessee, 37849, United States
Study Documents:

NCT Number: NCT04680442
Study Title: Safety of Continuing HER-2 Directed Therapy in Overt Left Ventricular Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT04680442
Acronym: SCHOLAR-2
Study Status: RECRUITING
Brief Summary: Trastuzumab is an important treatment for HER 2 positive breast cancer. But trastuzumab can cause injury to the heart, and this is one of the main reasons it cannot be administered as planned. Heart injury can often be successfully treated using cardiac medications. The objectives of SCHOLAR-2 are to evaluate whether is it safe and effective to continue trastuzumab, pertuzumab or trastuzumab-emtansine (T-DM1) in patients with early stage HER-2 positive breast cancer despite mild, minimally symptomatic or asymptomatic systolic left ventricular dysfunction as compared with a guideline-driven approach of withholding or discontinuing trastuzumab, pertuzumab or trastuzumab-emtansine (T-DM1).

In SCHOLAR-2, we will compare two thresholds of withholding or discontinuing trastuzumab/pertuzumab/trastuzumab-emtansine: a threshold that is currently advocated for by existing treatment practice guidelines versus a more aggressive threshold that allows trastuzumab/pertuzumab/trastuzumab-emtansine to continue at lower levels of LVEF than currently supported by guideline documents.
Study Results: NO
Conditions: Breast Cancer|Heart Failure
Interventions: DRUG: Trastuzumab|DRUG: Pertuzumab|DRUG: Trastuzumab emtansine
Primary Outcome Measures: primary efficacy outcome, the proportion of participants completing trastuzumab, pertuzumab, or trastuzumab-emtansine (T-DM1) as planned at its initiation, one year|co-primary safety outcomes, 1. LVEF at the close-out visit, and
2. The composite of NYHA class III or IV heart failure or cardiovascular death., one year
Secondary Outcome Measures: secondary outcome measures the composite of NYHA class III or IV heart failure, breast cancer relapse, or all-cause mortality., the composite of NYHA class III or IV heart failure, breast cancer relapse, or all-cause mortality., one year
Other Outcome Measures:
Sponsor: Population Health Research Institute
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 130
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: PHRI.SCHOLAR-2
Start Date: 2021-07-01
Primary Completion Date: 2024-01-01
Completion Date: 2025-12-01
First Posted: 2020-12-23
Results First Posted:
Last Update Posted: 2023-03-27
Locations: Hospital de Clínicas de Porto Alegre, Porto Alegre, Rio Grande Do Sul, 90035903 / 90410000, Brazil|Irmandade Da Santa Casa De Misericórdia De Porto Alegre, Porto Alegre, Rio Grande Do Sul, 90050-170, Brazil|Hospital Alemão Oswaldo Cruz, São Paulo, 01327-903, Brazil|Clínica de Pesquisa e Centro de Estudos em Oncologia Ginecológica e Mamária Ltda, São Paulo, 1317000, Brazil|Juravnski Cancer Centre, Hamitlon, Ontario, Canada|Ottawa Hospital Research Institute, Ottawa, Ontario, Canada|Toronto General Hospital, University Health Network, Toronto, Ontario, M5G 2N2, Canada|E.Meshalkin National medical research center of the Ministry of Health of the Russian Federation, Novosibirsk, 630055, Russian Federation
Study Documents:

NCT Number: NCT04852965
Study Title: Late Anthracycline Induced Cardiotoxicity- Childhood Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT04852965
Acronym:
Study Status: RECRUITING
Brief Summary: Anthracyclines treat up to 60% of childhood malignancies with remarkable improvements survival rates. Unfortunately anthracyclines are associated with an increased cardiomyopathy risk. One study showed an almost six-fold greater risk of developing cardiomyopathy compared to sibling controls. A retrospective pilot study showed evidence of subclinical dysfunction (including impaired global longitudinal strain) in 42/52 childhood cancer survivors. There is limited research in this area, therefore current guidelines are based on expert opinion alone and lack consensus. Current methods of detection diagnose cardiomyopathy at an irreversible stage i.e. when the compensatory mechanisms are exhausted and the left ventricular ejection fraction impaired. Small trials have shown that early treatment with standard heart failure therapy may reverse damage, further validation is however required in this cohort.

Newer techniques such as tissue doppler and strain rate imaging have shown promise for early prediction of cardiomyopathy in adult studies. Biomarkers such as troponin and NT-proBNP have also shown a correlation with cardiomyopathy.

This study (n=208) aims to use echocardiography, strain imaging, holter monitoring and MRI for early detection of cardiomyopathy. Biomarkers, both currently used (for example, troponin and NTproBNP,) and more novel (for example, IL6, MPO, and sST2) will be assessed to see if early cardiomyopathy can be predicted.

This study will explore biomarker discovery by analysing an age/gender matched subgroup for the top differentially expressed microRNA and protein biomarkers. Selected biomarkers will then be validated in a larger cohort.
Study Results: NO
Conditions: Anthracycline Induced Cardiotoxicity
Interventions:
Primary Outcome Measures: Cardiotoxicity, Number of participants with anthracycline related cardiotoxicity as defined by the British Society of Echocardiography and British Cardio-Oncology Society guidelines, 2 years
Secondary Outcome Measures: Incidence of myocardial injury, Levels of high sensitivity troponin T and NT-proBNP, 2 years
Other Outcome Measures:
Sponsor: Queen's University, Belfast
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 208
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: B21/01
Start Date: 2021-10-20
Primary Completion Date: 2023-07
Completion Date: 2024-01
First Posted: 2021-04-21
Results First Posted:
Last Update Posted: 2022-09-13
Locations: Belfast Health and Social Care Trust, Belfast, BT9 7AB, United Kingdom
Study Documents:

NCT Number: NCT04262830
Study Title: Cancer Therapy Effects on the Heart
Study URL: https://beta.clinicaltrials.gov/study/NCT04262830
Acronym: CTEH
Study Status: RECRUITING
Brief Summary: Anthracycline chemotherapies (e.g. doxorubicin, daunorubicin) are commonly given to treat pediatric cancer, and carry a risk of cardiotoxicity. Over the long term, children who receive these therapies have an increased risk of heart failure and early cardiovascular death. However, current strategies for identifying

patients who are at risk prior to the development of significant changes in heart function are limited. This study will focus on imaging markers of cardiac injury and dysfunction with the goal of developing improved diagnostic tests and treatment strategies.
Study Results: NO
Conditions: Cardiotoxicity|Pediatric Cancer|Heart Failure
Interventions: DIAGNOSTIC_TEST: Cardiac magnetic resonance imaging (MRI)|DIAGNOSTIC_TEST: Echocardiography|DIAGNOSTIC_TEST: Electrocardiogram
Primary Outcome Measures: Left ventricular ejection fraction (LVEF), LVEF is an assessment of left ventricular global systolic function., 5 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Hari Narayan
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 60
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 181758
Start Date: 2019-09-30
Primary Completion Date: 2022-09-30
Completion Date: 2029-09-30
First Posted: 2020-02-10
Results First Posted:
Last Update Posted: 2021-04-30
Locations: Rady Children's Hospital, San Diego, California, 92123, United States
Study Documents:

NCT Number: NCT03748030
Study Title: Hybrid PET/MR Imaging of Acute Cardiac Inflammation After Left-Sided Breast Cancer Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT03748030
Acronym: RICT-BREAST
Study Status: UNKNOWN
Brief Summary: Radiation therapy (RT) of the breast is a critical component of modern breast cancer treatment. RT treatments have led to improved local control and overall survival of breast cancer patients. However, the incidence of radiation induced harmful effects is increasing in these patients. This is because in delivering RT, it is difficult to completely avoid surrounding non-cancerous normal tissue, including the heart. The main concern here is that radiation induced effects on the heart may lead to an increased risk of cardiovascular disease later in a patient's life, potentially many years after radiation. Despite methods that can detect alterations in blood flow

one to two years following radiotherapy, knowledge of early radiation effects to the heart is still limited. A previous animal experiment performed by our group involved delivering a radiation dose to the heart in a manner similar to the way a heart would be exposed, during radiotherapy for a cancer involving the left breast. Taking several images over the months following radiation with a new imaging technique, hybrid PET/MRI, has suggested an increase in inflammation can be detected as early as one-week following irradiation and may be the triggering event for cardiac disease seen in women 10-15 years after radiotherapy. The investigators propose a pilot study where 15 left-sided breast cancer patients undergoing radiotherapy will be imaged before, as well as one week and one-year post radiotherapy with our hybrid PET/MRI scanner. Areas of inflammation, changes in blood flow, and scar formation within the heart, will be measured by looking at the difference between images that are taken after radiation treatment to the images taken before treatment. The expectation is that any areas of the heart that show detectable differences in the images will be directly related to how much radiation was deposited in those areas. The information gained from this pilot study which will correlate the amount of radiation administered to the degree and extent of injury will help aid in the design of new treatment strategies, that can hopefully decrease or eliminate inadvertent heart damage, thereby, improving the quality of life for breast cancer patients.
Study Results: NO
Conditions: Left-Sided Breast Cancer|Radiation Toxicity
Interventions: RADIATION: Confirmed Left-Sided Breast Cancer
Primary Outcome Measures: Detection of Imaging Biomarkers of acute cardiac inflammation, 18F-2-fluoro-2-deoxy-D-glucose fluorodeoxyglucose (FDG)-PET imaging to detect increase in cardiac inflammation compared to baseline with corresponding blood markers (Erythrocyte Sedimentation Rate (ESR), high sensitivity C-reactive protein, and troponin levels in blood (inflammation))., one month|Detection of Imaging Biomarkers of late cardiac inflammation, FDG-PET imaging to detect increase in cardiac inflammation compared to baseline with corresponding blood markers (Erythrocyte Sedimentation Rate (ESR), high sensitivity C-reactive protein, and troponin levels in blood (inflammation))., one year|Detection of Imaging Biomarkers of acute cardiac perfusion changes, N-13 Ammonia PET imaging to detect changes in acute cardiac perfusion changes compared to baseline., one month|Detection of Imaging Biomarkers of late cardiac perfusion changes, N-13 Ammonia PET imaging to detect changes in late cardiac perfusion changes, one year|Detection of cardiac fibrosis, Gadolinium Enhanced MR imaging to detect cardiac fibrosis compared to baseline, one year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Lawson Health Research Institute
Collaborators:
Sex: FEMALE

Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 15
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 112991
Start Date: 2019-01-01
Primary Completion Date: 2020-12-31
Completion Date: 2021-12-31
First Posted: 2018-11-20
Results First Posted:
Last Update Posted: 2018-11-27
Locations: Lawson Health Research Institute, London, Ontario, N6C 2R5, Canada
Study Documents:

NCT Number: NCT01809730
Study Title: Pilot Study: Cardiovascular Events in High Risk Orthopedic Surgical Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT01809730
Acronym:
Study Status: WITHDRAWN
Brief Summary: This is a non-randomized, non-interventional pilot observational study designed to follow high-risk patients through their surgical and hospital stay. The investigators will collect 2 4ml vial's of blood (total of 8ml) prior to surgery to assess CV biomarkers - inflammatory, metabolic, hypercoagulable and platelet.
Study Results: NO
Conditions: Coronary Artery Disease|Cerebral Vascular Disease|Peripheral Artery Disease|Renal Insufficiency|Diabetes|COPD|Hypertension|Active Smoker|Cancer|CHF|Prior DVT/PE
Interventions:
Primary Outcome Measures: Cardiac ischemia/necrosis, 30 days|Venous thromboembolism, 30 days|Pulmonary embolism, 30 dyas|Myocardial infarction, 30 Days|Cerebral vascular event, 30 days|Death, 30 days|Transient ischemic attack, 30 days|Surgical site infection, 30 days|Delayed wound healing, 30 days|Clinically relevant bleeding, 30 days|Transfusion within 48 hours post-op, 30 days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: NYU Langone Health
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 0
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p

Other IDs: S12-02513
Start Date: 2012-05
Primary Completion Date: 2020-01
Completion Date: 2020-01
First Posted: 2013-03-13
Results First Posted:
Last Update Posted: 2015-11-17
Locations: NYU Hospital for Joint Diseases, New York, New York, 10003, United States
Study Documents:

NCT Number: NCT05443321
Study Title: Advancing Health Information Exchange (HIE) During Inter-hospital Transfer (IHT) to Improve Patient Outcomes
Study URL: https://beta.clinicaltrials.gov/study/NCT05443321
Acronym:
Study Status: RECRUITING
Brief Summary: Sub-optimal transfer of clinical information during inter-hospital transfer (IHT, the transfer of patients between acute care hospitals) is common and can lead to patient harm. To address this problem, the investigators will use key stakeholder input to refine and implement an interoperable health information exchange platform that integrates with the electronic health record and improves the reliability of and access to necessary clinical information in three use cases involving transfer of patients between sending and receiving hospitals with varying levels of affiliation and health record integration. The investigators will assess the effect of this intervention on frequency of medical errors, evaluate the use and usability of this platform from the perspective of those that interact with it, and use these results to develop a dissemination plan to spread implementation and use of this platform across other similar institutions.
Study Results: NO
Conditions: Infections|Heart Failure|COPD Exacerbation|Asthma|Gastrointestinal Diseases|Cardiac Event|Arrythmia|Renal Failure|Renal Disease|Rheumatic Diseases|Urologic Diseases|Neurologic Disorder|Hematologic Diseases|Oncology Problem|Shock|Critical Illness
Interventions: OTHER: Health Information Exchange (HIE) platform
Primary Outcome Measures: Total clinician-reported medical errors, Collected via a survey of admitting clinicians 48-72 hours after patient transfer., Up to 72 hours after transfer
Secondary Outcome Measures: Clinician-reported medical errors attributable to poor information exchange, Collected via a survey of admitting clinicians 48-72 hours after patient transfer., Up to 72 hours after transfer|Total clinician-reported adverse events, Collected via a survey of admitting clinicians 48-72 hours after patient transfer., Up to 72 hours after transfer|Preventable clinician-reported adverse events, Collected via a survey of admitting clinicians 48-72 hours after patient transfer., Up to 72 hours after transfer|Ameliorable clinician-reported adverse events, Collected via

a survey of admitting clinicians 48-72 hours after patient transfer., Up to 72 hours after transfer|Clinician-reported quality of clinical information available, Collected via a survey of admitting clinicians 48-72 hours after patient transfer., Up to 72 hours after transfer|Length of stay after transfer, Collected from administrative data, From time-of-day and date of transfer to time-of-day and date of hospital discharge|Rapid response or ICU transfer within 72-hours of patient transfer, Collected from administrative data, Up to 72-hours after transfer|Time between acceptance of transfer to patient arrival, Collected from administrative data. From time documented that the patient was accepted for transfer until the time the patient arrives at the transferring hospital, Up to 3 days prior to transfer|Time between transferred patient arrival and entry of admission orders, Collected from administrative data. From time documented that the transferred patient arrived at the accepting hospital until the time that the admission orders were placed, Up to 24-hours after transfer
Other Outcome Measures:
Sponsor: Brigham and Women's Hospital
Collaborators: Agency for Healthcare Research and Quality (AHRQ)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1000
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SEQUENTIAL|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: 2022P001284
Start Date: 2022-11-01
Primary Completion Date: 2025-03-01
Completion Date: 2027-06-30
First Posted: 2022-07-05
Results First Posted:
Last Update Posted: 2023-05-19
Locations: Brigham & Women's Hospital, Boston, Massachusetts, 02115, United States
Study Documents:

NCT Number: NCT05724121
Study Title: Observational Study of Cardiac Arrhythmias in Subjects Treated With BTK Inhibitors
Study URL: https://beta.clinicaltrials.gov/study/NCT05724121
Acronym:
Study Status: RECRUITING
Brief Summary: Background:

Bruton s tyrosine kinase inhibitors (BTKi) are used to treat a form of leukemia. But taking BTKi can also increase a person s risk of developing an abnormal heart rhythm. This can cause sudden death. In this natural history study, researchers want to learn how BTKi affects

the heart.

Objective:

To identify and monitor the effects of BTKi on the heart.

Eligibility:

People aged 18 and older currently receiving or planning to receive BTKi.

Design:

Participants who have not yet started BTKi will have 2 required clinic visits: 1 before they start taking BTKi, and 1 about 6 months later. Participants who are already taking BTKi will have 1 required visit.

Participants will undergo multiple tests:

A physical exam, including collection of blood and saliva.

A test that measures heart activity via stickers placed on the chest.

A test that uses sound waves to capture images of the heart.

An exercise stress test that monitors heart activity and blood pressure while the participant works on a treadmill or stationary bike. Sound wave images of the heart may also be taken while the participant exercises.

Stress magnetic resonance imaging (MRI) may be done in place of an exercise test. Participants will lie on a table that slides into a tube. They will be given drugs to stress the heart while images are taken.

Participants may wear a device to monitor their heart at home.

Participants may have repeat visits if they develop heart symptoms or if they need to stop taking BTKi. They will have follow-up phone calls each year for up to 3 years.
Study Results: NO
Conditions: Chronic Lymphocytic Leukemia (CLL)|Waldenstr(SqrRoot)(Delta)m s Macroglobulinemia|Mantle Cell Lymphoma|Sudden Cardiac Death|Cardiac Arrhythmias|Hematologic Malignancies
Interventions:
Primary Outcome Measures: arrhythmogenic cardiac effects of BTKi and sudden death within the first 12 months of BTKi therapy, 1. Clinically significant cardiac arrhythmias while on a BTKi (treatment emergent in those without a history of arrhythmias and worsening of arrhythmia for those with an arrhythmia at the time of enrollment testing) within 12

months. For Cohort A, if a patient has an arrhythmia at the time of baseline testing, only worsening or new arrhythmias will be called an event. For Cohort B, all arrhythmias will be called an event. 2. Sudden death, 12 months
Secondary Outcome Measures: tests for identifying and monitoring cardiac arrhythmias in patients receiving BTKi, -Detection of arrhythmias on devices (rest EKG, stress EKG, ambulatory EKG monitor, KardiaMobile) -Clinically significant and other arrhythmias (treatment emergent or worsening) in patients on BTKi -Sudden death -Differences in cardiac arrhythmias and sudden death within BTKi (e.g., ibrutinib vs. non-ibrutinib group), 36 months
Other Outcome Measures:
Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 110
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 10000923|000923-H
Start Date: 2023-03-01
Primary Completion Date: 2027-04-08
Completion Date: 2027-04-08
First Posted: 2023-02-13
Results First Posted:
Last Update Posted: 2023-07-17
Locations: National Institutes of Health Clinical Center, Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT02975921
Study Title: Betadine Pleurodesis Via Tunneled Pleural Catheters
Study URL: https://beta.clinicaltrials.gov/study/NCT02975921
Acronym:
Study Status: WITHDRAWN
Brief Summary: The purpose of this study is to determine whether betadine (povidone-iodine) instillation during routine indwelling Tunneled Pleural Catheter (TPC) placement is efficacious in promoting pleurodesis and thus reducing the time to TPC removal.
Study Results: NO
Conditions: Pleural Effusion|Pleurodesis|Malignant Pleural Effusion|Pleural Effusion Due to Congestive Heart Failure|Pleural Effusion in Conditions Classified Elsewhere|Pleural Effusions, Chronic
Interventions: DRUG: Povidone-Iodine
Primary Outcome Measures: Time to Tunneled Pleural Catheter Removal, The time (in days) between Tunneled Pleural Catheter (TPC) placement to eventual removal within 6 months, 0-6 months
Secondary Outcome Measures: Pleurodesis Rate, Rate of patients who

achieved successful pleurodesis within 2 months as defined as successful TPC removal with no reaccumulation of pleural effusion on subsequent imaging (usually 2-3 weeks later). Typical for usual care is 45-50%. In observational studies using povidone-iodine pleurodesis in other manners (not via TPC), a 90% pleurodesis rate was observed (which should be similar to our study with intervention)., 2 months|Infection Rate, Any skin/site infections or empyemas (pleural based infections) noted within 6 months of TPC placement. The longer a TPC is in place, the higher the rate of infection we would expect. The expected infection rate is between 5-25% at 2 months and this should be dramatically lower in the intervention arm as most of them will have their TPCs removed within 1 week or so., 6 months|Death, Any deaths that occur and how long after TPC placement and the patients age at death. As patients are quite systemically ill when they receive TPCs, these comorbidities would be expected to be the primary drivers of patient mortality. Typical values seen in the literature is a mortality rate of 30-70% at 6 months. There should be essentially no difference between groups., 6 months|Mechanical Complications, Any mechanical complications related to the TPC itself such as catheter malfunction or accidental removal. This would be a rare complication and the expected rate will be \<5%. The incidence of this will rise the longer it is in place for., 6 months|Baseline Borg Dyspnea Index, The Borg Dyspnea Index is a standardized, validated tool to measure a patient's dyspnea. This will be measured at baseline prior to Tunneled Pleural Catheter Placement., Baseline|Borg Dyspnea Index at 2 weeks, The Borg Dyspnea Index is a standardized, validated tool to measure a patient's dyspnea. This will be measured 2 weeks after tunneled pleural catheter placement., 2 weeks|Borg Dyspnea Index at 2 months, The Borg Dyspnea Index is a standardized, validated tool to measure a patient's dyspnea. This will be measured 2 months after tunneled pleural catheter placement., 2 months|Borg Dyspnea Index at 4 months, The Borg Dyspnea Index is a standardized, validated tool to measure a patient's dyspnea. This will be measured 4 months after tunneled pleural catheter placement., 4 months|Borg Dyspnea Index at 6 months, The Borg Dyspnea Index is a standardized, validated tool to measure a patient's dyspnea. This will be measured 6 months after tunneled pleural catheter placement., 6 months|Quality of Life Questionnaire at Baseline, Quality of Life will be measured via a WHOQOL-BREF questionnaire which is a standardized, validated tool to measure a patient's quality of life. This will be measured at baseline prior to the procedure., Baseline|Quality of Life Questionnaire at 2 weeks, Quality of Life will be measured via a WHOQOL-BREF questionnaire which is a standardized, validated tool to measure a patient's quality of life. This will be measured 2 weeks after TPC placement., 2 weeks|Quality of Life Questionnaire at 2 months, Quality of Life will be measured via a WHOQOL-BREF questionnaire which is a standardized, validated tool to measure a patient's quality of life. This will be measured 2 months after TPC placement., 2 months|Quality of Life Questionnaire at 4 months, Quality of Life will be measured via a WHOQOL-BREF questionnaire which is a standardized, validated tool to

measure a patient's quality of life. This will be measured 4 months after TPC placement., 4 months|Quality of Life Questionnaire at 6 months, Quality of Life will be measured via a WHOQOL-BREF questionnaire which is a standardized, validated tool to measure a patient's quality of life. This will be measured 6 months after TPC placement., 6 months|Baseline Pain, Pain at baseline - immediately prior to procedure., Baseline|Pain 2 hours after procedure, Pain at 2 hours after the procedure., 2 hours after procedure|Pain 6 hours after procedure, Pain at 6 hours after the procedure., 6 hours after procedure|Immediate hemodynamic reactions following betadine administration, Any severe hemodynamic fluctuations (such as severe hypotension or hypertension) noted after the procedure. The patient will monitored by nursing staff in a recovery area and any events will be noted immediately. The expected rate of this is \<5%., 0-6 hours after procedure
Other Outcome Measures:
Sponsor: Yale University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: TREATMENT
Other IDs: 2000020017
Start Date: 2018-07
Primary Completion Date: 2020-09
Completion Date: 2021-06
First Posted: 2016-11-29
Results First Posted:
Last Update Posted: 2019-01-11
Locations:
Study Documents:

NCT Number: NCT05705531
Study Title: A Study About How Blood Cell Growth Patterns Relate to Heart Health After Treatment for Hodgkin Lymphoma
Study URL: https://beta.clinicaltrials.gov/study/NCT05705531
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: This study assesses how blood cell growth patterns (clonal hematopoiesis), relates to heart health or cardiovascular disease (CVD) after treatment in patients with Hodgkin lymphoma. In some patients, cancer treatment at a young age may lead to later complications, including problems with heart health. Checking for blood cell growth patterns called therapy-related clonal hematopoiesis (t-CH) can help predict who might be at risk for heart health problems after Hodgkin lymphoma treatment. If doctors know who may be at

greater risk for developing later heart complications, then they can more closely monitor those patients to prevent or detect heart complications early.
Study Results: NO
Conditions: Cardiovascular Disorder|Clonal Hematopoiesis|Hodgkin Lymphoma
Interventions: PROCEDURE: Biospecimen Collection|OTHER: Electronic Health Record Review|PROCEDURE: Magnetic Resonance Imaging|OTHER: Survey Administration
Primary Outcome Measures: Proportion of therapy-related clonal hematopoiesis (t-CH) for patients with cardiovascular disease (CVD) after Hodgkin Lymphoma therapy, The proportions will be compared with one-sided Fisher's Exact Test with normal approximation and significance level 0.05 for primary., Up to 1 year|Proportion of t-CH with mutations for patients with CVD after Hodgkin Lymphoma therapy, The proportions of t-CH mutation for patients without CVD after Hodgkin Lymphoma therapy. The proportions will be compared with one-sided Fisher's Exact Test with normal approximation and significance level 0.05 for primary., Up to 1 year|Proportion of t-CH for patients without CVD after Hodgkin Lymphoma therapy, The proportions will be compared with one-sided Fisher's Exact Test with normal approximation and significance level 0.05 for primary., Up to 1 year|Proportion of t-CH with mutations for patients without CVD after Hodgkin Lymphoma therapy, The proportions will be compared with one-sided Fisher's Exact Test with normal approximation and significance level 0.05 for primary., Up to 1 year|Objective signs of CVD, Left Ventricular Ejection Fraction (LVEF), \< 55%, Up to 1 year|Objective signs of CVD, Global Longitudinal Strain (GLS) less negative than -18%, Up to 1 year|Objective signs of CVD, Left Ventricular End Diastolic Volume indexed to body surface are (LVEDVi) \> 85 mL:/meter\^2., Up to 1 year
Secondary Outcome Measures: Expansion of CH, The outcome is the expansion of the CH, which will be expressed as the variant allele fraction (VAF) (CH verses the total normal DNA in the sample). Graphic analysis to reveal the time varying trend in the association between the expansion of CH over time and the presence/worsening of CVD signs and apply generalized estimating equation method (with each patient as cluster unit) to quantify this association while controlling for the potential correlation of repeated measurements within each patient., Up to 1 year|Association between the presence of CVD and individual variables, The outcome is the presence of CVD. This aim is to determine if there is an association between the presence of CVD and the individual variables constituting the clinical profile, either parametric (e.g., independent t-test, Chi\^2-test, Pearson correlation coefficients) or nonparametric (e.g., Wilcoxon rank sum tests, Spearman's rank correlation coefficients) methods will be applied. Bootstrapping techniques might be used as a method of inference which does not rely on a specific underlying distribution. The statistical significance level will be set to 0.05 and all data analysis will be done using SAS statistical software (version 9.4)., Up to 1 year
Other Outcome Measures: Prevalence and nature of CVD, CH and CH with

mutations associated with cardiovascular disease, The outcome is the expansion of the CH, which will be expressed as the variant allele fraction (VAF) (CH verses the total normal DNA in the sample). The VAFs and their exact 90% (Clopper-Pearson) confidence intervals are used to summarize the prevalence and nature of CVD, CH and CH with mutations associated with CVD for patients receiving mediastinal radiation., Up to 1 year|Patient characteristics and treatments, The outcome here is the incidence of t-CH with mutation. The specific patient characteristic and treatments (age, gender, race, dexrazoxane usage etc.) will be used to predict the incidence of t-CH with mutation. Regression model will be constructed to evaluate the effect of these patient characteristics and treatments on the incidence of t-CH with mutation rate, which will be presented by p-values, coefficients and their confidence intervals., Up to 1 year|Effect of therapy-related clonal hematopoiesis on cardiovascular disease, The outcome is the cardiovascular disease defined by cMRI (section 7.1). This aim is to evaluated the effect of other covariates such as patient characteristics (age, gender, race, etc.) and clinical conditions (radiation treatment with cardiac dosimetry, follow-up duration, etc.) on cardiovascular disease., Up to 1 year
Sponsor: Children's Oncology Group
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 161
Funder Type: NETWORK
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ALTE21C1|NCI-2022-09972|COG-ALTE21C1|COG-ALTE21C1|ALTE21C1|UG1CA189955
Start Date: 2023-05-20
Primary Completion Date: 2028-10-01
Completion Date: 2028-10-01
First Posted: 2023-01-30
Results First Posted:
Last Update Posted: 2023-04-11
Locations:
Study Documents:

NCT Number: NCT03981731
Study Title: Management of Perioperative Anxiety by the Cardiac Coherence Technique Coupled With a Hypnosis Session
Study URL: https://beta.clinicaltrials.gov/study/NCT03981731
Acronym: COHEC
Study Status: COMPLETED
Brief Summary: the investigator proposes to use the cardiac coherence technique coupled with a hypnosis session to improve post-operative recovery.
Study Results: NO

Conditions: Breast Cancer|Gynecologic Cancer
Interventions: OTHER: Cardiac coherence
Primary Outcome Measures: Proportion of patients who have enrolled in the pre-habilitation program, A patient will be considered to have optimally adhered to the program if she performs at least 2/3 of the proposed cardiac coherence sessions (that represents 67% of the total number of sessions), that is, at least 14 sessions over the 7 days preceding the surgery., 7 days
Secondary Outcome Measures: The preoperative anxiety score by using the Amsterdam Preoperative Anxiety and Information Scale (APAIS), The anxiety scale consists of six items, each of which could be scored from 1 to 5 with the end poles "not at all" (1) and "extremely" (5). The score of the anxiety scale is the sum of these four questions, with a scoring range from 6 to 30., 7 days|Patient's satisfaction with perioperative period by using "Evaluation of the Vecu of General Anesthesia" questionnaire (EVAN-G), The validated EVAN-G questionnaire includes 26 questions whose results are grouped together to define 6 "dimensions": Attention Focus, Information, Privacy, Pain, Discomfort and Wait Times. From these scores, an overall satisfaction score is calculated (average of all scores). For each of the scores: the higher the score, the higher the satisfaction. For each dimension, scores were reduced on a scale from 0 to 100. The higher the score, the higher the perceived quality of the experience. The total score was the sum of the scores of the six dimensions reduced to 100., 48 hours|Measurement of the Postoperative Quality of Recovery (QoR), The quality of postoperative functional recovery will be assessed by the QoR-15 questionnaire, which assesses five dimensions of recovery (physical comfort ; emotional state ; physical independence ; physiological support ; and pain). Each item was rated on a ten-point Likert scale: none of the time, some of the time, usually, most of the time, and all the time. The total score on the QoR-15 ranges from 0 (poorest quality of recovery) to 150 (best quality of recovery)., 10 days|Measurement of anxiety level by using a visual analogue scale, It's a visual scale from 0 (no anxiety) to 100 (highest anxiety), 7 days|Measurement of wake-up quality by using a visual analogue scale, It's a visual scale from 0 (best wake-up) to 100 (worst wake-up), 1 day|Measurement of post-operative pain by using a visual analogue scale, It's a visual scale from 0 (no pain) to 100 (highest pain), 1 day|Measurement of post-operative fatigue by using a visual analogue scale, It's a visual scale from 0 (no fatigue) to 100 (highest fatigue), 1 day|Measurement of comfort and satisfaction with care by using a visual analogue scale, It's a visual scale from 0 (ideal care) to 100 worst care), 1 day|Number of patients taking anesthetic drugs at induction of anaesthesia, 1 day|Number of patients taking anesthetic drugs during the post-interventional monitoring, 1 day|Number of patients taking morphine in recovery room, 1 day|Number of patients taking setrons (nausea and vomiting medication), 1 day|Rate of patients that consider continuing the program of cardiac coherence, 1 day|Rate of patients willing to recommend the technique, 1 day|Number of days of hospitalization, 1 month|Number of patients taking

morphine in peroperative, 1 day|Measurement of pain at inclusion by using a visual analogue scale, It's a visual scale from 0 (no pain) to 100 (highest pain), 1 day|The recruitment rate (proportion of patients consenting to participate in the study among eligible patients at the screening) and reasons for refusal., 1 day
Other Outcome Measures:
Sponsor: Institut du Cancer de Montpellier - Val d'Aurelle
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 53
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: PROICM 2019-06 COH
Start Date: 2020-02-14
Primary Completion Date: 2022-01-14
Completion Date: 2022-01-14
First Posted: 2019-06-11
Results First Posted:
Last Update Posted: 2022-01-24
Locations: Institut régional du cancer de Montpellier, Montpellier, Hérault, 34298, France
Study Documents:

NCT Number: NCT03510689
Study Title: Genetics and Heart Health After Cancer Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT03510689
Acronym: Gene-HEART
Study Status: COMPLETED
Brief Summary: The overall objective of this study is to use patient-centered in vitro and in vivo models to answer the fundamental question of whether or not pathogenic mutations in BRCA1/2 result in an increased risk of CV disease
Study Results: NO
Conditions: Breast Cancer|Hereditary Breast/Ovarian Cancer (brca1, brca2)|Heart Diseases|Drug-Induced Cardiomyopathy
Interventions: DIAGNOSTIC_TEST: echocardiography|OTHER: Cardiopulmonary Exercise Testing|OTHER: Blood Collection
Primary Outcome Measures: Left Ventricular Ejection Fraction, 6 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 79

Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 13117
Start Date: 2017-12-05
Primary Completion Date: 2022-05-31
Completion Date: 2022-05-31
First Posted: 2018-04-27
Results First Posted:
Last Update Posted: 2022-06-02
Locations: Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT02078388
Study Title: Correlation Between Genetic Variants and Long-term Cardiac Effects Induced by Doxorubicin in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02078388
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to identify the genetic variants that are associated with higher risk of doxorubicin-induced cardiotoxicity can contribute towards developing a predictive algorithm comprising both clinical and genetic factors to select patients who should avoid treatment with anthracyclines.

Hypothesis of this study is certain functional variants in genes that encode for metabolizing enzymes and/or targets in the doxorubicin pharmacology pathway may increase the risk of doxorubicin-induced cardiomyopathy
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Doxorubicin
Primary Outcome Measures: Change the functional variants in genes involved in doxorubicin pharmacology with doxorubicin-induced cardiomyopathy in adult breast cancer survivors., Identification of genetic variants that are associated with higher risk of doxorubicin-induced cardiotoxicity can contribute towards developing a predictive algorithm comprising both clinical and genetic factors to select patients who should avoid treatment with anthracyclines., 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National University Hospital, Singapore
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 500
Funder Type: OTHER
Study Type: OBSERVATIONAL

Study Design: Observational Model: |Time Perspective: p
Other IDs: 2013/01090
Start Date: 2013-11
Primary Completion Date: 2015-10
Completion Date:
First Posted: 2014-03-05
Results First Posted:
Last Update Posted: 2014-03-05
Locations: National University Hospital, Singapore, 119074, Singapore
Study Documents:

NCT Number: NCT02250989
Study Title: The Influence of Glycaemia and Insulinemia on Vasomotor Endothelial Function After Myocardial Infarction
Study URL: https://beta.clinicaltrials.gov/study/NCT02250989
Acronym: INGLIVEF
Study Status: UNKNOWN
Brief Summary: The objective of this study is to investigative the influence of different levels of glycaemia or insulinemia in vascular endothelium in ischemia/reperfusion lesion after myocardial infarction
Study Results: NO
Conditions: Myocardial Infarction
Interventions:
Primary Outcome Measures: Change in endothelial function after ischemia/reperfusion injury, Compare the effects of euglycemic/ hyperinsulinemic, hyperglycemic/hypoinsulinemic and hyperglycemic/ hyperinsulinemic on endothelial reactivity, measured by flow mediated dilation, after ischemia/reperfusion injury assessed at brachial artery., Between 144 and 168 h after Myocardial Infarction
Secondary Outcome Measures: Change in plasma pool of nitric oxide after ischemia/reperfusion injury, Compare the effects of euglycemic/ hyperinsulinemic, hyperglycemic/hypoinsulinemic and hyperglycemic/ hyperinsulinemic on nitric oxide generation before and after ischemia/ reperfusion injury assessed at brachial artery., Between 144 and 168 h after Myocardial Infarction|Change in inflammatory markers after ischemia/reperfusion injury, Compare the effects of euglycemic/ hyperinsulinemic, hyperglycemic/hypoinsulinemic and hyperglycemic/ hyperinsulinemic on markers of inflammatory activity (CRP, TNF alpha, IL-1 beta and IL-10) in after ischemia/reperfusion injury assessed at brachial artery., Between 144 and 168 h after Myocardial Infarction| Change in biomarkers of endothelial dysfunction before and after ischemia/reperfusion injury, Compare the effects of euglycemic/ hyperinsulinemic, hyperglycemic/hypoinsulinemic and hyperglycemic/ hyperinsulinemic on markers of endothelial activation (ICAM-1, VCAM-1, PAI-1) in after ischemia/reperfusion injury assessed at brachial artery., Between 144 and 168 h after MI|Change in biomarkers of oxidative stress before and after ischemia/reperfusion injury, Compare the effects of euglycemic/hyperinsulinemic, hyperglycemic/ hypoinsulinemic and hyperglycemic/hyperinsulinemic on markers of oxidative stress (nitrotyrosine and 8-isoprostane) before and after

ischemia/reperfusion injury assessed at brachial artery, Between 144 and 168h after MI
Other Outcome Measures:
Sponsor: University of Campinas, Brazil
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 75
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Ateroloab-1
Start Date: 2014-07
Primary Completion Date: 2016-02
Completion Date: 2016-02
First Posted: 2014-09-26
Results First Posted:
Last Update Posted: 2014-09-26
Locations: Clinics Hospital, Campinas, Sao Paulo, 13083-888, Brazil
Study Documents:

NCT Number: NCT05011721
Study Title: Digital Phenotyping in Young Breast Cancer Patients Treated With Neoadjuvant Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT05011721
Acronym: NeoFit
Study Status: RECRUITING
Brief Summary: NeoFit is a prospective, national, multicenter, single-arm open-label study. It will include a total of 300 participants under the age of 70 years treated with neoadjuvant chemotherapy for BC. Participants will receive a Withing Steel HR activity tracker, which they will be asked to wear 24 h per day for 12 months. The principal assessments will be performed at baseline, at the end of neoadjuvant chemotherapy and at 12 months. The investigators will evaluate clinical (e.g. toxicity, efficacy of chemotherapy), lifestyle, quality of life, fatigue, and physical activity parameters. All questionnaires will be completed on a REDCap form, via a secure internet link.
Study Results: NO
Conditions: Breast Cancer
Interventions: DEVICE: Activity tracker
Primary Outcome Measures: Describe physical activity profiles in breast cancer patients under 70 years of age treated by neoadjuvant chemotherapy, The activity tracker will register step counts for each day. the investigators will plot the average daily step counts and the 95% confidence interval across the entire study period. Then will will study the change in step count trajectory during the study. Linear mixed model will be used for describing change over time, Month 12| Describe heart rate profiles in breast cancer patients under 70 years

of age treated by neoadjuvant chemotherapy, The activity tracker will register heart rate at 10-minute intervals for each day. The investigators will plot the average heart rate frequency and the 95% confidence interval across the entire study period. Then will will study the change in heart rate frequency trajectory during the study. Linear mixed model will be used for describing change over time, Month 12|Describe sleep profiles in breast cancer patients under 70 years of age treated by neoadjuvant chemotherapy, The activity tracker will register sleep duration for each day. The investigators will plot the average sleep duration and the 95% confidence interval across the entire study period. Then will tudy the change in sleep duration trajectory during the study. Linear mixed model will be used for describing change over time, Month 12|Identify digital profiles (physical activity, heart rate, sleep) in breast cancer patients under 70 years of age treated by neoadjuvant chemotherapy, To identify digital profiles, The investigators will combine step counts profiles, heart frequency profiles and sleep profiles using mixed models with latent classes. The use of a mixed model will make it possible to analyze repeat data for the population, and to determine an average profile or trajectory for the whole population. The optimal number of classes will be determined a posteriori, based on a set of statistical and clinical criteria. The most widely used statistical criterion is the "Bayesian information criterion" (BIC), which penalizes the model's likelihood according to its complexity. The BIC, which is stricter than many other criteria, has been shown to have a better performance in simulations. The number of trajectories will also be based on clinical interpretation (whether it is worthwhile retaining classes containing very small numbers of subjects, etc.)., Month 12 Secondary Outcome Measures: Analyze the effects of digital profiles on treatment toxicity, Occurence of severe toxicity (grade \>2) according to the National Cancer Institute's Common Terminology Criteria for Adverse Events (NCI-CTCAE) Tests will be performed to compare means (Student's t test), or categorical variables (chi2test). The investigators will also perform multinomial logistic regression analyses with univariate and multivariate models, to determine the probability of belonging to a class relative to the corresponding reference class, End of neoadjuvant chemotherapy, Month 12|Analyze the effects of digital profiles on quality of life, Quality of life will be assessed with the European Organisation for Research and Treatment of Cancer (EORTC QLQ-C30) Quality of Life Questionnaire (EORTC QLQ-C30) version 3 validated in 2000, a multidimensional questionnaire validated for use with cancer patients. The QLQC30 questionnaire contains 30 items assessing five functional domains (physical, role, emotional, cognitive, and social), one overall quality-of-life domain, three symptom domains (pain, fatigue and nausea), and six individual items (dyspnea, insomnia, anorexia, diarrhea, constipation, and financial impact). Participants will respond on a Likert scale ranging from "not at all" to "very much" and from "very poor" to "excellent" for the overall quality-of-life questions only. Scores will be standardized on a scale of 0 to 100, according to the EORTC scoring

manual. Higher scores correspond to better functioning, a better overall quality of life and more symptoms., End of neoadjuvant chemotherapy, Month 12|Analyze the effects of digital profiles on fatigue, The multidimensional aspects of fatigue will be evaluated with the EORTC QLQ-FA12 version 1 module, which was validated for cancer-related fatigue in 2017. EORTC QLQ-FA12 contains 12 items assessing the physical, cognitive, and emotional domains of cancer-related fatigue. Participants will complete a four-point Likert-scale questionnaire, with responses ranging from "not at all" to "very much". All scores will be transformed to a scale of 0 to 100, with higher scores indicating a greater degree of fatigue. The estimated completion time for this questionnaire is five minutes.

Tests will be performed to compare means (Student's t test), or categorical variables (chi2test). The investigators will also perform multinomial logistic regression analyses with univariate and multivariate models, to determine the probability of belonging to a class relative to the corresponding reference class, End of neoadjuvant chemotherapy, Month 12|Develop models for predicting toxicity during the course of treatment, The prediction of treatment toxicity will be assessed by CTCAE v4.0., End of the neoadjuvant chemotherapy, Month 12|Develop models for predicting fatigue changes during the course of treatment, The prediction of fatigue will be assessed by change from baseline in fatigue scores on FA12 questionnaire and at the end of the neoadjuvant chemotherapy and at 12 months.., End of the neoadjuvant chemotherapy, Month 12|Develop models for predicting quality of life changes during the course of treatment, The prediction of a deterioration of the quality of life will be assessed by change in the global score in EORTC QLQC30 questionnaire from baseline and at the end of the neoadjuvant chemotherapy and at 12 months.., End of the neoadjuvant chemotherapy, Month 12
Other Outcome Measures:
Sponsor: Institut Curie
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 300
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IC 2020-20
Start Date: 2021-09-20
Primary Completion Date: 2023-09
Completion Date: 2024-09
First Posted: 2021-08-18
Results First Posted:
Last Update Posted: 2022-12-14
Locations: Institut Curie, Paris, 75005, France|Institut Jean Godinot,

Reims, 51100, France|Institut Curie, Saint-Cloud, 92, France
Study Documents:

NCT Number: NCT02907021
Study Title: Safety of Continuing CHemotherapy in Overt Left Ventricular Dysfunction Using Antibodies to HER-2
Study URL: https://beta.clinicaltrials.gov/study/NCT02907021
Acronym: SCHOLAR
Study Status: COMPLETED
Brief Summary: Trastuzumab is an important treatment for HER 2 positive breast cancer. But trastuzumab can cause injury to the heart, and this is one of the main reasons it cannot be administered as planned. Heart injury can often be successfully treated using cardiac medications. The aim of SCHOLAR is to evaluate whether it is safe to continue trastuzumab in individuals with mild or moderate cardiac injury, while treating them with appropriate cardiac medications. In this way the investigators hope to be able to optimise the delivery of a treatment to patients with breast cancer that has proven survival benefits, especially when administered for a full 12-month course.
Study Results: NO
Conditions: Heart Failure|Breast Cancer
Interventions: DRUG: standard-of-care treatments for LV impairment
Primary Outcome Measures: Safety outcomes, The primary safety outcome will be the development of cardiac dose-limiting toxicity (cDLT), defined as the occurrence of any of a)cardiovascular death, b)left ventricular ejection fraction (LVEF) \<40% together with any heart failure symptoms, or c) LVEF \<35%, one year|Efficacy outcomes, The efficacy outcome will be the number of trastuzumab cycles completed after enrollment as a proportion of the originally planned number of trastuzumab cycles., one year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Population Health Research Institute
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: SCHOLAR-2016
Start Date: 2016-11-01
Primary Completion Date: 2018-04-12
Completion Date: 2018-04-12
First Posted: 2016-09-20
Results First Posted:
Last Update Posted: 2020-10-09
Locations: Juravinski Hospital, Hamilton, Ontario, L8V 1C3, Canada

Study Documents:

NCT Number: NCT04143230
Study Title: Identification of In-hospital Patients in Need of Palliative Care Using a New Simplified Screening Tool
Study URL: https://beta.clinicaltrials.gov/study/NCT04143230
Acronym: SST2017
Study Status: COMPLETED
Brief Summary: Every day many patients affected by chronic life-limiting illnesses are admitted into Internal Medicine wards, coming from the Emergency Department. Many studies suggest that providing palliative care to these patients may improve their end-of-life care while reducing costs by minimizing futile treatments and unwanted intensive care unit admissions. Consequently, there is a strong need for acute care hospitals to more vigorously identify patients entering the final phase of their lives as well as their specific care needs.

In a previous study the investigators screened for need of palliative care patients affected by progressive chronic diseases by means of a tool, based on the Italian Society of Anesthesia, Analgesia, Resuscitation, and Intensive Care - SIAARTI - position paper reporting criteria for patients with end-stage chronic organ failures, and on the specific clinical indicators elaborated by the National Comprehensive Cancer Network (NCCN) for patients with locally advanced/metastatic cancer. In a further pilot study, the investigators compared the outcomes of PC patients depending on whether the palliative care team evaluated such patients only if requested by the physician staff or routinely, irrespectively of a specific request, finding a significant increase of discharges after the activation of an appropriate PC service or scheduled PC ambulatory visit.

In the present study the investigators enroll chronically ill patients admitted to an Internal Medicine Unit from the Emergency Department, to be screened for palliative care need, using the previously cited SIAARTI/NCCN screening tool (Extended Screening Tool - EST), or using a Simplified Screening Tool (SST), derived from the first instrument, which preliminary showed a superimposable efficacy. This latter tool has advantages related to much more shortness and therefore simplicity in the administration to a seriously ill patient and is much less time consuming, allowing the physician to use it routinely.

The aim of the study is to verify the accuracy of the SST in identifying chronically ill patients in need of a PC approach, in comparison to the SIAARTI/NCCN tool (EST). If the SST would show good accuracy, an easily manageable tool for the assessment of PC needs in chronically ill patients would be available for the daily routine.
Study Results: NO
Conditions: Locally Advanced Cancer|Metastatic Cancer|Chronic Respiratory Failure|Chronic Heart Failure|Chronic Liver Failure|

Chronic Renal Failure
Interventions: OTHER: Screening for PC by means of two different screening tools
Primary Outcome Measures: Accuracy of the Simplified Screening Tool (SST) with respect to the SIAARTI/NCCN screening tool (EST), BACKGROUND: The aims of this study were to evaluate the feasibility of an Emergency Department (ED)-initiated screening to identify seriously ill patients in need of palliative care (PC) and to develop a simplified screening tool (SST).

METHODS: Eligible patients with a known diagnosis of chronic heart, lung, liver, and kidney failures, or advanced cancer, awaiting to be hospitalized after an ED visit, were assessed with both screening tools (ie, EST and SST).

The outcome of this study is to evaluate the accuracy of the SST in identifying chronically ill patients in need of a palliative care assessment in the hospital setting., Through study completion, an average of 1 year
Secondary Outcome Measures: Accuracy of Surprise Question (SQ), BACKGROUND: The surprise question (SQ), "Would the investigator be surprised if this patient died within the next year?" is effective in identifying the end-stage disease patients and therefore potentially unmet palliative care needs. The SG is one of the criteria assessed by screening tools to identify people in need of palliative care assessment.

METHODS: Eligible patients with a known diagnosis of chronic heart, lung, liver, and kidney failures, or advanced cancer, awaiting to be hospitalized after an ED visit, underwent an evaluation of life expectancy using the Surprise Question (SQ).

The outcome of this study is to evaluate the accuracy of SQ in identifying palliative care patients in their last year of life., Through study completion, an average of 1 year|Symptom control in palliative care patients, BACKGROUND: Good symptom control is important for delivering effective palliative care METHODS: Patients with a diagnosis of chronic heart, lung, liver, and kidney failures, or advanced cancer, hospitalized after an ED visit, fully according to the screening tool score, in an acute palliative care unit due to uncontrolled symptoms

OUTCOME MEASURE: Measurements will be aggregated to arrive at a comparison between admission and discharge times of:

* frequency (n,%) of following symptoms: pain, activity, nausea, depression, anxiety, drowsiness, appetite, sense of well-being and shortness of breath
* frequency (n,%) of use of pain killer, interventional procedures, palliative sedation, Through study completion, an average of 1 year|

Intensity of symptoms in patients admitted in an acute palliative care unit, BACKGROUND: Good symptom control is important for delivering effective palliative care METHODS: Patients with a diagnosis of chronic heart, lung, liver, and kidney failures, or advanced cancer, hospitalized after an ED visit, fully according to the screening tool score, in an acute palliative care unit due to uncontrolled symptoms OUTCOME MEASURE: Measurements will be aggregated to arrive at a comparison between admission and discharge times of the intensity of symptoms using the Edmonton Symptom Assessment System, that consists of nine verbal numerical scales (0 as minimum value/better outcome; 10 as maximum value/ worse outcome), Through study completion, an average of 1 year|Survival of patients in need of palliative care assessment, BACKGROUND: Acute palliative care units (APCU) are new programs aimed at improving palliative care in hospitalized patients. Although most deaths in palliative care patients with end-stage diseases are expected, no data are available on survival.

METHODS: Eligible patients with a known diagnosis of chronic heart, lung, liver, and kidney failures, or advanced cancer, hospitalized after an ED visit, fully according to the screening tool score in an APCU, due to uncontrolled symptoms.

OUTCOME MEASURE DESCRIPTION: The aim of this study is to evaluate the survival time (day, months, years) from APCU admission to death for any cause (overall survival)., Through study completion, an average of 1 year|Discharge and unplanned hospital readmissions of patients in need of palliative care assessment, BACKGROUND: Discharge planning represents one of the most important and complex decisions for patients admitted to an acute palliative care unit (APCU).

METHODS: Eligible patients with a known diagnosis of chronic heart, lung, liver, and kidney failures, or advanced cancer, hospitalized after an ED visit, fully according to the screening tool score, in an APCU.

OUTCOME MEASURE DESCRIPTION:

This study is to evaluate:

* the frequency of discharge at home and to hospice care
* the frequency of unplanned hospital readmissions of palliative care patients discharged from our APCU., Through study completion, an average of 1 year|Clinical characteristics and outcomes of palliative care patients referred to an acute palliative care unit, BACKGROUND: Acute palliative care units (APCU) admit patients for symptom control, the transition to palliative care programs (home or hospice care), or end-of-life care.

METHODS: Patients with a known diagnosis of chronic heart, lung, liver, and kidney failures, or advanced cancer, hospitalized after an

ED visit, fully according to the screening tool score, in an APCU.

OUTCOME MEASURE: multiple measurements will be aggregated to arrive at one detailed description of:

* frequency (n,%) of following symptoms: pain, activity, nausea, depression, anxiety, drowsiness, appetite, sense of well-being and shortness of breath
* frequency (n,%) of discharge at home and to hospice care, Through study completion, an average of 1 year
Other Outcome Measures:
Sponsor: Azienda Ospedaliera Città della Salute e della Scienza di Torino
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 660
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: DOUBLE (PARTICIPANT, CARE_PROVIDER)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 0014892
Start Date: 2017-05-23
Primary Completion Date: 2019-05-22
Completion Date: 2019-10-15
First Posted: 2019-10-29
Results First Posted:
Last Update Posted: 2019-10-29
Locations: Pain Management and Palliative Care, Department of Anesthesia, Intensive Care and Emergency, Molinette Hospital, University of Turin, Turin, 10126, Italy
Study Documents:

NCT Number: NCT05130489
Study Title: CAR T Cell Therapy Related Cardiovascular Outcomes
Study URL: https://beta.clinicaltrials.gov/study/NCT05130489
Acronym: CARTCO
Study Status: COMPLETED
Brief Summary: This will be a cohort study of all patients receiving Cluster of Differentiation 19 (CD19)-specific CAR T cell therapy for relapsed/refractory B cell haematological malignancies. Patients will receive cardiac assessment and have serum cardiac biomarkers, ECG, transthoracic echocardiogram and cardiac magnetic resonance imaging performed at baseline prior to CAR T cell therapy, 7 days post CAR T cell infusion, and 3 months post CAR T cell infusion. Abnormalities in these cardiac investigations will be used to demonstrate cardiac injury and identify which patients are most at risk of developing cardiac injury related to CAR T cell therapy.

Study Results: NO
Conditions: Cardiovascular Diseases|B-cell Acute Lymphoblastic Leukemia|B-cell Lymphoma Refractory|B-cell Lymphoma Recurrent|Primary Mediastinal Large B-cell Lymphoma (PMBCL)|Diffuse Large B Cell Lymphoma|Cardiotoxicity|Cardiovascular Complication
Interventions:
Primary Outcome Measures: Detected abnormalities - Composite, The primary outcome is a composite of detected abnormalities on biomarkers, transthoracic echocardiogram (TTE), or Cardiac magnetic resonance (CMR) following CAR T cell infusion., 3 months
Secondary Outcome Measures: Detected abnormalities - Individual, The secondary outcome measures includes a composite of detected abnormalities of factors on cardiac biomarkers (troponin and N-terminal pro B-type natriuretic peptide) , electrocardiogram (ECG) changes and acute heart failure., 3 months
Other Outcome Measures:
Sponsor: University College London Hospitals
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 150
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 20/SC/0301
Start Date: 2021-01-18
Primary Completion Date: 2023-03-01
Completion Date: 2023-05-01
First Posted: 2021-11-23
Results First Posted:
Last Update Posted: 2023-05-12
Locations: University College London Hospitals, London, United Kingdom
Study Documents:

NCT Number: NCT02426788
Study Title: CBT Plus SMC Compared to SMC for Persistent Physical Symptoms in Secondary Care (PRINCE)
Study URL: https://beta.clinicaltrials.gov/study/NCT02426788
Acronym: PRINCE
Study Status: COMPLETED
Brief Summary: Brief Summary: Persistent Physical Symptoms (PPS), also known as medically unexplained symptoms (MUS) is a term used to describe a range of persistent bodily symptoms for which the exact cause is unclear. Between 20 and 40% of patients in primary care, and about 50% in secondary care experience PPS. Not only are PPS common, but the overlap across different patient groups may indicate that these phenomena are transdiagnostic. PPS are associated with profound disability and high health care costs, and if left untreated the prognosis of these patients is poor. There is an accumulating body of

evidence demonstrating that cognitive behavioural interventions can reduce levels of symptoms and improve functioning in patients with PPS. A pragmatic randomised controlled trial (RCT) was designed to evaluate the clinical and cost-effectiveness of cognitive behavioural therapy (CBT) + Standard Medical Care (SMC) versus Standard Medical Care alone, in the treatment of patients with PPS. The trial will focus on patients with a variety of symptoms (e.g., non-cardiac chest pain, fibromyalgia), across secondary care clinics (e.g., neurology, cardiology, and rheumatology).
Study Results: NO
Conditions: Persistent Physical Symptoms (PPS)
Interventions: BEHAVIORAL: Cognitive behavioural therapy (CBT)
Primary Outcome Measures: Work and social adjustment scale, Measures impairment in functioning, 52 weeks post randomisation
Secondary Outcome Measures: Persistent Physical Symptom Questionnaire, Measures severity, distress, interference and problematic nature of PPS, 52 weeks post randomisation|Patient Health Questionnaire-15 (PHQ-15), Measures physical symptoms severity, 52 weeks post randomisation|Patient Health Questionnaire-9 (PHQ-9), Measures mood, 52 weeks post randomisation|Generalized Anxiety Disorder-7 (GAD-7), Measures generalised anxiety, 52 weeks post randomisation|Clinical Global Impression (CGI), Measures patient's perception of their general health improvement, 52 weeks post randomisation|Client Service Receipt Inventory (CSRI), Measures health care service receipt, direct and indirect costs of illness, and cost-effectiveness of interventions, 52 weeks post randomisation|EuroQol-5D (EQ-5D), Measures health outcome, 52 weeks post randomisation|Cognitive Behavioural Responses Questionnaire, Measures beliefs and behaviours, 52 weeks post randomisation|Acceptance scale, assesses degree of acceptance of difficult symptoms, 52 weeks post randomisation
Other Outcome Measures: PSYCHLOPS, Measures improvement of patient-defined self-rated problems, 52 weeks post randomisation
Sponsor: King's College London
Collaborators: South London and Maudsley NHS Foundation Trust
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 324
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: STR130202 (Secondary)
Start Date: 2015-07
Primary Completion Date: 2019-01
Completion Date: 2019-01
First Posted: 2015-04-27
Results First Posted:
Last Update Posted: 2019-05-09
Locations: Guy's Hospital, London, United Kingdom|King's College

Hospital, London, United Kingdom|Queen Elizabeth Hospital, London, United Kingdom|Royal Free Hospital, London, United Kingdom|St Thomas' Hospital, London, United Kingdom|University Hospital Lewisham, London, United Kingdom|Princess Royal University Hospital, Orpington, United Kingdom
Study Documents:

NCT Number: NCT02096588
Study Title: Detection and Prevention of Anthracycline-Related Cardiac Toxicity With Concurrent Simvastatin
Study URL: https://beta.clinicaltrials.gov/study/NCT02096588
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Doxorubicin (Adriamycin), one of the drugs commonly used for the treatment of breast cancer, is in a class of medications called anthracyclines. Anthracyclines may cause heart damage that can lead to weakening of the heart muscle. This heart damage may happen right away or may occur many years after the anthracycline is given

Simvastatin is an oral medication approved by the FDA to lower cholesterol. Simvastatin is in a class of medications called statins. Some research has shown that statins may prevent heart damage that can be caused by anthracyclines like Doxorubicin (Adriamycin).

The purpose of this study is to determine if taking simvastatin while receiving the chemotherapy Doxorubicin (Adriamycin) will minimize damage to the heart.

This study is for women who will be receiving the anthracycline doxorubicin (Adriamycin) as part of their breast cancer treatment.
Study Results: YES
Conditions: Breast Cancer|Stage I Breast Cancer|Stage II Breast Cancer|Stage III Breast Cancer
Interventions: DRUG: Simvastatin|DRUG: Doxorubicin/cyclophosphamide
Primary Outcome Measures: Change in Echocardiographic Global Longitudinal Strain (GLS), To compare the absolute change in echocardiographic GLS (Global Longitudinal Strain) from baseline (T0) to 2-3 weeks after (T2) completion of 4 cycles of (neo)adjuvant anthracycline-based chemotherapy in early stage breast cancer patients who do and do not receive concurrent simvastatin therapy, up to 15 weeks
Secondary Outcome Measures: Number of Participants With Adverse Events as a Measure of Safety and Tolerability, Number of participants with concurrent administration of simvastatin with (neo)adjuvant anthracycline-based chemotherapy in early stage breast cancer patients who experience adverse events as defined by NCI CTCAE v4.0., 52 weeks| Recurrence Free Survival (RFS) With Concurrent Simvastatin, To describe the recurrence free survival (RFS) in early stage breast cancer patients treated with anthracycline-based chemotherapy with and without concurrent simvastatin, 5 years

Other Outcome Measures:
Sponsor: Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
Collaborators: Avon Foundation
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 34
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: J13160|J13160|NA_00091900
Start Date: 2014-05-20
Primary Completion Date: 2017-04-25
Completion Date: 2024-03-01
First Posted: 2014-03-26
Results First Posted: 2019-05-14
Last Update Posted: 2023-07-11
Locations: Kimmel Cancer Center at Johns Hopkins at Sibley Memorial Hospital, Washington, District of Columbia, 20016, United States| Kimmel Cancer Center at Johns Hopkins, Baltimore, Maryland, 21287-0013, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT01904331
Study Title: Breast Cancer Long-term Outcome of Cardiac Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT01904331
Acronym: BLOC
Study Status: COMPLETED
Brief Summary: The purpose of this study is to assess the prevalence of cardiac dysfunction and (undiagnosed) heart failure in women registered in general practice with a history of breast cancer who received chemotherapy and / or radiotherapy as compared to a matched female control population.
Study Results: NO
Conditions: Breast Neoplasms
Interventions:
Primary Outcome Measures: Cardiac dysfunction, systolic and diastolic parameters at time of inclusion, on average 11 years after treatment with breast cancer
Secondary Outcome Measures: Biomarkers +DNA, Plasma EDTA, lithium-heparin plasma and serum are stored at -80 freezer at the the time of inclusion. Determination of biomarkers will take place at the end of the study period Whole blood is frozen for DNA analysis at time of inclusion., on average 11 years after treatment with breast cancer
Other Outcome Measures: Clinical complaints and signs at inclusion, Questionnaires (CVRM, HADS and MFI-20), a short physical examination and a electrocardiography at time of inclusion, on average 11 years after treatment with breast cancer
Sponsor: University Medical Center Groningen

Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 700
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 686317
Start Date: 2013-06
Primary Completion Date: 2016-02-06
Completion Date: 2017-10-24
First Posted: 2013-07-22
Results First Posted:
Last Update Posted: 2018-06-15
Locations: University Medical Center Groningen (UMCG), Groningen, 9700RB, Netherlands
Study Documents:

NCT Number: NCT03694431
Study Title: Comparative Trial of Home-Based Palliative Care
Study URL: https://beta.clinicaltrials.gov/study/NCT03694431
Acronym: HomePal
Study Status: TERMINATED
Brief Summary: Background: To effectively alleviate suffering and improve quality of life for patients with serious illness and their caregivers, palliative care (PC) services must be offered across multiple settings. Research is needed to determine how best to optimize home-based palliative care (HBPC) services to meet the needs of individuals with high symptom burden and functional limitations.

Aim: The investigators will compare a standard HBPC model that includes routine home visits by a nurse and provider with a more efficient tech-supported HBPC model that promotes timely inter-professional team coordination via synchronous video consultation with the provider while the nurse is in the patient's home. The investigators hypothesize that tech-supported HBPC will be as effective as standard HBPC.

Design: Cluster randomized trial. Registered nurses (n\~130) will be randomly assigned to the tech-supported or standard HBPC model so that half of the patient-caregiver dyads will receive one of the two models.

Setting/Participants: Kaiser Permanente (15 Southern California and Oregon sites). Patients (n=10,000) with any serious illness and a prognosis of 1-2 years and their caregivers (n=4,800)

Methods: Patients and caregivers will receive standard PC services: comprehensive needs assessment and care planning, pain and symptom

management, education/skills training, medication management, emotional/spiritual support; care coordination, referral to other services, and 24/7 phone assistance.

Results: Primary patient outcomes: symptom improvement at 1 month and days spent at home in the last six months of life; caregiver outcome: perception of preparedness for caregiving.

Conclusion: Should the more efficient tech-supported HBPC model achieves comparable improvements in outcomes that matter most to patients and caregivers, this would have a lasting impact on PC practice and policy.
Study Results: NO
Conditions: Cancer|Chronic Obstructive Pulmonary Disease|Heart Failure|Dementia|End Stage Liver Disease|End Stage Renal Disease|Neuromuscular Diseases
Interventions: OTHER: Tech-supported HBPC|OTHER: Standard HBPC
Primary Outcome Measures: Symptom severity (total score) using the Edmonton Symptom Assessment Scale (ESAS), The ESAS is a 10-item survey measuring symptom severity. Scores range from 0-100 with higher scores indicating worse symptoms., Change from baseline to 1 month|Days at home in the last 180 days of life among patients surviving at least 180 days after enrolling in HBPC, Baseline to 12 months|Caregiver preparedness for caregiving using the Preparedness for Caregiving Scale, The Preparedness for Caregiving Scale is a 9-item survey measuring caregivers' perception of their preparedness for caregiving. Scores range from 0-36 with higher scores indicating higher perception of preparedness, Change from baseline to 1 month
Secondary Outcome Measures: Days at home between study enrollment and death or study completion (365 days), Variable, up to 12 months|Patient quality of life measured with the PROMIS-10 survey, The PROMIS-10 is a 10-item survey measuring general health related quality of life. Scores range from 0-100 with higher scores indicating better quality of life, Change from baseline to 1 and 6 months|Patient general distress measured with the distress thermometer, Scores for this single item distress thermometer range from 0-10 with higher scores indicating greater distress, Change from baseline to 1 and 6 months|Palliative performance scale will be measured using all data available from routine clinical practice as documented in the electronic medical record (EMR), The Palliative Performance Scale measures overall functional status. A clinician completes this assessment using a scale of 0-100 with higher scores indicating better functional performance, Baseline and variable time periods due to reliance on available data from the EMR|Patient satisfaction-care experience measured by a study-specific survey, This 8-item satisfaction-care experience survey was developed specifically to measure satisfaction and care experience with home-based palliative care., 1 and 6 months|Patient acute and post-acute care utilization, Frequency of hospitalizations, emergency department visits and skilled nursing facility stay, Baseline to 12 months|Patient outpatient health

care utilization, Frequency of primary and specialty care visits, Baseline to 12 months|Patient enrollment in and days on hospice before death, Baseline to 12 months|Patient death, Baseline to 12 months|Caregiver quality of life measured with the PROMIS-10, The PROMIS-10 is a 10-item survey measuring general health related quality of life. Scores range from 0-100 with higher scores indicating better quality of life, Change from baseline to 1 and 6 months|Caregiver burden measured with the Zarit-12 Caregiver Burden Scale, The Zarit-12 is a 12-item survey measuring caregiver burden. Scores range from 0-48 with higher scores indicating greater caregiver burden, Change from baseline to 1 and 6 months|Caregiver acute and post-acute care utilization, Frequency of hospitalizations, emergency department visits and skilled nursing facility stay for caregivers who are members of Kaiser Permanente, Baseline to 12 months|Caregiver outpatient health care utilization, Frequency of primary and specialty care visits for caregivers who are members of Kaiser Permanente, Baseline to 12 months|HBPC clinician perception of facilitators and barriers to implementation of HBPC services, Study specific survey (under development), Yearly, up to four years
Other Outcome Measures:
Sponsor: Kaiser Permanente
Collaborators: Patient-Centered Outcomes Research Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 3999
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: PLC-1609-36108
Start Date: 2019-01-07
Primary Completion Date: 2020-01-24
Completion Date: 2020-01-24
First Posted: 2018-10-03
Results First Posted:
Last Update Posted: 2020-02-20
Locations: Kaiser Permanente Southern California, Pasadena, California, 91101, United States|Kaiser Permanente Northwest, Portland, Oregon, 97227, United States
Study Documents:

NCT Number: NCT05869721
Study Title: Effects of Yoga on Women With Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05869721
Acronym:
Study Status: RECRUITING
Brief Summary: Upper limb complications and sleep disturbances are prevalent, persistent, and serious health problems in women with breast cancer. However, these problems are underrecognized in clinical

practice and thus have substantial adverse impacts on the health and quality of life of women with breast cancer. As yoga practices have been shown to improve physical and psychological health in people with cancer, such practices may also alleviate upper limb complications and sleep disturbances in women with breast cancer. However, there are few evidence-based guidelines or protocols to support the integration of yoga therapy into clinical practice for managing the health conditions of women with breast cancer. Therefore, this study aims to investigate the effects of yoga therapy on improving the upper limb functions, sleep quality, and quality of life in women with breast cancer.
Study Results: NO
Conditions: Upper Limb Functions|Sleep Quality|Upper Limb Muscle Strength|Shoulder Mobility|Heart Rate Variability|Mood|Health-related Quality of Life
Interventions: OTHER: Yoga
Primary Outcome Measures: Upper limb functional status, score range 0-100%, higher score means more severe disability, Will be assessed using the short form of the Chinese (Hong Kong) version of the Disabilities of Arm-Shoulder-Hand Questionnaire (quickDASH-HKPWH), T1: baseline (before the study begins).|Change from baseline Upper limb functional status at 4 weeks, Will be assessed using the short form of the Chinese (Hong Kong) version of the Disabilities of Arm-Shoulder-Hand Questionnaire (quickDASH-HKPWH), score range 0-100%, higher score means more severe disability, T2: mid-intervention (week 4)|Change from baseline Upper limb functional status at 8 weeks, Will be assessed using the short form of the Chinese (Hong Kong) version of the Disabilities of Arm-Shoulder-Hand Questionnaire (quickDASH-HKPWH), score range 0-100%, higher score means more severe disability, T3: immediately post-intervention (week 8)|Change from baseline Upper limb functional status at 12 weeks, Will be assessed using the short form of the Chinese (Hong Kong) version of the Disabilities of Arm-Shoulder-Hand Questionnaire (quickDASH-HKPWH), score range 0-100%, higher score means more severe disability, T4: 1 month follow up (week 12)|Sleep quality, Will be assessed by the Chinese (for Hong Kong) version of the Pittsburgh Sleep Quality Index questionnaire, score range 0-21, higher score means poorer sleep, T1: baseline (before the study begins)|Change from baseline Sleep quality at 4 weeks, Will be assessed by the Chinese (for Hong Kong) version of the Pittsburgh Sleep Quality Index questionnaire, score range 0-21, higher score means poorer sleep, T2: mid-intervention (week 4)|Change from baseline Sleep quality at 8 weeks, Will be assessed by the Chinese (for Hong Kong) version of the Pittsburgh Sleep Quality Index questionnaire, score range 0-21, higher score means poorer sleep, T3: immediately post intervention (week 8)|Change from baseline Sleep quality at 12 weeks, Will be assessed by the Chinese (for Hong Kong) version of the Pittsburgh Sleep Quality Index questionnaire, score range 0-21, higher score means poorer sleep, T4: 1 month follow up (week 12)
Secondary Outcome Measures: Upper limb muscle strength, Will be determined using a handheld dynamometer, measures muscle strength in kg, higher score means better muscle strength, T1: baseline (before

the study begins)|Change from baseline Upper limb muscle strength at 4 weeks, Will be determined using a handheld dynamometer, measures muscle strength in kg, higher score means better muscle strength, T2: mid-intervention (week 4)|Change from baseline Upper limb muscle strength at 8 weeks, Will be determined using a handheld dynamometer, measures muscle strength in kg, higher score means better muscle strength, T3: immediately post intervention (week 8)|Change from baseline Upper limb muscle strength at 12 weeks, Will be determined using a handheld dynamometer, measures muscle strength in kg, higher score means better muscle strength, T4: 1 month follow up (week 12)|Shoulder mobility, Will be determined by measuring the active range of motion using a goniometer, measures range of movement in degree, higher score means better shoulder flexibility, T1: baseline (before the study begins)|Change from baseline Shoulder mobility at 4 weeks, Will be determined by measuring the active range of motion using a goniometer, measures range of movement in degree, higher score means better shoulder flexibility, T2: mid-intervention (week 4)|Change from baseline Shoulder mobility at 8 weeks, Will be determined by measuring the active range of motion using a goniometer, measures range of movement in degree, higher score means better shoulder flexibility, T3: immediately post intervention (week 8)|Change from baseline Shoulder mobility at 12 weeks, Will be determined by measuring the active range of motion using a goniometer, measures range of movement in degree, higher score means better shoulder flexibility, T4: 1 month follow up (week 12)|Mood (including anxiety and depression symptoms), Will be assessed using The Cantonese/Chinese version of the Hospital Anxiety and Depression questionnaire, score range 0-21, higher score means more severe anxiety and depression, T1: baseline (before the study begins)|Change from baseline Mood (including anxiety and depression symptoms) at 4 weeks, Will be assessed using The Cantonese/Chinese version of the Hospital Anxiety and Depression questionnaire, score range 0-21, higher score means more severe anxiety and depression, T2: mid-intervention (week 4)|Change from baseline Mood (including anxiety and depression symptoms) at 8 weeks, Will be assessed using The Cantonese/Chinese version of the Hospital Anxiety and Depression questionnaire, score range 0-21, higher score means more severe anxiety and depression, T3: immediately post intervention (week 8)|Change from baseline Mood (including anxiety and depression symptoms) at 12 weeks, Will be assessed using The Cantonese/Chinese version of the Hospital Anxiety and Depression questionnaire, score range 0-21, higher score means more severe anxiety and depression, T4: 1 month follow up (week 12)|Fatigue, Will be assessed using the Chinese (Cantonese) version of the Fatigue Assessment Scale questionnaire, score range 10-50, higher score means more severe fatigue, T1: baseline (before the study begins)|Change from baseline Fatigue at 4 weeks, Will be assessed using the Chinese (Cantonese) version of the Fatigue Assessment Scale questionnaire, score range 10-50, higher score means more severe fatigue, T2: mid-intervention (week 4)|Change from baseline Fatigue at 8 weeks, Will be assessed using the Chinese (Cantonese) version of the Fatigue Assessment Scale

questionnaire, score range 10-50, higher score means more severe fatigue, T3: mid-intervention (week 8)|Change from baseline Fatigue at 12 weeks, Will be assessed using the Chinese (Cantonese) version of the Fatigue Assessment Scale questionnaire, score range 10-50, higher score means more severe fatigue, T4: 1 month follow up (week 12)|Heart rate variability, Will be recorded over a 5-minute period using a validated wearable monitor, T1: baseline (before the study begins)|Change from baseline Heart rate variability at 4 weeks, Will be recorded over a 5-minute period using a validated wearable monitor, T2: mid-intervention (week 4)|Change from baseline Heart rate variability at 8 weeks, Will be recorded over a 5-minute period using a validated wearable monitor, T3: immediately post intervention (week 8)|Change from baseline Heart rate variability at 12 weeks, Will be recorded over a 5-minute period using a validated wearable monitor, T4: 1 month follow up (week 12)|Health-related quality of Life, Will be assessed by the Chinese-Traditional version of the Functional Assessment of Cancer Therapy-Lymphedema questionnaire, score range 0-148, higher score means better quality of life, T1: baseline (before the study begins)|Change from baseline Health-related quality of Life at 4 weeks, Will be assessed by the Chinese-Traditional version of the Functional Assessment of Cancer Therapy-Lymphedema questionnaire, score range 0-148, higher score means better quality of life, T2: mid-intervention (week 4)|Change from baseline Health-related quality of Life at 8 weeks, Will be assessed by the Chinese-Traditional version of the Functional Assessment of Cancer Therapy-Lymphedema questionnaire, score range 0-148, higher score means better quality of life, T3: immediately post intervention (week 8)|Change from baseline Health-related quality of Life at 12 weeks, Will be assessed by the Chinese-Traditional version of the Functional Assessment of Cancer Therapy-Lymphedema questionnaire, score range 0-148, higher score means better quality of life, T4: 1 month follow up (week 12)
Other Outcome Measures:
Sponsor: The Hong Kong Polytechnic University
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 34
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: 2023_Yoga_Breastcancer
Start Date: 2023-05-04
Primary Completion Date: 2023-07-30
Completion Date: 2023-07-30
First Posted: 2023-05-22
Results First Posted:
Last Update Posted: 2023-05-22
Locations: A university-affiliated rehabilitation laboratory, Hung

Hom, Kowloon, Hong Kong|The Hong Kong Polytechnic University, Hong Kong, Hong Kong
Study Documents:

NCT Number: NCT00526331
Study Title: Evaluation of Arterial Pressure Based Cardiac Output for Goal-Directed Perioperative Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT00526331
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine whether the early identification and more precise intervention of operating room (OR) patient fluid administration optimization using arterial pressure-based cardiac output (APCO) yields comparable patient outcome as fluid administration optimization using a global standard care method.
Study Results: YES
Conditions: Esophageal Diseases|Gastrointestinal Diseases|Disorder of the Genitourinary System|Gynecologic Diseases|Kidney Diseases|Liver Diseases|Pancreatic Diseases|Prostate Cancer|Spinal Disease
Interventions: DEVICE: Vigileo Monitor|DEVICE: FloTrac Sensor
Primary Outcome Measures: Length of Hospital Stay (LOS) by Participant, Length of hospital stay of arterial pressure-based cardiac output (APCO) monitor participants versus the participants using the global standard care guided by esophageal Doppler, measured in days., From baseline (first day of hospital stay) to release from hospital (anticipate 5 days minimally)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators: Edwards Lifesciences
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 49
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: TREATMENT
Other IDs: 2007-0231
Start Date: 2007-08
Primary Completion Date: 2008-09
Completion Date: 2008-09
First Posted: 2007-09-10
Results First Posted: 2011-12-08
Last Update Posted: 2012-01-16
Locations: U.T.M.D. Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT02009631
Study Title: A Study to Evaluate the Effects of Veliparib on Heart Rhythms in Patients With Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT02009631
Acronym:
Study Status: COMPLETED
Brief Summary: This is a randomized Phase 1 study to evaluate the effects of Veliparib on cardiac repolarization in patients with solid tumors who's cancer has recurred or is no longer responding to current treatment.
Study Results: NO
Conditions: Breast Cancer|Ovarian Cancer|Colon Cancer|Lung Cancer|Gastric Cancer|Solid Tumors
Interventions: DRUG: Veliparib (ABT-888)|DRUG: Placebo
Primary Outcome Measures: To evaluate the effect of Veliparib on corrected QT interval calculated by Fridericia's formula (QTcF), Electrocardiograms (ECGs) will be done at Screening, 6 time points on Day 1 of Periods 1, 2 and 3 in triplicate, 1 time point on Day 2 of Periods 1, 2, and 3 and 1 time point on Day 3 of Period 3.
Secondary Outcome Measures: Pharmacokinetic sampling maximum observed plasma concentration (Cmax), Pharmacokinetic samples will be drawn at Screening, 6 time points on Day 1 of Periods 1, 2 and 3 and 1 time point on Day 2 of Periods 1, 2, and 3.|Pharmacokinetic sampling - time to maximum observed plasma concentration (Tmax), Pharmacokinetic samples will be drawn at Screening, 6 time points on Day 1 of Periods 1, 2 and 3 and 1 time point on Day 2 of Periods 1, 2, and 3.|Pharmacokinetic sampling - the area under the plasma concentration-time curve (AUC) from time 0-24 hours (AUC 0-24), Pharmacokinetic samples will be drawn at Screening, 6 time points on Day 1 of Periods 1, 2 and 3 and 1 time point on Day 2 of Periods 1, 2, and 3.|The number of subjects with adverse events, Up to 30 days after last dose of study drug.|Vital Signs, Blood pressure, heart rate and temperature., Up to 30 days after last dose of study drug.|Clinical Laboratory Tests, Hematology, chemistry, urinalysis, Up to 30 days after last dose of study drug.|Tumor Assessment, A computerized tomography scan will be done at screening to document tumor size., Screening
Other Outcome Measures:
Sponsor: AbbVie
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 45
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: OTHER
Other IDs: M12-020|2013-002028-18

Start Date: 2013-11
Primary Completion Date: 2014-12
Completion Date: 2014-12
First Posted: 2013-12-12
Results First Posted:
Last Update Posted: 2017-11-20
Locations: Site Reference ID/Investigator# 116015, Scottsdale, Arizona, 85258, United States|Site Reference ID/Investigator# 116016, San Antonio, Texas, 78229, United States|Site Reference ID/Investigator# 117320, Groningn, 9713 GZ, Netherlands|Site Reference ID/Investigator# 117336, Maastricht, 6229 HX, Netherlands|Site Reference ID/Investigator# 117517, Madrid, 28050, Spain
Study Documents:

NCT Number: NCT05465031
Study Title: Sacubitril/Valsartan in PriMAry preventIoN of the Cardiotoxicity of Systematic breaST canceR trEAtMent (MAINSTREAM)
Study URL: https://beta.clinicaltrials.gov/study/NCT05465031
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: Breast cancer is the most commonly cancer in women in the overall global population. According to the World Cancer Research Fund International, there were more than 2.25 million new cases of breast cancer in women in 2020. Although the modern treatment strategies, based on the complex care, which consists of surgery, radiotherapy, hormone therapy, and targeted chemotherapy directed at specific cancer molecules have substantially reduced the risk of death due to breast cancer, their wide adoption results in the wider prevalence of cardiotoxicity, defined as either symptomatic heart failure, or asymptomatic contractile dysfunction. The occurrence of cardiotoxicity induced by anti-cancer therapies is estimated at 5-15%, and its development is the primary cause of therapy termination, which significantly reduces the probability of the efficacy of treatment. Several attempts have been made to determine the efficacious preventive strategy, which could diminish the risk of cancer-therapy induced cardiotoxicity. The results of the prior studies indicated a trend towards lower risk of troponin elevation, or left ventricular contractile dysfunction with the introduction of drugs interfering with the renin-angiotensin-aldosterone (RAA) axis, which constitute the primary treatment modality in heart failure with reduced ejection fraction (HFrEF). Sacubitril/valsartan, the novel therapeutic agent, has been demonstrated to significantly improve prognosis in patients with HFrEF. Prior retrospective, small, single-center studies have shown that treatment with sacubitril/valsartan may reduce the risk of cancer-therapy induced cardiotoxicity, or reverse contractile dysfunction caused by anti-cancer therapy. However, no large randomized data confirmed these findings. Therefore, the Sacubitril/Valsartan in PriMAry preventIoN of the cardiotoxicity of systematic breaST canceR trEAtMent) study, has been designed to verify, whether the preventive use of sacubitril/valsartan administered in the doses

recommended in patients with HFrEF in breast cancer patients undergoing adjuvant chemotherapy with anthracyclines or anthracyclines and HER-2 monoclonal antibodies, will reduce the incidence of cardiotoxicity defined as impaired left ventricular systolic function on cardiac magnetic resonance imaging (MRI). In the trial, a total of 480 patients with histologically confirmed breast cancer, who are eligible for chemotherapy with anthracyclines or anthracyclines and HER-2 monoclonal antibodies, will undergo 1:1 randomization to either preventive treatment with sacubitril/valsartan or placebo. The patients will be followed for 24 months, and will have repetitive efficacy and safety examinations, including echocardiography, MRI, electrocardiography including 24-h Holter monitoring, blood tests, functional capacity tests and quality of life assessment.
Study Results: NO
Conditions: Breast Cancer|Neoplasm, Breast|Breast Diseases|Antihypertensive Agents|Sacubitril/Valsartan|Angiotensin II Type 1 Receptor Blockers|Angiotensin Receptor Antagonists|Molecular Mechanisms of Pharmacological Action|Heart Failure|Cardiac Toxicity|Cancer, Therapy-Related|Cancer Therapy-Related Cardiac Dysfunction|Cardiotoxicity
Interventions: DRUG: Sacubitril-valsartan
Primary Outcome Measures: Decrease in left ventricular ejection fraction ≥ 5%, Reduction of LVEF assessed on magnetic resonance imaging (MRI), At 12 months from the randomization visit
Secondary Outcome Measures: Death from any cause or hospitalization for heart failure, Composite clinical endpoint, From Randomization till the end of blinded therapy - at 24 months|Death from any cause, From Randomization till the end of blinded therapy - at 24 months|Death from cardiovascular causes, From Randomization till the end of blinded therapy - at 24 months|Hospitalization for other cardiovascular causes, From Randomization till the end of blinded therapy - at 24 months|Decrease in left ventricular ejection fraction ≥ 5%, Reduction of LVEF assessed on echocardiography, From Randomization till the end of blinded therapy - at 24 months|Occurrence of diastolic dysfunction (UKG) within 24 months of randomization, Diastolic dysfunction assessed on echocardiography, From Randomization till the end of blinded therapy - at 24 months|-Development of pathological pericardial fluid volume or increase in pericardial fluid volume from baseline, Assessed with any available clinical modality, From Randomization till the end of blinded therapy - at 24 months|Occurrence of cardiac tamponade, Assessed with any clinical modality, From Randomization till the end of blinded therapy - at 24 months|Occurrence of pericarditis, Assessed with any clinical modality, From Randomization till the end of blinded therapy - at 24 months|Occurrence of myocarditis, Assessed with any clinical modality, From Randomization till the end of blinded therapy - at 24 months|Development of ventricular arrhythmias, Assessed with any clinical modality, From Randomization till the end of blinded therapy - at 24 months|Development of supraventricular arrhythmias, Assessed with any clinical modality, From Randomization till the end of blinded therapy

- at 24 months|Presence of conduction disturbances, Assessed with any clinical modality, From Randomization till the end of blinded therapy - at 24 months|Changes in corrected QT interval, From Randomization till the end of blinded therapy - at 24 months|Changes in BNP, NT pro-BNP, troponin T or troponin I levels, Assessed with serial laboratory measurements, From Randomization till the end of blinded therapy - at 24 months
Other Outcome Measures:
Sponsor: Silesian Centre for Heart Diseases
Collaborators: Medical Research Agency, Poland
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 600
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: LCZ696ABM001.001
Start Date: 2023-02
Primary Completion Date: 2027-12
Completion Date: 2028-02
First Posted: 2022-07-19
Results First Posted:
Last Update Posted: 2022-07-19
Locations: Regional Cancer Centre in Opole, Opole, Opolskie, 45-061, Poland|Maria Sklodowska-Curie Institute - Oncology Centre (MSCI), Gliwice Branch, Gliwice, Silesia, 44102, Poland|Silesian Center for Heart Diseases, Zabrze, Silesia, 41800, Poland|Holy Cross Cancer Centre, Cardio-Oncology Division, Kielce, Świętokrzyskie, 25-734, Poland
Study Documents:

NCT Number: NCT05945121
Study Title: Prehabilitation Program to Improve Cardiac Reserve in High-Risk Patients Undergoing Hematopoietic Stem Cell Transplantation
Study URL: https://beta.clinicaltrials.gov/study/NCT05945121
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: To assess the feasibility and preliminary effectiveness of a Cardio-Oncology Prehabilitation program in patients at high-risk of developing Cardiovascular (CV) events in improving Cardiorespiratory fitness (CRF) and reducing acute CV complications in Hematopoietic stem cell transplant (HSCT) recipients.
Study Results: NO
Conditions: Hematopoietic Stem Cell Transplant
Interventions: OTHER: Cardio-oncology program
Primary Outcome Measures: Feasibility of a cardio-oncology prehabilitation program in high-risk HSCT candidates (Recruitment

Rate)., Percent of eligible participants who are screened and give informed consent, 8 weeks post enrollment|Feasibility of a cardio-oncology prehabilitation program in high-risk HSCT candidates (retention Rates)., percentage of enrolled participants who complete pre-post CV assessments, 8 weeks post enrollment|Feasibility of a cardio-oncology prehabilitation program in high-risk HSCT candidates (Duration of Recruitment)., the number of participants recruited per month, 8 weeks post enrollment|Feasibility of a cardio-oncology prehabilitation program in high-risk HSCT candidates (time to implement study protocol)., the average amount of time required for participants to complete initial and follow-up CV assessments, 8 weeks post enrollment|Feasibility of a cardio-oncology prehabilitation program in high-risk HSCT candidates (adherence to program- Days)., The percentage of days of exercised out of 24 days recommended over the 8 weeks for both aerobic and resistance activities., 8 weeks post enrollment|Feasibility of a cardio-oncology prehabilitation program in high-risk HSCT candidates (adherence to program- Time)., The average duration (min) of aerobic and resistance workouts over the course of the intervention., 8 weeks post enrollment|Feasibility of a cardio-oncology prehabilitation program in high-risk HSCT candidates (adherence to program- Missing data)., the percentage of missing data from study questionnaires., 8 weeks post enrollment|Feasibility of a cardio-oncology prehabilitation program in high-risk HSCT candidates (overall satisfaction)., Assessed qualitatively with in-depth, semi-structured, one-to-one exit interviews with participants. A member of the research team experienced with telephone interviews, but not involved in intervention delivery, will contact all patients within 1 week after completion of the final follow-up assessment.The researcher will facilitate the interviews using a conversational-style approach whilst referring to a topic guide. Topics will focus on patients' perceived expectations, benefits, motives, and barriers to the program. The researcher will additionally ask questions regarding reasons for non-adherence to the exercise intervention, and reasons for dropout amongst discontinuing patients. The topic guide will be used flexibly to allow patients to raise additional issues which they consider important to the study. Interviews will be recorded with participants knowledge and then transcribed, coded, and assessed for relevant themes and recommendations using iterative thematic analysis, 8 weeks post enrollment|Preliminary effectiveness of an 8-week cardio-oncology prehabilitation on measures of CRF in high-risk HSCT candidates (change in anaerobic threshold)., change in anaerobic threshold from pre to post intervention reported in L/min, 8 weeks post enrollment|Preliminary effectiveness of an 8-week cardio-oncology prehabilitation on measures of CRF in high-risk HSCT candidates (change in VO2peak)., change in VO2peak from pre to post intervention reported in ml/kg/min, 8 weeks post enrollment|Preliminary effectiveness of an 8-week cardio-oncology prehabilitation on measures of CRF in high-risk HSCT candidates (comparison of V02 peak to predicted)., Comparison of V02 peak assessed after intervention in comparison to the predicted values reported as the percent difference

between the values, 8 weeks post enrollment|Preliminary effectiveness of an 8-week cardio-oncology prehabilitation on measures of CRF in high-risk HSCT candidates (RER)., change in RER (a ratio between cardiac dioxide output (VCO2)/oxygen uptake (VO2)) from pre to post intervention reported as the percent difference between the values, 8 weeks post enrollment|Preliminary effectiveness of an 8-week cardio-oncology prehabilitation on measures of CRF in high-risk HSCT candidates (VE/VC02 slope)., Change in VE/VC02 slope (defined as the change in minute ventilation per unit of carbon dioxide production) from pre to post intervention, 8 weeks post enrollment
Secondary Outcome Measures: Symptom assessment scores after an 8-week cardio-oncology prehabilitation program., Frequency and severity of cardiovascular symptoms (fatigue, shortness of breath, edema) will be assessed using the short Kansas City Cardiomyopathy Questionnaire (KCCQ-12). Responses are given on a Likert scale that for each individual item is scored on a scale of 0-100 with higher scores indicating better health. Items are grouped into the four domains; Physical limitation, Symptom frequency, Quality of life, and Social limitation., 8 weeks post enrollment|Changes in patient reported quality of life after an 8-week cardio-oncology prehabilitation program, Overall quality of life will be assessed using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30). Responses are given on a single-item ranging in score from 0 to 100. A high scale score represents a higher response level., 8 weeks post enrollment|Difference in biomarkers after an 8-week cardio-oncology prehabilitation program, High-sensitivity troponin-I (RayBiotech), B-type natriuretic peptide (BNP) (RayBiotech), and soluble urokinase plasminogen activator receptor (suPAR) (Virogates) will be measured in residual serum samples collected as part of usual care using enzyme-linked immunosorbent assays., 8 weeks post enrollment|Change in patient HSCT eligibility after an 8-week cardio-oncology prehabilitation program, We will calculate the percentage of participants evaluated who end up being eligible for HSCT and compare rates to the number of participants who are referred to cardio-oncology, do not receive the intervention, and are considered ineligible., 8 weeks post enrollment
Other Outcome Measures:
Sponsor: University of Michigan Rogel Cancer Center
Collaborators: National Institutes of Health (NIH)|National Heart, Lung, and Blood Institute (NHLBI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: UMCC 2023.004|HUM00223835|U24HL157560
Start Date: 2023-07

Primary Completion Date: 2027-07
Completion Date: 2027-07
First Posted: 2023-07-14
Results First Posted:
Last Update Posted: 2023-07-14
Locations: University of Michigan Rogel Cancer Center, Ann Arbor, Michigan, 48109, United States
Study Documents:

NCT Number: NCT03431896
Study Title: Monitoring of Early Disease Progression in Hereditary Transthyretin Amyloidosis
Study URL: https://beta.clinicaltrials.gov/study/NCT03431896
Acronym: MED-hATTR
Study Status: RECRUITING
Brief Summary: This study measures circulating, misfolded ATTR oligomers in asymptomatic ATTRm amyloidosis genetic carriers longitudinally over five years.
Study Results: NO
Conditions: Amyloidosis|Amyloid|Amyloid Neuropathies, Familial|Amyloid Cardiomyopathy|Amyloid - Primary|Transthyretin Amyloidosis|AL Amyloidosis
Interventions:
Primary Outcome Measures: Average % change in oligomers in patients with new onset TTR amyloid symptoms, Change (%) for oligomer level at the time of TTR amyloid symptoms compared to baseline, Annually over 5 years
Secondary Outcome Measures: % change of oligomer levels relative to baseline level in patients with ATTR specific medication changes, Change (%) for oligomer level at the time of ATTR specific medication changes compared to baseline, Annually over 5 years
Other Outcome Measures:
Sponsor: The Cleveland Clinic
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 30
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 17-1301
Start Date: 2018-02-01
Primary Completion Date: 2024-02-15
Completion Date: 2024-02-15
First Posted: 2018-02-13
Results First Posted:
Last Update Posted: 2023-04-18
Locations: Cleveland Clinic, Cleveland, Ohio, 44195, United States
Study Documents:

NCT Number: NCT02771795
Study Title: A Long-term Follow-up Study for Cardiac Safety in the Patients With HER2 (+) Breast Cancer Who Have Completed the SB3-G31-BC
Study URL: https://beta.clinicaltrials.gov/study/NCT02771795
Acronym:
Study Status: TERMINATED
Brief Summary: A Long-term Follow-up Study for Cardiac Safety in the Patients with HER2 Positive Early or Locally Advanced Breast Cancer Who Have Completed the SB3-G31-BC
Study Results: NO
Conditions: Breast Neoplasms
Interventions: DRUG: Herceptin (trastuzumab)|DRUG: SB3 (proposed trastuzumab biosimilar)
Primary Outcome Measures: The incidence of congestive heart failure and LVEF decrease, Incidence of symptomatic congestive heart failure (CHF) NYHA class II, III, and IV and asymptomatic significant LVEF decrease, 60 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Samsung Bioepis Co., Ltd.
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 549
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SB3-G31-BC-E
Start Date: 2016-04
Primary Completion Date: 2020-12
Completion Date: 2020-12
First Posted: 2016-05-13
Results First Posted:
Last Update Posted: 2021-01-07
Locations: Complex Oncological Center - Vratsa, EOOD, Vratsa, 3000, Bulgaria|ONKOCENTRUM Medicon Services s.r.o., Praha, 14000, Czechia|CHU Besançon - Hôpital Jean Minjoz, Besançon, 25030, France|Centre Hospitalier de Belfort-Montbeliard, Montbéliard, 25209, France|Bialostockie Centrum Onkologii im.M.Sklodowskiej-Curie w Bialymstoku, Bialystok, 15 027, Poland|Centrum Onkologii im. Prof. Franciszka Lukaszczyka w Bydgoszczy, Bydgoszcz, 85 796, Poland|Uniwersyteckie Centrum Kliniczne, Klinika Onkologii I Radioterapii, Gdansk, 80 952, Poland|Samodzielny Publiczny Zakład Opieki Zdrowotnej, Olsztyn, 10 228, Poland|Samodzielny Publiczny ZOZ Opolskiego Centrum Onkologii w Opolu im. T. Koszarowskiego, Opole, 45-060, Poland|Wielkopolskie Centrum Onkologii, im Marii Sklodowskiej-Curie, Poznań, 61 866, Poland|Centrum Onkologii-Instytut im. M. Sklodowskiej Curie, Warsaw, 02 781, Poland|Magodent Sp. Z o.o., Warszawa, 03-984, Poland|Spitalul

Judetean de Urgenta "Dr. Constantin Opris" Baia Mare, Baia Mare, 430031, Romania|SC Centrul Medical Unirea SRL-Policlinica Baneasa, Specialitatea Oncologie Medicala, Bucuresti, 013811, Romania|Spitalul Clinic Filantropia, Compartimentul Oncologie Ginecologica, Bucuresti, 11171, Romania|Institutul Oncologic "Prof. Dr. Ion Chiricuta" Cluj-Napoca, Cluj-Napoca, 400015, Romania|Spitalul Clinic Judetean de Urgenta Cluj Napoca, Cluj-Napoca, 400349, Romania|Spitalul Municipal Ploiesti, Sectia Oncologie Medicala, Ploiesti, 100337, Romania|S.C Oncomed S.R.L, Timisoara, 300239, Romania|Spitalul Clinic Municipal de Urgenta Timisoara, Timisoara, 300595, Romania|SBHI of Moscow City "Moscow City Oncology Hospital №62" of Moscow Healthcare Department, Istra, Krasnogorsk District, 143423, Russian Federation|S.I. Russian Oncological Research Center n.a. N.N. Blokhin, Moscow, 115478, Russian Federation|Federal State Budgetary Institution "Federal Medical Research Center n.a. P.A Gertsen" of Ministry of healthcare of RF/3, Moscow, 125284, Russian Federation|SBI of Ryazan region "Regional Clinical Oncological Dispensary", Ryazan, 390026, Russian Federation|Non-state Healthcare Institution "Roadway Clinical Hospital of OJSC Russian Railways", Saint Petersburg, 195271, Russian Federation|Saint-Petersburg SBHI "City Clinical Oncology Dispensary", Saint Petersburg, 197022, Russian Federation|SBHI "Leningrad Regional Oncology Dispensary", Saint-Petersburg, 191014, Russian Federation|FSI "Scientific and Research Institution of Oncology n.a. N.N.Petrov" of Ministry of Healthcare and SD of RF, Saint-Petersburg, 197758, Russian Federation|SBHI "Saint-Petersburg Scientific and Practical Center of Specialized Methods of Medical Help (oncological), Saint-Petersburg, 197758, Russian Federation|SHBI of Yaroslavl Region "Regional Clinical Oncology Hospital", Yaroslavl, 150054, Russian Federation|BHI of Omsk Region "Clinical Oncology Dispensary", Omsk, 644013, Russian Federation|Communal Institution Cherkasy Regional Oncological Dispensary of Cherkasy Regional Council, Cherkasy, 18009, Ukraine|Communal Institution Dnipropetrovsk City Multifield Clinical Hospital No.4 of Dnipropetrovsk Regional Council, Dnipropetrovsk, 49102, Ukraine|Communal Non-commercial Enterprise Regional Center of Oncology, Kharkiv, 61070, Ukraine|Communal Institution of Kherson Regional Council Kherson Regional Oncological Dispensary, Kherson, 73000, Ukraine|Lviv State Oncological Regional Treatment and Diagnostic Center, Lviv, 79031, Ukraine|Regional Communal Institution Sumy Regional Clinical Oncological Dispensary, Sumy, 40005, Ukraine|Uzhgorod Central City Clinical Hospital City Oncological Center, Uzhgorod, 88000, Ukraine|Vinnytsia Regional Clinical Oncological Dispensary, Vinnytsia, 21029, Ukraine|Communal Institution Zaporizhzhia Regional Clinical Oncological Dispensary of Zaporizhzhia Regional Council, Zaporizhzhia, 69040, Ukraine
Study Documents:

NCT Number: NCT01574196
Study Title: Assessment of Cardiac Autonomic Function in Adulthood After Chemotherapy or Radiotherapy in Childhood
Study URL: https://beta.clinicaltrials.gov/study/NCT01574196

Acronym: SALTO-SNA
Study Status: COMPLETED
Brief Summary: The SALTO-SNA study is an ancillary study of the SALTO study (Suivi À Long Terme en Oncologie des enfants guéris d'un cancer pédiatrique en régions Rhône-Alpes et Auvergne) coordinated by Dr. Claire Berger, pediatric oncologist at the CHU, Saint Etienne. It aims at re-examining, in their initial treatment center, all patients (a cohort of 495 patients alive in 2011), diagnosed between 1987 and 1992, and cured of childhood cancer (except leukemia) in the Rhône-Alpes and Auvergne regions.

The rationale for this study is based on the observation that although the survival rate of childhood cancers has now reached 75%, complications of chemotherapy and radiotherapy are high and greatly increase the risk of mortality in later years (estimated to be 14% in the literature).

The morbidity risk of chemotherapy and radiotherapy can be quantified by assessing the activity of the intrinsic cardiac autonomic regulation, which represents a powerful predictor of cardiovascular morbidity to the individual.
Study Results: NO
Conditions: Cancer|Sequels|Complications|Autonomic Nervous System
Interventions: OTHER: Autonomic nervous system activity records
Primary Outcome Measures: Autonomic nervous system activity, The autonomic status will be classified in sympatho-vagal equilibrium as "normal", "altered" or "severely abnormal" according to the values obtained for some temporal indices (SDNN, SDaNN, RMSSD etc. ..) and frequencies (Ptot, HF, LF , VLF, ratio LF / HF) compared to validated standards for the age (mean +/- standard deviation)., 15 years after the end of the cancer treatment
Secondary Outcome Measures: Doses of radiotherapy, Regarding radiotherapy, the doses of different vital organs of the body (151 anatomic sites) will be estimated from the radiotherapy technical records with the help of the Dos-EG software proposed by the INSERM team of F De Vathaire., 15 years after the end of the cancer treatment
Other Outcome Measures:
Sponsor: Centre Hospitalier Universitaire de Saint Etienne
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 83
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 1108162|2011-A01357-34
Start Date: 2012-09
Primary Completion Date: 2014-12
Completion Date: 2014-12

First Posted: 2012-04-10
Results First Posted:
Last Update Posted: 2015-03-31
Locations: CHU de Clermont-Ferrand, Clermont-ferrand, 63000, France|CHU de Grenoble, Grenoble, 38000, France|IHOP, Lyon, 69000, France|CHU de Saint-Etienne, Saint-etienne, 42000, France
Study Documents:

NCT Number: NCT02502396
Study Title: Rivaroxaban Utilization for Treatment and Prevention of Thromboembolism in Cancer Patients: Experience at a Comprehensive Cancer Center
Study URL: https://beta.clinicaltrials.gov/study/NCT02502396
Acronym:
Study Status: COMPLETED
Brief Summary: The primary objective of this study is to evaluate the practice patterns of rivaroxaban usage invenous-thromboembolism (VTE) and non-valvular atrial fibrillation (NVAF) in cancer patients.

The secondary objectives are to evaluate outcomes such as recurrent VTE, stroke and bleeding for cancer patients on rivaroxaban.
Study Results: NO
Conditions: Cancer|Deep-vein Thrombosis of the Lower and Upper Extremities|Pulmonary Embolism|Non-valvular Atrial Fibrillation
Interventions: OTHER: Retrospective Chart Review
Primary Outcome Measures: Chart Review of Usage Pattern of Rivaroxaban in Participants with Cancer and Invenous-Thromboembolism (VTE) at MD Anderson Cancer Center, Proportion (95% confidence interval (CI)) of cancer patients who were on rivaroxaban with indication of VTE obtained among cancer patients who were on rivaroxaban.

Analyses made among patients with VTE summarizing practice patterns of rivaroxaban by means, SDs, and ranges for continuous variables (e.g. platelet counts before a procedure) and the counts and percentages for categorical variables (e.g. stopping rivaroxaban before a procedure, stopping rivaroxaban when the platelets dropped \< 50K, adjusting rivaroxaban dose when the platelets dropped \< 50K, restarting rivaroxaban after it stopped)., 1 year|Chart Review of Usage Pattern of Rivaroxaban in Participants with Cancer and Non-Valvular Atrial Fibrillation (NVAF) at MD Anderson Cancer Center, Proportion (95% confidence interval (CI)) of cancer patients who were on rivaroxaban with indication of NVAF obtained among cancer patients who were on rivaroxaban.

Analyses made among patients with NVAF summarizing practice patterns of rivaroxaban by means, SDs, and ranges for continuous variables (e.g. platelet counts before a procedure) and the counts and percentages for categorical variables (e.g. stopping rivaroxaban before a procedure, stopping rivaroxaban when the platelets dropped \< 50K, adjusting rivaroxaban dose when the platelets dropped \< 50K,

restarting rivaroxaban after it stopped)., 1 year
Secondary Outcome Measures: Chart Review of Stroke Outcome Evaluation of Rivaroxaban in Cancer Participants with Invenous-Thromboembolism (VTE) at MD Anderson Cancer Center, Proportions of patients with recurrent stroke along with 95% CIs, estimated among patients with VTE . SAS 9.4 (SAS Institute INC, Cary, NC) used for data analysis., 1 year|Chart Review of Bleeding Outcome Evaluation of Rivaroxaban in Cancer Participants with Invenous-Thromboembolism (VTE) at MD Anderson Cancer Center, Proportions of patients with recurrent bleeding, along with 95% CIs, estimated among patients with VTE. SAS 9.4 (SAS Institute INC, Cary, NC) used for data analysis., 1 year|Chart Review of Stroke Outcome Evaluation of Rivaroxaban in Cancer Participants with Non-Valvular Atrial Fibrillation (NVAF) at MD Anderson Cancer Center, Proportions of patients with recurrent NVAF along with 95% CIs, estimated among patients with NVAF. SAS 9.4 (SAS Institute INC, Cary, NC) used for data analysis., 1 year|Chart Review of Bleeding Outcome Evaluation of Rivaroxaban in Cancer Participants with Non-Valvular Atrial Fibrillation (NVAF) at MD Anderson Cancer Center, Proportions of patients with recurrent bleeding, along with 95% CIs, estimated among patients with NVAF. SAS 9.4 (SAS Institute INC, Cary, NC) used for data analysis., 1 year
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators: Janssen Scientific Affairs, LLC
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 265
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PA14-1027
Start Date: 2015-09-28
Primary Completion Date: 2022-03-15
Completion Date: 2022-03-15
First Posted: 2015-07-20
Results First Posted:
Last Update Posted: 2022-03-24
Locations: University of Texas MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT02541435
Study Title: Acute and Long-term Cardiovascular Toxicity After Modern Radiotherapy for Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02541435
Acronym:
Study Status: RECRUITING
Brief Summary: In Europe, breast cancer is by far the most common form of cancer diagnosed in women today, accounting for 29% of all cases.

The 5-year survival rate is approximately 90%. Surgery is usually combined with radiotherapy (RT), anthracyclines, aromatase inhibitors and/or trastuzumab (Herceptin) which all have improved the life expectancy and survival in breast cancer patients.

Unfortunately, RT is associated with a broad spectrum of cardiovascular diseases, which includes coronary artery disease, valvular dysfunction, congestive heart failure and stroke, and is the most common non-malignancy cause of death. During the last two decades, RT regimens for breast cancer have changed and the doses of radiation to which the heart is exposed are now potentially lower due to new and improved RT techniques. However, there are no data on whether these new regimes decrease the risk of cardiovascular disease.

In this study the incidence and prevalence of cardiovascular diseases will be estimated 8 and 15 years after both conventional and laser assisted breath controlled RT, and compared with cardiovascular diseases in the general female population. A further aim is to evaluate signs and prevalence of acute cardiotoxicity from RT with the use of cardiac magnetic resonance imaging, coronary fractional flow reserve, ECG and inflammatory and cardiac biomarkers and to investigate whether these signs can predict later cardiovascular disease. The importance of traditional cardiovascular risk factors (age, hypertension, hypercholesterolemia, smoking habits and physical activity, as registered before RT) will also be evaluated.
Study Results: NO
Conditions: Breast Neoplasms|Cardiovascular Diseases
Interventions:
Primary Outcome Measures: incidence of cardiovascular disease, compared with corresponding estimates from the female general population (HUNT-registry data, age-matched sample), 8 years|incidence of cardiovascular disease, compared with corresponding estimates from the female general population (HUNT-registry data, age-matched sample), 15 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: St. Olavs Hospital
Collaborators: Norwegian University of Science and Technology|Alesund Hospital
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1600
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2015/583
Start Date: 2016-11
Primary Completion Date: 2029-12
Completion Date: 2036-12

First Posted: 2015-09-04
Results First Posted:
Last Update Posted: 2022-12-06
Locations: St Olavs University Hospital, Trondheim, Norway|Ålesund Hospital, Ålesund, Norway
Study Documents:

NCT Number: NCT04198896
Study Title: The Sakakibara Health Integrative Profile of Atherosclerotic-Carcinogenesis Hypothesis (SHIP-AC)
Study URL: https://beta.clinicaltrials.gov/study/NCT04198896
Acronym: SHIP-AC
Study Status: COMPLETED
Brief Summary: As previously reported (IJC Heart \& Vasculature 2017; 17: 11.), our epidemiological analysis showing high incidence of cancers in patients with atherosclerotic cardiovascular diseases as compared with those with non-atherosclerotic cardiovascular diseases may imply a clinical possibility of a role of atherosclerosis in cancer developments. In the present study, to address our hypothesis that cancer developments may come with a strength of atherosclerosis, we traced an incidence of cancers in a total of 8,856 patients with coronary artery diseases (CAD) for a median follow-up of 1,095 days (interquartile range, 719-1,469 days) using the Sakakibara Health Integrative Profile (SHIP) database.
Study Results: NO
Conditions: Cancers|Atheroscleroses, Coronary|Atherosclerosis of Artery
Interventions: OTHER: incidece of cancers
Primary Outcome Measures: inicidence of cancers, number of all types of cancers during follow-up periods, through study completion, an average of 3 years
Secondary Outcome Measures: all-cause mortality, number of all types of death during follow-up periods, through study completion, an average of 3 years
Other Outcome Measures:
Sponsor: Sakakibara Heart Institute
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 8856
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SHIP03
Start Date: 2009-01
Primary Completion Date: 2019-10
Completion Date: 2019-10
First Posted: 2019-12-13
Results First Posted:

Last Update Posted: 2019-12-18
Locations:
Study Documents:

NCT Number: NCT05927246
Study Title: Radiotherapy-Associated Atrial Fibrillation
Study URL: https://beta.clinicaltrials.gov/study/NCT05927246
Acronym: RADAF
Study Status: COMPLETED
Brief Summary: Radiotherapy associated Atrial Fibrillation (RADAF) is an observational study to evaluate onset time and frequency of atrial fibrillation in patients with thoracic malignancies and breast cancer.

Each patient will have 12 lead ECG prior, and daily during radiotherapy.
Study Results: NO
Conditions: Atrial Fibrillation New Onset
Interventions: DIAGNOSTIC_TEST: ECG
Primary Outcome Measures: Occurrence of atrial fibrillation, Occurrence of atrial fibrillation, 1 day During radiotherapy|Onset time of atrial fibrillation, Onset time of atrial fibrillation, 1 day During radiotherapy
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Istanbul University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 400
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: COEXIST-1
Start Date: 2023-01-01
Primary Completion Date: 2023-06-01
Completion Date: 2023-06-01
First Posted: 2023-07-03
Results First Posted:
Last Update Posted: 2023-07-03
Locations: Istanbul Faculty of Medicine, Fatih, Istanbul, 34093, Turkey
Study Documents:

NCT Number: NCT00939146
Study Title: Outlook: An Intervention to Improve Quality of Life in Serious Illness
Study URL: https://beta.clinicaltrials.gov/study/NCT00939146
Acronym:
Study Status: COMPLETED

Brief Summary: This study will demonstrate whether an end-of-life preparation and completion intervention reduces anxiety, depression, pain and other symptoms and improves functional status, spiritual well-being, and quality of life. If effective, the intervention offers a brief, inexpensive, and transportable non-physician treatment method for improving the experience of individuals in the latter stages of life-limiting illness.
Study Results: NO
Conditions: Neoplasms|Pulmonary Disease, Chronic Obstructive|Heart Failure|Renal Disease
Interventions: OTHER: Outlook Attention Control|OTHER: Outlook Intervention
Primary Outcome Measures: QUAL-E subscale describing preparation for death (Quality of Life at End of Life, Steinhauser et al. 2004), Eight weeks
Secondary Outcome Measures: Remaining subscales of the QUAL-E instrument (Quality of Life at End of Life, Steinhauser et al. 2004), Eight weeks
Other Outcome Measures:
Sponsor: Duke University
Collaborators: National Institute of Nursing Research (NINR)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 154
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose:
Other IDs: Pro00011193|1P01NR010948-01
Start Date: 2010-02
Primary Completion Date: 2013-09
Completion Date: 2013-09
First Posted: 2009-07-14
Results First Posted:
Last Update Posted: 2014-02-07
Locations: Duke University Medical Center, Durham, North Carolina, 27705, United States
Study Documents:

NCT Number: NCT03259438
Study Title: The Vitality Project for Fatigued Female Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT03259438
Acronym:
Study Status: UNKNOWN
Brief Summary: This parallel, randomized, non-inferiority trial will examine whether a ten week qigong intervention is not inferior to a ten week exercise-nutrition comparison group in reducing fatigue in cancer survivors. To build a more mechanistic understanding of physiological changes associated with fatigue reduction, it will

secondly collect several different types of data to build an integrative brain-body model of vigor in cancer survivorship including:

1. data related to neural correlates of body awareness: cortical EEG data measuring each subject's ability to use attention to control neurons in primary somatosensory cortex (replication of Kerr et al 2011 study in mindfulness), and resting state fMRI measures of insular connectivity with nodes of the default mode network and salience network
2. data related to inflammation measured via inflammatory cytokines (e.g., interleukin-6 and tnf-alpha)
3. data related to cardiorespiratory functioning including cardiac impedance (ICG) and mechanical lung function
4. data related to parasympathetic and sympathetic signaling between the nervous system and the rest of the periphery.

Study Results: NO
Conditions: Fatigue|Cancer Survivorship
Interventions: BEHAVIORAL: Qigong|BEHAVIORAL: Healthy Living (CHIP + Pre-Train)
Primary Outcome Measures: Reduction in Fatigue (via FACIT-Fatigue scale), Fatigue assessed via the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) questionnaire, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)
Secondary Outcome Measures: Electrocardiogram (ECG), Will be measured to calculate heart rate variability (HRV), Measured at baseline (time 1) and after 10-week intervention (time 2)|Impedance Cardiography, Will be used to assess exercise related improvements in cardiovascular tone., Measured at baseline (time 1) and after 10-week intervention (time 2)|Electroencephalography (EEG), Will be used to assess changes in cortical brain waves (particularly alpha and beta rhythms), Measured at baseline (time 1) and after 10-week intervention (time 2)|Tactile Acuity, A task that involves subtle taps to the finger tips, EEG is simultaneously recorded to examine modulation in brain rhythms across somatosensory cortex related to cued attention to the tap, Measured at baseline (time 1) and after 10-week intervention (time 2)|Electromyography (EMG), A measure of muscle rhythms, Measured at baseline (time 1) and after 10-week intervention (time 2)|Precision Grip, A measure of one's ability to hold a lever at a steady force, EEG and EMG simultaneously record corticomuscular coherence that may facilitate steady grip, Measured at baseline (time 1) and after 10-week intervention (time 2)|Electrodermal Activity (skin conductance), to assess sympathetic tone, Measured at baseline (time 1) and after 10-week intervention (time 2)|Working memory capacity (WMC), Assessed via the short-form O-SPAN computer-based task to assess overall memory impairments, Measured at baseline (time 1) and after 10-week intervention (time 2)|Mechanical lung function, to determine the impact of exercise and movement on overall lung function, Measured at baseline (time 1) and after 10-week intervention (time 2)|Inflammatory

cytokines (eg Il-1, Il-6) collected via a blood draw, To measure the interaction between the brain measures of bodily awareness and the immune system, Measured at baseline (time 1) and after 10-week intervention (time 2)|Resting State Functional Magnetic Resonance Imaging (rs-fMRI), Optional measure: To assess changes in functional connectivity associated with participation in the intervention, Measured at baseline (time 1) and after 10-week intervention (time 2)|Muscle Strength, Assessed via jamar hand dynamometers and back, leg, and arm dynamometers to assess changes in muscle tone associated with the classes, Measured at baseline (time 1) and after 10-week intervention (time 2)|6 Minute Walk Test, Test of how far a participant can walk in six minutes to assess overall endurance, Measured at baseline (time 1) and after 10-week intervention (time 2)|Patient Health Questionnaire, Measure of anxiety and depression, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Functional Assessment of cancer therapy-General (FACT-G) Questionnaire, Measure of physical, social, emotional, and functional well-being, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Multidimensional Assessment of Interoceptive Awareness (MAIA) Questionnaire, Questionnaire to measure subjectively reported interoceptive and bodily awareness (including body-specific sensations, emotions, and cognitions), Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Profile of Mood States (POMS) Questionnaire, To assess fatigue, vigor, and overall mood, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Pittsburgh Sleep Quality Index (PSQI), Measurement of sleep quality, habits, and patterns, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Rand 36-Item Short Form Health Survey (SF-36), Measurement of overall quality of life, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Difficulties in Emotion Regulation Scale (DERS), Measures multiple factors of emotional dysregulation, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Fatigue Symptom Inventory (FSI), Measures overall fatigue interfrerence, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3) Other Outcome Measures: Apple watches Heart Rate and Physical Steps Tracking, Apple watches will be supplied to interested participants to monitor their heart rate and physical steps taken throughout the day to assess changes in movement patterns while participating in the classes, Optional Measure: For those involved, tracked daily for five days before the intervention starts, for the 70 days during the 10-week intervention, and for five days after the intervention ends.|Perceived Stress Scale (PSS) Questionnaire, To assess changes in self-reported stress, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|

Multidimensional Scale of Perceived Social Support (MSPSS), Measure of self-reported social support, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Unmitigated Communion Scale, A measure of a person's tendency to care for other's before themselves, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)|Godin Leisure time Questionnaire, Measure of how much a person has been excising or relaxing, Measured at baseline (time 1) and after 10-week intervention (time 2) and 3 months after end of intervention (time 3)
Sponsor: The Miriam Hospital
Collaborators: Brown University
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 75
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: MiriamH 1040485
Start Date: 2017-07-24
Primary Completion Date: 2017-12-20
Completion Date: 2018-01-30
First Posted: 2017-08-23
Results First Posted:
Last Update Posted: 2017-08-23
Locations: Miriam Hospital Outpatient 146 West River Street, Providence, Rhode Island, 02904, United States
Study Documents:

NCT Number: NCT03461588
Study Title: Prospective Assessment of Radiation-induced Heart Injury in Left-sided Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03461588
Acronym:
Study Status: COMPLETED
Brief Summary: This study is to prospectively investigate the cardiac dose-sparing effect and clinical benefit of deep inspiration breath-hold (DIBH) technique. Patients with left-sided breast cancer treated with breast conserving surgery followed by radiotherapy is enrolled. Radiotherapy is delivered with either free-breathing or deep inspiration breath-hold (DIBH) technique. The cardiac dose parameters and cardiac toxicity are prospective evaluated, and the dose-effect relationship is analyzed.
Study Results: NO
Conditions: Breast Neoplasms|Heart Injuries|Radiation Toxicity
Interventions: RADIATION: free-breathing|RADIATION: deep inspiratory breath-holding

Primary Outcome Measures: Number of participants with treatment-related cardiac adverse events as assessed by CTCAE v4.0, The cardiac adverse events are regularly assessed with cardiac symptoms,cardiac enzymes(TnT, BNP),electrocardiogram(ECG) and normal gated single-photon emission computed tomography-myocardial perfusion imaging., up to 2 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Shu lian Wang
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 140
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: LC2016A09
Start Date: 2017-01-01
Primary Completion Date: 2020-01-30
Completion Date: 2020-01-30
First Posted: 2018-03-12
Results First Posted:
Last Update Posted: 2020-03-25
Locations: Cancer Hospital, Chinese Academy of Medical Sciences, Beijing, 100021, China|Cancer Hosptical, Chinese Academy of Medical Sciences, Beijing, 100021, China
Study Documents:

NCT Number: NCT05923242
Study Title: Translating ECHOS2 Into an mHealth Platform
Study URL: https://beta.clinicaltrials.gov/study/NCT05923242
Acronym: ECHOS2
Study Status: RECRUITING
Brief Summary: Childhood cancer survivors are at an increased risk of cardiac toxicity due to prior anti-cancer therapy. However, adherence to cardiac screening in this population remains low. This study aims to assess the feasibility of an mHealth motivational interviewing platform called Computerized Authoring Intervention Software (CIAS) in childhood cancer survivors. Participants will be recruited from the Childhood Cancer Survivorship Study.
Study Results: NO
Conditions: Childhood Cancer|Cardiac Toxicity|Pediatric Cancer
Interventions: BEHAVIORAL: Computerized Intervention Authoring Software (CIAS)
Primary Outcome Measures: Change in health belief model (HBM) construct scale of knowledge about echocardiograms and the effects of their treatment on health, Patients will be asked about their knowledge of echocardiograms and the effects of their treatment on

health on a 3 point scale consisting of possible answers of yes, no, and "don't know", with "don't know" being scored as incorrect. The scoring will be the summary of correct responses., From baseline survey to post-test survey (expected to be about 1 week)|Change in self-determination theory (SDT) construct scale of competence, defined by confidence in getting an echocardiogram, Patients will be asked about their confidence in getting an echocardiogram on a Likert scale with multiple choice between 0 to 10 with 0 indicating not at all sure and 10 indicating extremely sure. Scores will range from 0 and 10 with a higher value indicating higher confidence., From baseline survey to post-test survey (expected to be about 1 week)|Change in self-determination theory (SDT) construct scale of autonomy, defined by the perceived choice of getting an echocardiogram, Patients will be asked about their perceived choice of getting an echocardiogram on a 5-point Likert scale with 1 indicating disagree strongly and 5 indicating agree strongly. Scores will range from 3 to 15 with a higher score indicating higher perceived choice., From baseline survey to post-test survey (expected to be about 1 week)|Change in self-determination theory (SDT) construct scale of relatedness, as defined by the effect of social norms/influence on the patient's decision of getting echocardiogram, Patients will be asked about the effects of social norms/influence on a 5-point Likert scale with 1 indicating disagree strongly and 5 indicating agree strongly. Scores will range from 6 to 30 with a higher score indicating more effect of social norms and influence on the patient's decision., From baseline survey to post-test survey (expected to be about 1 week)|Change in movement toward screening, Movement toward screening will consist of checking if patient made a plan to set an appointment with healthcare provider to discuss screening, made an appointment to discuss screening, had appointment to discuss screening, scheduled screening, or obtained screening, and if this plan changed between post-test survey and 1 month follow-up., From post-test survey to 1 month follow-up (expected to be about 1 month and 1 week)
Secondary Outcome Measures: Change in health belief model (HBM) construct scale of perceived risk of having heart problems, Patients will be asked about their perceived risk of having heart problems on a 5 point scale, with 1 indicating no likelihood of heart problems, and 5 indicating extremely likely. Scores will range from 1 to 5 with a higher score indicating more perceived risk., From baseline survey to post-test survey (expected to be about 1 week)|Change in health belief model (HBM) construct scale of perceived severity of having heart problems, Patients will be asked about their perceived severity of heart problems on a 5 point scale, with 1 indicating not serious and 5 indicating extremely serious. Scores will range from 1 to 5 with a higher score indicating higher perceived severity., From baseline survey to post-test survey (expected to be about 1 week)|Change in health belief model (HBM) construct scale of perceived barriers to getting echocardiogram, Patients will be asked about their perceived barriers to getting an echocardiogram on a 5-point Likert scale with 1 indicating disagree strongly and 5 indicating agree strongly. Scores

will range from 6 to 30 with a higher score indicating fewer perceived barriers., From baseline survey to post-test survey (expected to be about 1 week)|Change in health belief model (HBM) construct scale of perceived benefits of getting echocardiogram, Patients will be asked about their perceived benefits of getting an echocardiogram on a 5-point Likert scale with 1 indicating disagree strongly and 5 indicating agree strongly. Scores will range from 6 to 30 with a higher score indicating more perceived benefits., From baseline survey to post-test survey (expected to be about 1 week)|Change in health belief model (HBM) construct scale of overall self-efficacy of getting echocardiogram, Patients will be asked about their overall self-efficacy of getting an echocardiogram on a 5-point Likert scale with 1 indicating disagree strongly and 5 indicating agree strongly. Scores will range from 3 to 15 with a higher score indicating higher overall self-efficacy., From baseline survey to post-test survey (expected to be about 1 week)|Change in health belief model (HBM) construct scale of worry about having heart problems, Patients will be asked about their worry about having heart problems on a 5-point scale with 1 indicating not worried at all and 5 indicating extremely worried. Scores will range from 1 to 5 with a higher score indicating more worry., From baseline survey to post-test survey (expected to be about 1 week)|Change in health belief model (HBM) construct scale intentions of getting echocardiogram, Patients will be asked about their intentions of getting an echocardiogram on a 5-point Likert scale with 1 indicating disagree strongly and 5 indicating agree strongly. Scores will range from 3 to 15 with a higher score indicating a higher intention of getting an echocardiogram., From baseline survey to post-test survey (expected to be about 1 week)|Change in self-determination theory (SDT) construct scale of intrinsic motivation, defined by the perceived importance of getting an echocardiogram, Patients will be asked about their perceived importance of getting an echocardiogram on both a Likert scale with multiple choice between 0 to 10 with 0 indicating not at all important and 10 indicating extremely important, and a 5-point Likert scale with 1 indicating disagree strongly and 5 indicating agree strongly. Scores will range from 8 to 50 with a higher value indicating higher perceived importance., From baseline survey to post-test survey (expected to be about 1 week)|Change in self-determination theory (SDT) construct scale of intrinsic motivation, defined by decision-making readiness, Patients will be asked about their decision-making readiness in getting an echocardiogram on a Likert scale with multiple choice between 0 to 10 with 0 indicating not at all ready and 10 indicating extremely ready. Scores will range from 0 to 10 with a higher score indicating higher decision-making readiness., From baseline survey to post-test survey (expected to be about 1 week)|Implementation process outcome of engagement with the app as measured by the time spent on the app, This will be defined as the total time spent on the app during session 1 and session 2., Through the second CIAS session (expected to be about 1 week)|Implementation process outcome of engagement with the app as measured by the number of modules started/completed, This will be

defined as the total number of modules started and total number of modules completed on the app during session 1 and session 2., Through the second CIAS session (expected to be about 1 week)|Implementation process outcome of engagement with the app as measured by the number of sessions started/completed, This will be defined as the total number of sessions started and total number of sessions completed on the app during session 1 and session 2., Through the second CIAS session (expected to be about 1 week)
Other Outcome Measures:
Sponsor: Washington University School of Medicine
Collaborators: St. Jude Children's Research Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 202305110
Start Date: 2023-07-05
Primary Completion Date: 2024-01-07
Completion Date: 2024-01-07
First Posted: 2023-06-28
Results First Posted:
Last Update Posted: 2023-07-10
Locations: Washington University School of Medicine, Saint Louis, Missouri, 63110, United States
Study Documents:

NCT Number: NCT05180942
Study Title: Statins and prOgression of Coronary atheRosclerosis in melanomA Patients Treated With chEckpoint inhibitorS
Study URL: https://beta.clinicaltrials.gov/study/NCT05180942
Acronym: SOCRATES
Study Status: RECRUITING
Brief Summary: This study will incorporate a prospective randomised open blinded end-point trial in participants with stage 2, 3 or 4 melanoma treated with ICI to evaluate the impact of statin therapy on changes in coronary plaque burden and composition.
Study Results: NO
Conditions: Melanoma|Atherosclerosis
Interventions: DRUG: Atorvastatin Calcium 40Mg Tab
Primary Outcome Measures: Change in non-calcified plaque volume according to treatment with statins, Difference in non-calcified plaque volume as measured on serial CTCA between patients treated with and without statin therapy, 18 months
Secondary Outcome Measures: Change in total plaque volume in patients treated with ICI compared to historical cohorts, Difference in total plaque volume as measured on serial CTCA between patients treated with

ICI therapy against historical cohorts, 18 months|Change in pericoronary adipose tissue attenuation and volume according to treatment with statins, Difference in pericoronary adipose tissue attenuation and volume as measured on serial CTCA between patients treated with and without statin therapy, 18 months|Cost-effectiveness of the use of CTCA as measured by net costs per life year gained in patients with melanoma treated with ICI therapy, Differences in cost-effectiveness ratios in terms of net costs per life year gained between patients with melanoma treated with ICI therapy who had CTCA performed compared to historical cohorts who did not have CTCA performed, 18 months|Incidence of adverse events with statin therapy, Incidence and number of patients treated with and without statin therapy with reported adverse events and serious adverse events, 18 months|Cost-effectiveness of statin therapy in patients with melanoma treated with ICI therapy as measured by net costs per life year gained, Difference in cost-effectiveness ratios between patients with melanoma on ICI therapy who are treated with and without statin therapy, in terms of net costs per life year gained, 18 months|Effect of statins on depression in patients with melanoma treated with ICI therapy as measured on the Patient Health Questionnaire-9, Differences in mean changes in scores for the Patient Health Questionnaire-9 for each patient according to statin use, with a minimum score of 0 and a maximum score of 27, and higher scores indicating higher likelihood of depression, 18 months|Effect of statins on anxiety in patients with melanoma treated with ICI therapy as measured on the Generalized Anxiety Disorder-7 questionnaire, Differences in mean changes in scores for the Generalized Anxiety Disorder-7 questionnaire for each patient according to statin use, with a minimum score of 0 and a maximum score of 21, and higher scores indicating higher likelihood of anxiety, 18 months|Effect of statins on quality of life in patients with melanoma treated with ICI therapy as measured on the European Organization for Research and Treatment of Cancer QLQ-C30 questionnaire, Differences in mean changes in scores for the European Organization for Research and Treatment of Cancer QLQ-C30 questionnaire for each patient according to statin use, with a minimum score of 30 and a maximum score of 126, and higher scores indicating poorer quality of life, 18 months|Effect of statins on quality of life in patients with melanoma treated with ICI therapy as measured on the EuroQoL Group EQ-5D questionnaire, Differences in mean changes in scores for the EuroQoL Group EQ-5D questionnaire for each patient according to statin use, with a minimum score of 1 and a maximum score of 15, and higher scores indicating poorer quality of life, 18 months|Effect of statins on quality of life in patients with melanoma treated with ICI therapy as measured on the FACT-M questionnaire, Differences in mean changes in scores for each section of the FACT-M questionnaire for each patient according to statin use.

The score ranges for each individual section are: physical well-being 0-28, social well-being 0-28, emotional well-being 0-24, functional well-being 0-28, additional well-being 0-64, and melanoma-specific

questions 0-32.

Interpretation of scoring depends on the individual sections in the questionnaire, with higher scores in the physical, emotional, additional and melanoma-specific questions indicating poorer quality of life, whilst lower scores in the social and emotional questions indicate poorer quality of life, 18 months
Other Outcome Measures:
Sponsor: Monash University
Collaborators: National Health and Medical Research Council, Australia
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 180
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: SOCRATES
Start Date: 2022-11-07
Primary Completion Date: 2025-06
Completion Date: 2025-06
First Posted: 2022-01-06
Results First Posted:
Last Update Posted: 2023-06-08
Locations: Monash Health, Clayton, Victoria, 3168, Australia|Cabrini Health, Malvern, Victoria, 3144, Australia|Latrobe Regional Hospital, Traralgon, Victoria, 3844, Australia
Study Documents:

NCT Number: NCT04568161
Study Title: Effect of Anthracyclines and Cyclophosphamide on Cardiovascular Responses
Study URL: https://beta.clinicaltrials.gov/study/NCT04568161
Acronym:
Study Status: RECRUITING
Brief Summary: The present study aims to investigate the chronic effect of treatment with doxorubicin and cyclophosphamide on neurovascular control and blood pressure in women undergoing adjuvant treatment for breast cancer.
Study Results: NO
Conditions: Cardiotoxicity|Cardiovascular Disease|Neurovascular Disorder|Endothelial Disfunction|Breast Cancer
Interventions: PROCEDURE: Physical Characteristics|PROCEDURE: Muscular Sympathetic Nervous Activity|DIAGNOSTIC_TEST: Cardiac Function|DIAGNOSTIC_TEST: Heart rate|DIAGNOSTIC_TEST: Blood pressure|DIAGNOSTIC_TEST: Blood Assessments|DIAGNOSTIC_TEST: Muscle blood flow|DIAGNOSTIC_TEST: Endothelium-dependent vascular function|DIAGNOSTIC_TEST: Vascular intima-media thickness|DIAGNOSTIC_TEST: Physical Capacity|DRUG: Anthracycline & Cyclophosphamide treatment

scheme
Primary Outcome Measures: Muscle sympathetic nerve activity, Change in muscular sympathetic nerve activity measured by microneurography, 15-20 days after the end of AC regimen
Secondary Outcome Measures: Muscle blood flow, Change in muscle blood flow measured by venous oclusion plethysmography, 15-20 days after the end of AC regimen|Blood Pressure, Change in blood pressure measured by finometer, 15-20 days after the and of AC regimen|Physical capacity, Change in physical capacity measured by cardiopulmonary exercise test, 15-20 days after the end of AC regimen|Cardiac Function Impairment, Change in cardiac function measured by echocardiography, 15-20 days after the end of AC regimen
Other Outcome Measures:
Sponsor: University of Sao Paulo General Hospital
Collaborators: Universidade Federal Fluminense|Hospital Israelita Albert Einstein
Sex: FEMALE
Age: ADULT
Phases: NA
Enrollment: 15
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: Breast Cancer Chemotherapy
Start Date: 2020-08-03
Primary Completion Date: 2022-09-03
Completion Date: 2023-11-03
First Posted: 2020-09-29
Results First Posted:
Last Update Posted: 2023-06-13
Locations: Instituto do Coracao (InCor), Hospital das Clinicas HCFMUSP, Faculdade de Medicina, Universidade de Sao Paulo, Sao Paulo, 05403-900, Brazil
Study Documents:

NCT Number: NCT02471053
Study Title: Exercise to Prevent AnthrCycline-based Cardio-Toxicity Study
Study URL: https://beta.clinicaltrials.gov/study/NCT02471053
Acronym: EXACT
Study Status: COMPLETED
Brief Summary: As the numbers of cancer survivors grow, the long-term adverse effects of cancer therapy are becoming increasingly apparent. Most prominent are the toxic effects on the heart (cardiotoxicity) which may lead to cardiac dysfunction and increased risk of cardiovascular disease (CVD). The investigators hypothesize that an individualized aerobic training program for cancer patients receiving active treatment will be both feasible and safe and will result in improvements in overall levels of physical activity and quality of

life.

Feasibility will be assessed by evaluating the recruitment, adherence and attrition rates, along with program safety. Efficacy will be assessed by evaluating changes in health-related outcomes.
Study Results: NO
Conditions: Neoplasms|Heart; Disease, Functional|Inflammation
Interventions: OTHER: Moderate Intensity Exercise
Primary Outcome Measures: Feasibility as measured by rate of recruitment, The rate of recruitment will be measured by comparing the number of patients screened to the number of patients enrolled (patients per month)., 12 Weeks|Number of adverse events, The number of adverse events associated with exercise program will be used to examine safety., 12 Weeks
Secondary Outcome Measures: Feasibility as measured by program adherence, The program adherence will be calculated by dividing the total number of exercise sessions by the number of actual session attended., 12 Weeks|Feasibility as measured by attrition rate, The attrition rate will be measured by the number of patients who drop out of the study., 12 Weeks|Cardiac Function, Cardiac function will be measured by examining heart chamber size, ventricular function and blood flow between the cardiac chambers using a Multigated acquisition (MUGA) scan., 12 Weeks|Cardiac Disease Risk, Cardiac disease risk will be measured using the Framingham Risk Score., 12 Weeks|Aerobic Fitness, Aerobic fitness will be measured by comparing baseline and 12 week cardiac stress tests and the associated peak oxygen uptake values., 12 Weeks|Fatigue, The Functional Assessment of Cancer Therapy - Fatigue questionnaire will be used to compare baseline and 12 week self-reported levels of fatigue., 12 Weeks|Physical Activity Behaviours, Baseline and 12 week levels of physical activity will be measured using the International Physical Activity Questionnaire., 12 Weeks|Life Quality, The Functional Assessment of Cancer Therapy - General questionnaire along with the appropriate tumor specific appendix, will be used to compare baseline and 12 week quality of life measures., 12 Weeks|Lipid Profile, Baseline and 12 week levels will be compared., 12 Weeks|Fasting Glucose, Baseline and 12 week levels will be compared., 12 Weeks|High-sensitivity Troponin (hs-TNT), Baseline and 12 week levels will be compared., 12 Weeks|N-terminal of the prohormone brain natriuretic peptide (NTproBNP), Baseline and 12 week levels will be compared., 12 Weeks|C-reactive protein (CRP), Baseline and 12 week levels will be compared., 12 Weeks|Cytokines (IL-1α), Baseline and 12 week levels (picogram per milileter) will be compared., 12 Weeks|Cytokines (IL-1β), Baseline and 12 week levels (picogram per milileter) will be compared., 12 Weeks|Cytokines (IL-4), Baseline and 12 week levels (picogram per milileter) will be compared., 12 Weeks|Cytokines (IL-6), Baseline and 12 week levels (picogram per milileter) will be compared., 12 Weeks|Cytokines (IL-10), Baseline and 12 week levels (picogram per milileter) will be compared., 12 Weeks|Cytokines (IL-17), Baseline and 12 week levels (picogram per milileter) will be compared., 12 Weeks|Cytokines (TNFα),

Baseline and 12 week levels (picogram per milileter) will be compared., 12 Weeks
Other Outcome Measures:
Sponsor: Nova Scotia Health Authority
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 12
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: EXACT2015
Start Date: 2016-02
Primary Completion Date: 2017-09
Completion Date: 2017-09
First Posted: 2015-06-12
Results First Posted:
Last Update Posted: 2022-12-06
Locations: QEII Health Science Center, Nova Scotia Health Authority, Halifax, Nova Scotia, B3H 3A7, Canada
Study Documents:

NCT Number: NCT05089461
Study Title: A Study to Evaluate the Cardiac Safety of Mitoxantrone Hydrochloride Liposome Injection in the Treatment of Advanced Malignant Tumor
Study URL: https://beta.clinicaltrials.gov/study/NCT05089461
Acronym:
Study Status: SUSPENDED
Brief Summary: This is a multicenter, open-label, phase II study to evaluate the cardiac safety of Mitoxantrone Hydrochloride Liposome in patients with advanced malignant tumor who has received at least first-line treatment.
Study Results: NO
Conditions: Advanced Malignant Tumor
Interventions: DRUG: Mitoxantrone Hydrochloride Liposome
Primary Outcome Measures: Cardiac adverse event, up to approximately 5 years.
Secondary Outcome Measures: Overall response rate (ORR), up to approximately 3 years|Progression-free survival (PFS), up to approximately 3 years.|Overall survival (OS), up to approximately 5 years|Incidence of treatment emergent adverse event (TEAE), up to approximately 3 years.
Other Outcome Measures:
Sponsor: CSPC ZhongQi Pharmaceutical Technology Co., Ltd.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: PHASE2
Enrollment: 120
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: HE071-CSP-020
Start Date: 2022-03-07
Primary Completion Date: 2022-06-20
Completion Date: 2022-12-30
First Posted: 2021-10-22
Results First Posted:
Last Update Posted: 2022-09-10
Locations: the first affiliated hospital of Dalian medical university, Dalian, Liaoning, 116011, China
Study Documents:

NCT Number: NCT03418961
Study Title: S1501 Carvedilol in Preventing Cardiac Toxicity in Patients With Metastatic HER-2-Positive Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03418961
Acronym:
Study Status: RECRUITING
Brief Summary: This phase III trial studies how well carvedilol works in preventing cardiac toxicity in patients with human epidermal growth factor receptor (HER)-2-positive breast cancer that has spread to other places in the body. A beta-blocker, such as carvedilol, is used to treat heart failure and high blood pressure, and it may prevent the heart from side effects of chemotherapy.
Study Results: NO
Conditions: Cardiotoxicity|HER2/Neu Positive|Metastatic Malignant Neoplasm in the Brain|Recurrent Breast Carcinoma|Stage IV Breast Cancer AJCC v6 and v7
Interventions: DRUG: Carvedilol|OTHER: Laboratory Biomarker Analysis|OTHER: Patient Observation
Primary Outcome Measures: Time to the first identification of cardiac dysfunction, Real-time, blinded, central echocardiography (ECHO) read as a decrease in the left ventricular ejection fraction (LVEF) of \>= 10 percentage points from baseline to a value of \< 50% OR decrease of LVEF by \>= 5 percentage points from baseline to LVEF \< 50% in those baselines having a baseline LVEF of 50-54%. The distributions of time to cardiac dysfunction will be described using cumulative incidence estimates, with the statistical significance of treatment arm differences assessed by Cox and Fine-Gray regression models with adjustment for stratification factors. Gray's test will also be applied, Up to 108 weeks
Secondary Outcome Measures: Incidence of adverse events associated with beta blocker treatment, Adverse events associated with beta blocker treatment will be assessed., Up to 108 weeks|Rate of first interruption of trastuzumab, The distributions of time to interruption

of trastuzumab-based therapy will be described using cumulative incidence estimates, with the statistical significance of treatment arm differences assessed by Cox and Fine-Gray regression models with adjustment for stratification factors. Gray?s test will also be applied to the primary endpoint to assess whether the results are sensitive to different model assumptions., Up to 108 weeks|Rate of death, Will compare rate of death from competing causes between treatment arms via Cox regression to evaluate whether those rates impact the primary analysis comparison., Up to 108 weeks|Time to first occurrence of cardiac event, any of the following treating physician documented events requiring hospitalization or medical treatment, and subsequent temporary or permanent discontinuation of trastuzumab-based HER-2 targeted therapy: arrhythmia, unstable angina, non-ST segment elevated myocardial infarction, myocardial infarction, or congestive heart failure., Up to 108 weeks|Drug adherence, Patients on the active arm will be asked to record study drug consumption on a monthly intake calendar. Amount of study drug taken among patients randomized to the active arm and study drug adoption among patients randomized to the no intervention arm (i.e., contamination) will be recorded by study site staff on a case report form at each follow-up visit to assess the sensitivity of the primary treatment effect to observed conditions., Up to 108 weeks
Other Outcome Measures:
Sponsor: SWOG Cancer Research Network
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 817
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: S1501|NCI-2016-01047|S1501|SWOG-S1501|UG1CA189974
Start Date: 2017-11-01
Primary Completion Date: 2029-01-01
Completion Date: 2029-01-01
First Posted: 2018-02-01
Results First Posted:
Last Update Posted: 2023-06-09
Locations: Anchorage Associates in Radiation Medicine, Anchorage, Alaska, 98508, United States|Alaska Breast Care and Surgery LLC, Anchorage, Alaska, 99508, United States|Alaska Oncology and Hematology LLC, Anchorage, Alaska, 99508, United States|Alaska Women's Cancer Care, Anchorage, Alaska, 99508, United States|Anchorage Oncology Centre, Anchorage, Alaska, 99508, United States|Katmai Oncology Group, Anchorage, Alaska, 99508, United States|Providence Alaska Medical Center, Anchorage, Alaska, 99508, United States|Fairbanks Memorial Hospital, Fairbanks, Alaska, 99701, United States|CHI Saint Vincent Cancer Center Hot Springs, Hot Springs, Arkansas, 71913, United

States|Kaiser Permanente–Deer Valley Medical Center, Antioch, California, 94531, United States|Providence Saint Joseph Medical Center/Disney Family Cancer Center, Burbank, California, 91505, United States|Enloe Medical Center, Chico, California, 95926, United States|City of Hope Comprehensive Cancer Center, Duarte, California, 91010, United States|Epic Care–Dublin, Dublin, California, 94568, United States|Bay Area Breast Surgeons Inc, Emeryville, California, 94608, United States|Epic Care Partners in Cancer Care, Emeryville, California, 94608, United States|Kaiser Permanente–Fremont, Fremont, California, 94538, United States|Fresno Cancer Center, Fresno, California, 93720, United States|Kaiser Permanente–Fresno, Fresno, California, 93720, United States|USC / Norris Comprehensive Cancer Center, Los Angeles, California, 90033, United States|Contra Costa Regional Medical Center, Martinez, California, 94553-3156, United States|City of Hope Mission Hills, Mission Hills, California, 91345, United States|Kaiser Permanente–Modesto, Modesto, California, 95356, United States|City of Hope Newport Beach, Newport Beach, California, 92660, United States|Alta Bates Summit Medical Center - Summit Campus, Oakland, California, 94609, United States|Bay Area Tumor Institute, Oakland, California, 94609, United States|Kaiser Permanente Oakland-Broadway, Oakland, California, 94611, United States|Kaiser Permanente-Oakland, Oakland, California, 94611, United States|Kaiser Permanente-Rancho Cordova Cancer Center, Rancho Cordova, California, 95670, United States|Kaiser Permanente–Redwood City, Redwood City, California, 94063, United States|Kaiser Permanente–Richmond, Richmond, California, 94801, United States|Rohnert Park Cancer Center, Rohnert Park, California, 94928, United States|Kaiser Permanente–Roseville, Roseville, California, 95661, United States|The Permanente Medical Group–Roseville Radiation Oncology, Roseville, California, 95678, United States|University of California Davis Comprehensive Cancer Center, Sacramento, California, 95817, United States|Kaiser Permanente–South Sacramento, Sacramento, California, 95823, United States|South Sacramento Cancer Center, Sacramento, California, 95823, United States|Kaiser Permanente - Sacramento, Sacramento, California, 95825, United States|Kaiser Permanente–San Francisco, San Francisco, California, 94115, United States|Kaiser Permanente–Santa Teresa–San Jose, San Jose, California, 95119, United States|Kaiser Permanente San Leandro, San Leandro, California, 94577, United States|Kaiser Permanente–San Rafael, San Rafael, California, 94903, United States|Kaiser San Rafael–Gallinas, San Rafael, California, 94903, United States|Kaiser Permanente Medical Center - Santa Clara, Santa Clara, California, 95051, United States|Kaiser Permanente–Santa Rosa, Santa Rosa, California, 95403, United States|City of Hope South Pasadena, South Pasadena, California, 91030, United States|Kaiser Permanente Cancer Treatment Center, South San Francisco, California, 94080, United States|Kaiser Permanente–South San Francisco, South San Francisco, California, 94080, United States|Kaiser Permanente-Stockton, Stockton, California, 95210, United States|City of Hope South Bay, Torrance, California, 90503, United States|City of Hope Upland, Upland, California, 91786, United States|Kaiser Permanente

Medical Center-Vacaville, Vacaville, California, 95688, United States|Kaiser Permanente-Vallejo, Vallejo, California, 94589, United States|Kaiser Permanente-Walnut Creek, Walnut Creek, California, 94596, United States|Penrose-Saint Francis Healthcare, Colorado Springs, Colorado, 80907, United States|Rocky Mountain Cancer Centers-Penrose, Colorado Springs, Colorado, 80907, United States|Kaiser Permanente-Franklin, Denver, Colorado, 80205, United States|Porter Adventist Hospital, Denver, Colorado, 80210, United States|SCL Health Saint Joseph Hospital, Denver, Colorado, 80218, United States|Mercy Medical Center, Durango, Colorado, 81301, United States|Southwest Oncology PC, Durango, Colorado, 81301, United States|Mountain Blue Cancer Care Center, Golden, Colorado, 80401, United States|Good Samaritan Medical Center, Lafayette, Colorado, 80026, United States|Kaiser Permanente-Rock Creek, Lafayette, Colorado, 80026, United States|Rocky Mountain Cancer Centers-Lakewood, Lakewood, Colorado, 80228, United States|Saint Anthony Hospital, Lakewood, Colorado, 80228, United States|Littleton Adventist Hospital, Littleton, Colorado, 80122, United States|Kaiser Permanente-Lone Tree, Lone Tree, Colorado, 80124, United States|Longmont United Hospital, Longmont, Colorado, 80501, United States|Rocky Mountain Cancer Centers-Longmont, Longmont, Colorado, 80501, United States|Parker Adventist Hospital, Parker, Colorado, 80138, United States|Rocky Mountain Cancer Centers-Parker, Parker, Colorado, 80138, United States|Saint Mary Corwin Medical Center, Pueblo, Colorado, 81004, United States|Rocky Mountain Cancer Centers - Pueblo, Pueblo, Colorado, 81008, United States|Rocky Mountain Cancer Centers-Thornton, Thornton, Colorado, 80260, United States|Middlesex Hospital, Middletown, Connecticut, 06457, United States|Stamford Hospital/Bennett Cancer Center, Stamford, Connecticut, 06904, United States|Bayhealth Hospital Kent Campus, Dover, Delaware, 19901, United States|Beebe South Coastal Health Campus, Frankford, Delaware, 19945, United States|Beebe Medical Center, Lewes, Delaware, 19958, United States|Delaware Clinical and Laboratory Physicians PA, Newark, Delaware, 19713, United States|Helen F Graham Cancer Center, Newark, Delaware, 19713, United States|Medical Oncology Hematology Consultants PA, Newark, Delaware, 19713, United States|Christiana Care Health System-Christiana Hospital, Newark, Delaware, 19718, United States|Beebe Health Campus, Rehoboth Beach, Delaware, 19971, United States|TidalHealth Nanticoke / Allen Cancer Center, Seaford, Delaware, 19973, United States|Christiana Care Health System-Wilmington Hospital, Wilmington, Delaware, 19801, United States|Broward Health Medical Center, Fort Lauderdale, Florida, 33316, United States|Mount Sinai Medical Center, Miami Beach, Florida, 33140, United States|Moffitt Cancer Center, Tampa, Florida, 33612, United States|Cleveland Clinic-Weston, Weston, Florida, 33331, United States|Emory University Hospital Midtown, Atlanta, Georgia, 30308, United States|Emory University Hospital/Winship Cancer Institute, Atlanta, Georgia, 30322, United States|Emory Saint Joseph's Hospital, Atlanta, Georgia, 30342, United States|Northside Hospital, Atlanta, Georgia, 30342, United States|John B Amos Cancer Center, Columbus, Georgia, 31904, United States|Northeast Georgia Medical Center-Gainesville, Gainesville,

Georgia, 30501, United States|Low Country Cancer Care, Savannah, Georgia, 31404, United States|Lewis Cancer and Research Pavilion at Saint Joseph's/Candler, Savannah, Georgia, 31405, United States|Summit Cancer Care-Candler, Savannah, Georgia, 31405, United States|Lewis Hall Singletary Oncology Center, Thomasville, Georgia, 31792, United States|Pali Momi Medical Center, 'Aiea, Hawaii, 96701, United States|Queen's Cancer Center - Pearlridge, 'Aiea, Hawaii, 96701, United States|The Cancer Center of Hawaii-Pali Momi, 'Aiea, Hawaii, 96701, United States|Hawaii Cancer Care Inc - Waterfront Plaza, Honolulu, Hawaii, 96813, United States|Island Urology, Honolulu, Hawaii, 96813, United States|Queen's Cancer Cenrer - POB I, Honolulu, Hawaii, 96813, United States|Queen's Medical Center, Honolulu, Hawaii, 96813, United States|Straub Clinic and Hospital, Honolulu, Hawaii, 96813, United States|University of Hawaii Cancer Center, Honolulu, Hawaii, 96813, United States|Hawaii Cancer Care Inc-Liliha, Honolulu, Hawaii, 96817, United States|Kuakini Medical Center, Honolulu, Hawaii, 96817, United States|Queen's Cancer Center - Kuakini, Honolulu, Hawaii, 96817, United States|The Cancer Center of Hawaii-Liliha, Honolulu, Hawaii, 96817, United States|Kaiser Permanente Moanalua Medical Center, Honolulu, Hawaii, 96819, United States|Kapiolani Medical Center for Women and Children, Honolulu, Hawaii, 96826, United States|Wilcox Memorial Hospital and Kauai Medical Clinic, Lihue, Hawaii, 96766, United States|Saint Alphonsus Cancer Care Center-Boise, Boise, Idaho, 83706, United States|Saint Luke's Cancer Institute - Boise, Boise, Idaho, 83712, United States|Saint Alphonsus Cancer Care Center-Caldwell, Caldwell, Idaho, 83605, United States|Kootenai Health - Coeur d'Alene, Coeur d'Alene, Idaho, 83814, United States|Walter Knox Memorial Hospital, Emmett, Idaho, 83617, United States|Saint Luke's Cancer Institute - Fruitland, Fruitland, Idaho, 83619, United States|Idaho Urologic Institute-Meridian, Meridian, Idaho, 83642, United States|Saint Luke's Cancer Institute - Meridian, Meridian, Idaho, 83642, United States|Saint Alphonsus Medical Center-Nampa, Nampa, Idaho, 83686, United States|Saint Luke's Cancer Institute - Nampa, Nampa, Idaho, 83686, United States|Kootenai Clinic Cancer Services - Post Falls, Post Falls, Idaho, 83854, United States|Kootenai Cancer Clinic, Sandpoint, Idaho, 83864, United States|Saint Luke's Cancer Institute - Twin Falls, Twin Falls, Idaho, 83301, United States|Rush - Copley Medical Center, Aurora, Illinois, 60504, United States|Illinois CancerCare-Bloomington, Bloomington, Illinois, 61704, United States|Illinois CancerCare-Canton, Canton, Illinois, 61520, United States|Memorial Hospital of Carbondale, Carbondale, Illinois, 62902, United States|SIH Cancer Institute, Carterville, Illinois, 62918, United States|Illinois CancerCare-Carthage, Carthage, Illinois, 62321, United States|Centralia Oncology Clinic, Centralia, Illinois, 62801, United States|John H Stroger Jr Hospital of Cook County, Chicago, Illinois, 60612, United States|University of Illinois, Chicago, Illinois, 60612, United States|Carle on Vermilion, Danville, Illinois, 61832, United States|Cancer Care Specialists of Illinois - Decatur, Decatur, Illinois, 62526, United States|Decatur Memorial Hospital, Decatur, Illinois, 62526, United States|Carle Physician Group-Effingham,

Effingham, Illinois, 62401, United States|Crossroads Cancer Center, Effingham, Illinois, 62401, United States|Illinois CancerCare–Eureka, Eureka, Illinois, 61530, United States|Illinois CancerCare–Galesburg, Galesburg, Illinois, 61401, United States|Western Illinois Cancer Treatment Center, Galesburg, Illinois, 61401, United States|Illinois CancerCare–Kewanee Clinic, Kewanee, Illinois, 61443, United States| Illinois CancerCare–Macomb, Macomb, Illinois, 61455, United States| Carle Physician Group–Mattoon/Charleston, Mattoon, Illinois, 61938, United States|Loyola University Medical Center, Maywood, Illinois, 60153, United States|Good Samaritan Regional Health Center, Mount Vernon, Illinois, 62864, United States|Cancer Care Center of O'Fallon, O'Fallon, Illinois, 62269, United States|Illinois CancerCare–Ottawa Clinic, Ottawa, Illinois, 61350, United States|Illinois CancerCare–Pekin, Pekin, Illinois, 61554, United States|OSF Saint Francis Radiation Oncology at Pekin Cancer Treatment Center, Pekin, Illinois, 61554, United States|Illinois CancerCare–Peoria, Peoria, Illinois, 61615, United States|OSF Saint Francis Radiation Oncology at Peoria Cancer Center, Peoria, Illinois, 61615, United States|Methodist Medical Center of Illinois, Peoria, Illinois, 61636, United States|OSF Saint Francis Medical Center, Peoria, Illinois, 61637, United States| Illinois CancerCare–Peru, Peru, Illinois, 61354, United States|Valley Radiation Oncology, Peru, Illinois, 61354, United States|Illinois CancerCare–Princeton, Princeton, Illinois, 61356, United States| Southern Illinois University School of Medicine, Springfield, Illinois, 62702, United States|Springfield Clinic, Springfield, Illinois, 62702, United States|Memorial Medical Center, Springfield, Illinois, 62781, United States|Southwest Illinois Health Services LLP, Swansea, Illinois, 62226, United States|Carle Cancer Center, Urbana, Illinois, 61801, United States|The Carle Foundation Hospital, Urbana, Illinois, 61801, United States|Rush–Copley Healthcare Center, Yorkville, Illinois, 60560, United States|Franciscan Health Indianapolis, Indianapolis, Indiana, 46237, United States|Franciscan Saint Elizabeth Health – Lafayette East, Lafayette, Indiana, 47905, United States|Franciscan Health Mooresville, Mooresville, Indiana, 46158, United States|Reid Health, Richmond, Indiana, 47374, United States|Union Hospital, Terre Haute, Indiana, 47804, United States| Medical Oncology and Hematology Associates–West Des Moines, Clive, Iowa, 50325, United States|Mercy Cancer Center–West Lakes, Clive, Iowa, 50325, United States|Alegent Health Mercy Hospital, Council Bluffs, Iowa, 51503, United States|Greater Regional Medical Center, Creston, Iowa, 50801, United States|Iowa Methodist Medical Center, Des Moines, Iowa, 50309, United States|Medical Oncology and Hematology Associates–Des Moines, Des Moines, Iowa, 50309, United States| Broadlawns Medical Center, Des Moines, Iowa, 50314, United States| Mercy Medical Center – Des Moines, Des Moines, Iowa, 50314, United States|Mission Cancer and Blood – Laurel, Des Moines, Iowa, 50314, United States|Iowa Lutheran Hospital, Des Moines, Iowa, 50316, United States|Methodist West Hospital, West Des Moines, Iowa, 50266–7700, United States|Mercy Medical Center–West Lakes, West Des Moines, Iowa, 50266, United States|Coffeyville Regional Medical Center, Coffeyville,

Kansas, 67337, United States|Central Care Cancer Center - Garden City, Garden City, Kansas, 67846, United States|Saint Catherine Hospital, Garden City, Kansas, 67846, United States|Central Care Cancer Center - Great Bend, Great Bend, Kansas, 67530, United States|HaysMed University of Kansas Health System, Hays, Kansas, 67601, United States|University of Kansas Cancer Center-West, Kansas City, Kansas, 66112, United States|University of Kansas Cancer Center, Kansas City, Kansas, 66160, United States|Kansas Institute of Medicine Cancer and Blood Center, Lenexa, Kansas, 66219, United States|Minimally Invasive Surgery Hospital, Lenexa, Kansas, 66219, United States|Olathe Health Cancer Center, Olathe, Kansas, 66061, United States|Menorah Medical Center, Overland Park, Kansas, 66209, United States|University of Kansas Cancer Center-Overland Park, Overland Park, Kansas, 66210, United States|University of Kansas Hospital-Indian Creek Campus, Overland Park, Kansas, 66211, United States|Saint Luke's South Hospital, Overland Park, Kansas, 66213, United States|Ascension Via Christi - Pittsburg, Pittsburg, Kansas, 66762, United States|Salina Regional Health Center, Salina, Kansas, 67401, United States| University of Kansas Health System Saint Francis Campus, Topeka, Kansas, 66606, United States|University of Kansas Hospital-Westwood Cancer Center, Westwood, Kansas, 66205, United States|Flaget Memorial Hospital, Bardstown, Kentucky, 40004, United States|Commonwealth Cancer Center-Corbin, Corbin, Kentucky, 40701, United States|Saint Joseph Radiation Oncology Resource Center, Lexington, Kentucky, 40504, United States|Saint Joseph Hospital East, Lexington, Kentucky, 40509, United States|Saint Joseph London, London, Kentucky, 40741, United States|Jewish Hospital, Louisville, Kentucky, 40202, United States| Saints Mary and Elizabeth Hospital, Louisville, Kentucky, 40215, United States|UofL Health Medical Center Northeast, Louisville, Kentucky, 40245, United States|Jewish Hospital Medical Center South, Shepherdsville, Kentucky, 40165, United States|LSU Health Baton Rouge-North Clinic, Baton Rouge, Louisiana, 70805, United States|Louisiana Hematology Oncology Associates LLC, Baton Rouge, Louisiana, 70809, United States|Mary Bird Perkins Cancer Center, Baton Rouge, Louisiana, 70809, United States|Ochsner Health Center-Summa, Baton Rouge, Louisiana, 70809, United States|Our Lady of the Lake Physicians Group - Medical Oncology, Baton Rouge, Louisiana, 70809, United States| Medical Center of Baton Rouge, Baton Rouge, Louisiana, 70816, United States|Louisiana Hematology Oncology Associates, Baton Rouge, Louisiana, 70817, United States|Our Lady of the Lake Medical Oncology, Baton Rouge, Louisiana, 70817, United States|Woman's Hospital, Baton Rouge, Louisiana, 70817, United States|Ochsner Hematology Oncology North Shore - Covington (West Region), Covington, Louisiana, 70433, United States|Ochsner Medical Center Jefferson, New Orleans, Louisiana, 70121, United States|LSU Health Sciences Center at Shreveport, Shreveport, Louisiana, 71103, United States|UM Upper Chesapeake Medical Center, Bel Air, Maryland, 21014, United States| Lahey Hospital and Medical Center, Burlington, Massachusetts, 01805, United States|Winchester Hospital, Winchester, Massachusetts, 01890, United States|Saint Joseph Mercy Hospital, Ann Arbor, Michigan, 48106,

United States|University of Michigan Comprehensive Cancer Center, Ann Arbor, Michigan, 48109, United States|Bronson Battle Creek, Battle Creek, Michigan, 49017, United States|McLaren Cancer Institute-Bay City, Bay City, Michigan, 48706, United States|McLaren Cancer Institute-Bloomfield, Bloomfield, Michigan, 48302, United States|Saint Joseph Mercy Brighton, Brighton, Michigan, 48114, United States| Trinity Health IHA Medical Group Hematology Oncology - Brighton, Brighton, Michigan, 48114, United States|Henry Ford Cancer Institute-Downriver, Brownstown, Michigan, 48183, United States|Saint Joseph Mercy Canton, Canton, Michigan, 48188, United States|Trinity Health IHA Medical Group Hematology Oncology - Canton, Canton, Michigan, 48188, United States|Caro Cancer Center, Caro, Michigan, 48723, United States|Saint Joseph Mercy Chelsea, Chelsea, Michigan, 48118, United States|Trinity Health IHA Medical Group Hematology Oncology - Chelsea Hospital, Chelsea, Michigan, 48118, United States|Hematology Oncology Consultants-Clarkston, Clarkston, Michigan, 48346, United States| McLaren Cancer Institute-Clarkston, Clarkston, Michigan, 48346, United States|Newland Medical Associates-Clarkston, Clarkston, Michigan, 48346, United States|Henry Ford Macomb Hospital-Clinton Township, Clinton Township, Michigan, 48038, United States|Henry Ford Medical Center-Fairlane, Dearborn, Michigan, 48126, United States|Wayne State University/Karmanos Cancer Institute, Detroit, Michigan, 48201, United States|Henry Ford Hospital, Detroit, Michigan, 48202, United States| Ascension Saint John Hospital, Detroit, Michigan, 48236, United States|Great Lakes Cancer Management Specialists-Doctors Park, East China Township, Michigan, 48054, United States|Genesee Cancer and Blood Disease Treatment Center, Flint, Michigan, 48503, United States| Genesee Hematology Oncology PC, Flint, Michigan, 48503, United States| Genesys Hurley Cancer Institute, Flint, Michigan, 48503, United States|Hurley Medical Center, Flint, Michigan, 48503, United States| McLaren Cancer Institute-Flint, Flint, Michigan, 48532, United States| Singh and Arora Hematology Oncology PC, Flint, Michigan, 48532, United States|Mercy Health Saint Mary's, Grand Rapids, Michigan, 49503, United States|Spectrum Health at Butterworth Campus, Grand Rapids, Michigan, 49503, United States|Academic Hematology Oncology Specialists, Grosse Pointe Woods, Michigan, 48236, United States|Great Lakes Cancer Management Specialists-Van Elslander Cancer Center, Grosse Pointe Woods, Michigan, 48236, United States|Michigan Breast Specialists-Grosse Pointe Woods, Grosse Pointe Woods, Michigan, 48236, United States|Allegiance Health, Jackson, Michigan, 49201, United States|Bronson Methodist Hospital, Kalamazoo, Michigan, 49007, United States|West Michigan Cancer Center, Kalamazoo, Michigan, 49007, United States|Borgess Medical Center, Kalamazoo, Michigan, 49048, United States|Karmanos Cancer Institute at McLaren Greater Lansing, Lansing, Michigan, 48910, United States|Sparrow Hospital, Lansing, Michigan, 48912, United States|McLaren Cancer Institute-Lapeer Region, Lapeer, Michigan, 48446, United States|Hope Cancer Clinic, Livonia, Michigan, 48154, United States|Trinity Health Saint Mary Mercy Livonia Hospital, Livonia, Michigan, 48154, United States|Great Lakes Cancer Management Specialists-Macomb Medical Campus, Macomb, Michigan, 48044, United

States|Michigan Breast Specialists–Macomb Township, Macomb, Michigan, 48044, United States|Saint Mary's Oncology/Hematology Associates of Marlette, Marlette, Michigan, 48453, United States|McLaren Cancer Institute–Macomb, Mount Clemens, Michigan, 48043, United States|Mercy Health Mercy Campus, Muskegon, Michigan, 49444, United States|Lakeland Hospital Niles, Niles, Michigan, 49120, United States|Ascension Providence Hospitals – Novi, Novi, Michigan, 48374, United States|Henry Ford Medical Center–Columbus, Novi, Michigan, 48377, United States|21st Century Oncology–Pontiac, Pontiac, Michigan, 48341, United States|Hope Cancer Center, Pontiac, Michigan, 48341, United States|Newland Medical Associates–Pontiac, Pontiac, Michigan, 48341, United States|Saint Joseph Mercy Oakland, Pontiac, Michigan, 48341, United States|Spectrum Health Reed City Hospital, Reed City, Michigan, 49677, United States|Great Lakes Cancer Management Specialists–Rochester Hills, Rochester Hills, Michigan, 48309, United States|Ascension Saint Mary's Hospital, Saginaw, Michigan, 48601, United States|Oncology Hematology Associates of Saginaw Valley PC, Saginaw, Michigan, 48604, United States|Lakeland Medical Center Saint Joseph, Saint Joseph, Michigan, 49085, United States|Marie Yeager Cancer Center, Saint Joseph, Michigan, 49085, United States|Ascension Providence Hospitals – Southfield, Southfield, Michigan, 48075, United States|Bhadresh Nayak MD PC–Sterling Heights, Sterling Heights, Michigan, 48312, United States|Ascension Saint Joseph Hospital, Tawas City, Michigan, 48764, United States|Munson Medical Center, Traverse City, Michigan, 49684, United States|Advanced Breast Care Center PLLC, Warren, Michigan, 48088, United States|Great Lakes Cancer Management Specialists–Macomb Professional Building, Warren, Michigan, 48093, United States|Macomb Hematology Oncology PC, Warren, Michigan, 48093, United States|Michigan Breast Specialists–Warren, Warren, Michigan, 48093, United States|Saint John Macomb–Oakland Hospital, Warren, Michigan, 48093, United States|Henry Ford West Bloomfield Hospital, West Bloomfield, Michigan, 48322, United States|Saint Mary's Oncology/Hematology Associates of West Branch, West Branch, Michigan, 48661, United States|Metro Health Hospital, Wyoming, Michigan, 49519, United States|Huron Gastroenterology PC, Ypsilanti, Michigan, 48106, United States|Trinity Health IHA Medical Group Hematology Oncology Ann Arbor Campus, Ypsilanti, Michigan, 48197, United States|Sanford Joe Lueken Cancer Center, Bemidji, Minnesota, 56601, United States|Essentia Health Saint Joseph's Medical Center, Brainerd, Minnesota, 56401, United States|Fairview Ridges Hospital, Burnsville, Minnesota, 55337, United States|Mercy Hospital, Coon Rapids, Minnesota, 55433, United States|Essentia Health Cancer Center, Duluth, Minnesota, 55805, United States|Essentia Health Saint Mary's Medical Center, Duluth, Minnesota, 55805, United States|Miller–Dwan Hospital, Duluth, Minnesota, 55805, United States|Fairview Southdale Hospital, Edina, Minnesota, 55435, United States|Lake Region Healthcare Corporation–Cancer Care, Fergus Falls, Minnesota, 56537, United States|Unity Hospital, Fridley, Minnesota, 55432, United States|Essentia Health Hibbing Clinic, Hibbing, Minnesota, 55746, United States|Fairview Clinics and Surgery Center Maple Grove, Maple Grove, Minnesota, 55369, United States|

Minnesota Oncology Hematology PA–Maplewood, Maplewood, Minnesota, 55109, United States|Saint John's Hospital – Healtheast, Maplewood, Minnesota, 55109, United States|Abbott–Northwestern Hospital, Minneapolis, Minnesota, 55407, United States|Hennepin County Medical Center, Minneapolis, Minnesota, 55415, United States|Health Partners Inc, Minneapolis, Minnesota, 55454, United States|Monticello Cancer Center, Monticello, Minnesota, 55362, United States|New Ulm Medical Center, New Ulm, Minnesota, 56073, United States|North Memorial Medical Health Center, Robbinsdale, Minnesota, 55422, United States|Park Nicollet Clinic – Saint Louis Park, Saint Louis Park, Minnesota, 55416, United States|Regions Hospital, Saint Paul, Minnesota, 55101, United States|United Hospital, Saint Paul, Minnesota, 55102, United States|Saint Francis Regional Medical Center, Shakopee, Minnesota, 55379, United States|Lakeview Hospital, Stillwater, Minnesota, 55082, United States|Essentia Health Virginia Clinic, Virginia, Minnesota, 55792, United States|Ridgeview Medical Center, Waconia, Minnesota, 55387, United States|Rice Memorial Hospital, Willmar, Minnesota, 56201, United States|Minnesota Oncology Hematology PA–Woodbury, Woodbury, Minnesota, 55125, United States|Fairview Lakes Medical Center, Wyoming, Minnesota, 55092, United States|Baptist Memorial Hospital and Cancer Center–Golden Triangle, Columbus, Mississippi, 39705, United States|Baptist Cancer Center–Grenada, Grenada, Mississippi, 38901, United States|University of Mississippi Medical Center, Jackson, Mississippi, 39216, United States|Baptist Memorial Hospital and Cancer Center–Union County, New Albany, Mississippi, 38652, United States|Baptist Memorial Hospital and Cancer Center–Oxford, Oxford, Mississippi, 38655, United States|Singing River Hospital, Pascagoula, Mississippi, 39581, United States|Baptist Memorial Hospital and Cancer Center–Desoto, Southhaven, Mississippi, 38671, United States|Saint Louis Cancer and Breast Institute–Ballwin, Ballwin, Missouri, 63011, United States|Central Care Cancer Center – Bolivar, Bolivar, Missouri, 65613, United States|Parkland Health Center–Bonne Terre, Bonne Terre, Missouri, 63628, United States|Cox Cancer Center Branson, Branson, Missouri, 65616, United States|Saint Francis Medical Center, Cape Girardeau, Missouri, 63703, United States|Southeast Cancer Center, Cape Girardeau, Missouri, 63703, United States|Siteman Cancer Center at West County Hospital, Creve Coeur, Missouri, 63141, United States|Centerpoint Medical Center LLC, Independence, Missouri, 64057, United States|Capital Region Southwest Campus, Jefferson City, Missouri, 65109, United States|Freeman Health System, Joplin, Missouri, 64804, United States|Mercy Hospital Joplin, Joplin, Missouri, 64804, United States|Truman Medical Centers, Kansas City, Missouri, 64108, United States|Saint Luke's Hospital of Kansas City, Kansas City, Missouri, 64111, United States|Research Medical Center, Kansas City, Missouri, 64132, United States|University of Kansas Cancer Center – North, Kansas City, Missouri, 64154, United States|University of Kansas Cancer Center – Lee's Summit, Lee's Summit, Missouri, 64064, United States|Saint Luke's East – Lee's Summit, Lee's Summit, Missouri, 64086, United States|University of Kansas Cancer Center at North Kansas City Hospital, North Kansas City,

Missouri, 64116, United States|Delbert Day Cancer Institute at PCRMC, Rolla, Missouri, 65401, United States|Mercy Clinic-Rolla-Cancer and Hematology, Rolla, Missouri, 65401, United States|Heartland Regional Medical Center, Saint Joseph, Missouri, 64506, United States|Saint Louis Cancer and Breast Institute-South City, Saint Louis, Missouri, 63109, United States|Washington University School of Medicine, Saint Louis, Missouri, 63110, United States|Mercy Hospital South, Saint Louis, Missouri, 63128, United States|Siteman Cancer Center-South County, Saint Louis, Missouri, 63129, United States|Missouri Baptist Medical Center, Saint Louis, Missouri, 63131, United States|Siteman Cancer Center at Christian Hospital, Saint Louis, Missouri, 63136, United States|Mercy Hospital Saint Louis, Saint Louis, Missouri, 63141, United States|Siteman Cancer Center at Saint Peters Hospital, Saint Peters, Missouri, 63376, United States|Sainte Genevieve County Memorial Hospital, Sainte Genevieve, Missouri, 63670, United States| Mercy Hospital Springfield, Springfield, Missouri, 65804, United States|CoxHealth South Hospital, Springfield, Missouri, 65807, United States|Missouri Baptist Sullivan Hospital, Sullivan, Missouri, 63080, United States|Missouri Baptist Outpatient Center-Sunset Hills, Sunset Hills, Missouri, 63127, United States|Mercy Hospital Washington, Washington, Missouri, 63090, United States|Community Hospital of Anaconda, Anaconda, Montana, 59711, United States|Billings Clinic Cancer Center, Billings, Montana, 59101, United States|Bozeman Deaconess Hospital, Bozeman, Montana, 59715, United States|Benefis Healthcare- Sletten Cancer Institute, Great Falls, Montana, 59405, United States|Great Falls Clinic, Great Falls, Montana, 59405, United States|Saint Peter's Community Hospital, Helena, Montana, 59601, United States|Kalispell Regional Medical Center, Kalispell, Montana, 59901, United States|Saint Patrick Hospital - Community Hospital, Missoula, Montana, 59802, United States|Community Medical Hospital, Missoula, Montana, 59804, United States|CHI Health Saint Francis, Grand Island, Nebraska, 68803, United States|Heartland Hematology and Oncology, Kearney, Nebraska, 68845, United States|CHI Health Good Samaritan, Kearney, Nebraska, 68847, United States|Saint Elizabeth Regional Medical Center, Lincoln, Nebraska, 68510, United States| Alegent Health Immanuel Medical Center, Omaha, Nebraska, 68122, United States|Hematology and Oncology Consultants PC, Omaha, Nebraska, 68122, United States|Alegent Health Bergan Mercy Medical Center, Omaha, Nebraska, 68124, United States|Alegent Health Lakeside Hospital, Omaha, Nebraska, 68130, United States|Creighton University Medical Center, Omaha, Nebraska, 68131, United States|Midlands Community Hospital, Papillion, Nebraska, 68046, United States|Morristown Medical Center, Morristown, New Jersey, 07960, United States|Newton Medical Center, Newton, New Jersey, 07860, United States|Robert Wood Johnson University Hospital Somerset, Somerville, New Jersey, 08876, United States|Overlook Hospital, Summit, New Jersey, 07902, United States| Holy Name Hospital, Teaneck, New Jersey, 07666, United States| University of New Mexico Cancer Center, Albuquerque, New Mexico, 87102, United States|NYP/Columbia University Medical Center/Herbert Irving Comprehensive Cancer Center, New York, New York, 10032, United

States|Nyack Hospital, Nyack, New York, 10960, United States|Stony Brook University Medical Center, Stony Brook, New York, 11794, United States|Dickstein Cancer Treatment Center, White Plains, New York, 10601, United States|Southeastern Medical Oncology Center–Clinton, Clinton, North Carolina, 28328, United States|Southeastern Medical Oncology Center–Goldsboro, Goldsboro, North Carolina, 27534, United States|Wayne Memorial Hospital, Goldsboro, North Carolina, 27534, United States|Onslow Memorial Hospital, Jacksonville, North Carolina, 28546, United States|Southeastern Medical Oncology Center–Jacksonville, Jacksonville, North Carolina, 28546, United States|Sanford Bismarck Medical Center, Bismarck, North Dakota, 58501, United States|Essentia Health Cancer Center–South University Clinic, Fargo, North Dakota, 58103, United States|Sanford Broadway Medical Center, Fargo, North Dakota, 58122, United States|Sanford Roger Maris Cancer Center, Fargo, North Dakota, 58122, United States|Cleveland Clinic Akron General, Akron, Ohio, 44307, United States|UHHS–Chagrin Highlands Medical Center, Beachwood, Ohio, 44122, United States|Indu and Raj Soin Medical Center, Beavercreek, Ohio, 45431, United States|Aultman Health Foundation, Canton, Ohio, 44710, United States|Dayton Physicians LLC–Miami Valley South, Centerville, Ohio, 45459, United States|Miami Valley Hospital South, Centerville, Ohio, 45459, United States|Geauga Hospital, Chardon, Ohio, 44024, United States|The Christ Hospital, Cincinnati, Ohio, 45219, United States|University of Cincinnati Cancer Center–UC Medical Center, Cincinnati, Ohio, 45219, United States|Good Samaritan Hospital – Cincinnati, Cincinnati, Ohio, 45220, United States|Oncology Hematology Care Inc–Kenwood, Cincinnati, Ohio, 45236, United States|Bethesda North Hospital, Cincinnati, Ohio, 45242, United States|TriHealth Cancer Institute–Westside, Cincinnati, Ohio, 45247, United States|TriHealth Cancer Institute–Anderson, Cincinnati, Ohio, 45255, United States|Case Western Reserve University, Cleveland, Ohio, 44106, United States|Cleveland Clinic Cancer Center/Fairview Hospital, Cleveland, Ohio, 44111, United States|Cleveland Clinic Foundation, Cleveland, Ohio, 44195, United States|Good Samaritan Hospital – Dayton, Dayton, Ohio, 45406, United States|Miami Valley Hospital, Dayton, Ohio, 45409, United States|Dayton Physician LLC–Miami Valley Hospital North, Dayton, Ohio, 45415, United States|Miami Valley Hospital North, Dayton, Ohio, 45415, United States|Mercy Cancer Center–Elyria, Elyria, Ohio, 44035, United States|Armes Family Cancer Center, Findlay, Ohio, 45840, United States|Blanchard Valley Hospital, Findlay, Ohio, 45840, United States|Orion Cancer Care, Findlay, Ohio, 45840, United States|Atrium Medical Center–Middletown Regional Hospital, Franklin, Ohio, 45005–1066, United States|Dayton Physicians LLC–Atrium, Franklin, Ohio, 45005, United States|Dayton Physicians LLC–Wayne, Greenville, Ohio, 45331, United States|Wayne Hospital, Greenville, Ohio, 45331, United States|Cleveland Clinic Cancer Center Independence, Independence, Ohio, 44131, United States|Greater Dayton Cancer Center, Kettering, Ohio, 45409, United States|First Dayton Cancer Care, Kettering, Ohio, 45420, United States|Kettering Medical Center, Kettering, Ohio, 45429, United States|Cleveland Clinic Cancer Center Mansfield, Mansfield, Ohio,

44906, United States|Hillcrest Hospital Cancer Center, Mayfield Heights, Ohio, 44124, United States|UH Seidman Cancer Center at Lake Health Mentor Campus, Mentor, Ohio, 44060, United States|UH Seidman Cancer Center at Southwest General Hospital, Middleburg Heights, Ohio, 44130, United States|North Coast Cancer Care, Sandusky, Ohio, 44870, United States|Springfield Regional Cancer Center, Springfield, Ohio, 45504, United States|Springfield Regional Medical Center, Springfield, Ohio, 45505, United States|Cleveland Clinic Cancer Center Strongsville, Strongsville, Ohio, 44136, United States|Dayton Physicians LLC-Upper Valley, Troy, Ohio, 45373, United States|Upper Valley Medical Center, Troy, Ohio, 45373, United States|University Hospitals Sharon Health Center, Wadsworth, Ohio, 44281, United States|South Pointe Hospital, Warrensville Heights, Ohio, 44122, United States|University of Cincinnati Cancer Center-West Chester, West Chester, Ohio, 45069, United States|UH Seidman Cancer Center at Saint John Medical Center, Westlake, Ohio, 44145, United States|UHHS-Westlake Medical Center, Westlake, Ohio, 44145, United States|Cleveland Clinic Wooster Family Health and Surgery Center, Wooster, Ohio, 44691, United States|University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, 73104, United States|Mercy Hospital Oklahoma City, Oklahoma City, Oklahoma, 73120, United States|Oklahoma Cancer Specialists and Research Institute-Tulsa, Tulsa, Oklahoma, 74146, United States|Saint Alphonsus Medical Center-Baker City, Baker City, Oregon, 97814, United States|Saint Charles Health System, Bend, Oregon, 97701, United States|Clackamas Radiation Oncology Center, Clackamas, Oregon, 97015, United States|Providence Cancer Institute Clackamas Clinic, Clackamas, Oregon, 97015, United States|Bay Area Hospital, Coos Bay, Oregon, 97420, United States|Providence Newberg Medical Center, Newberg, Oregon, 97132, United States|Saint Alphonsus Medical Center-Ontario, Ontario, Oregon, 97914, United States|Providence Portland Medical Center, Portland, Oregon, 97213, United States|Providence Saint Vincent Medical Center, Portland, Oregon, 97225, United States|Kaiser Permanente Northwest, Portland, Oregon, 97227, United States|Oregon Health and Science University, Portland, Oregon, 97239, United States|Saint Charles Health System-Redmond, Redmond, Oregon, 97756, United States|Lehigh Valley Hospital-Cedar Crest, Allentown, Pennsylvania, 18103, United States|Lehigh Valley Hospital - Muhlenberg, Bethlehem, Pennsylvania, 18017, United States|Bryn Mawr Hospital, Bryn Mawr, Pennsylvania, 19010, United States|Christiana Care Health System-Concord Health Center, Chadds Ford, Pennsylvania, 19317, United States|Pocono Medical Center, East Stroudsburg, Pennsylvania, 18301, United States|Lehigh Valley Hospital-Hazleton, Hazleton, Pennsylvania, 18201, United States|Penn State Milton S Hershey Medical Center, Hershey, Pennsylvania, 17033-0850, United States|Riddle Memorial Hospital, Media, Pennsylvania, 19063, United States|Paoli Memorial Hospital, Paoli, Pennsylvania, 19301, United States|Phoenixville Hospital, Phoenixville, Pennsylvania, 19460, United States|Guthrie Medical Group PC-Robert Packer Hospital, Sayre, Pennsylvania, 18840, United States|Lankenau Medical Center, Wynnewood, Pennsylvania, 19096, United

States|Prisma Health Cancer Institute – Spartanburg, Boiling Springs, South Carolina, 29316, United States|Medical University of South Carolina, Charleston, South Carolina, 29425, United States|Prisma Health Cancer Institute – Laurens, Clinton, South Carolina, 29325, United States|Prisma Health Cancer Institute – Easley, Easley, South Carolina, 29640, United States|Prisma Health Cancer Institute – Butternut, Greenville, South Carolina, 29605, United States|Prisma Health Cancer Institute – Faris, Greenville, South Carolina, 29605, United States|Prisma Health Greenville Memorial Hospital, Greenville, South Carolina, 29605, United States|Prisma Health Cancer Institute – Eastside, Greenville, South Carolina, 29615, United States|Self Regional Healthcare, Greenwood, South Carolina, 29646, United States|Prisma Health Cancer Institute – Greer, Greer, South Carolina, 29650, United States|Prisma Health Cancer Institute – Seneca, Seneca, South Carolina, 29672, United States|Sanford Cancer Center Oncology Clinic, Sioux Falls, South Dakota, 57104, United States|Sanford USD Medical Center – Sioux Falls, Sioux Falls, South Dakota, 57117-5134, United States|Memorial Hospital, Chattanooga, Tennessee, 37404, United States|Baptist Memorial Hospital and Cancer Center-Collierville, Collierville, Tennessee, 38017, United States|Pulmonary Medicine Center of Chattanooga-Hixson, Hixson, Tennessee, 37343, United States|Baptist Memorial Hospital and Cancer Center-Memphis, Memphis, Tennessee, 38120, United States|Baptist Memorial Hospital for Women, Memphis, Tennessee, 38120, United States|Memorial GYN Plus, Ooltewah, Tennessee, 37363, United States|Saint Joseph Regional Cancer Center, Bryan, Texas, 77802, United States|UT Southwestern/Simmons Cancer Center-Dallas, Dallas, Texas, 75390, United States|UT Southwestern/Simmons Cancer Center-Fort Worth, Fort Worth, Texas, 76104, United States|UMC Cancer Center / UMC Health System, Lubbock, Texas, 79415, United States|UT Southwestern Clinical Center at Richardson/Plano, Richardson, Texas, 75080, United States|University Hospital, San Antonio, Texas, 78229, United States|University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78229, United States|Augusta Health Center for Cancer and Blood Disorders, Fishersville, Virginia, 22939, United States|Providence Regional Cancer System-Aberdeen, Aberdeen, Washington, 98520, United States|MultiCare Auburn Medical Center, Auburn, Washington, 98001, United States|Virginia Mason Bainbridge Island Medical Center, Bainbridge Island, Washington, 98110, United States|Overlake Medical Center, Bellevue, Washington, 98004, United States|PeaceHealth Saint Joseph Medical Center, Bellingham, Washington, 98225, United States|Harrison HealthPartners Hematology and Oncology-Bremerton, Bremerton, Washington, 98310, United States|Harrison Medical Center, Bremerton, Washington, 98310, United States|Highline Medical Center-Main Campus, Burien, Washington, 98166, United States|Providence Regional Cancer System-Centralia, Centralia, Washington, 98531, United States|Swedish Cancer Institute-Edmonds, Edmonds, Washington, 98026, United States|Saint Elizabeth Hospital, Enumclaw, Washington, 98022, United States|Providence Regional Cancer Partnership, Everett, Washington, 98201, United States|Virginia Mason Federal Way Medical Center, Federal Way,

Washington, 98002, United States|Saint Francis Hospital, Federal Way, Washington, 98003, United States|Tacoma/Valley Radiation Oncology Centers-Gig Harbor, Gig Harbor, Washington, 98332, United States|MultiCare Gig Harbor Medical Park, Gig Harbor, Washington, 98335, United States|Swedish Cancer Institute-Issaquah, Issaquah, Washington, 98029, United States|Kadlec Clinic Hematology and Oncology, Kennewick, Washington, 99336, United States|Northwest Cancer Clinic, Kennewick, Washington, 99336, United States|Providence Regional Cancer System-Lacey, Lacey, Washington, 98503, United States|Saint Clare Hospital, Lakewood, Washington, 98499, United States|PeaceHealth Saint John Medical Center, Longview, Washington, 98632, United States|Virginia Mason Lynnwood Medical Center, Lynnwood, Washington, 98036, United States|Jefferson Healthcare, Port Townsend, Washington, 98368, United States|Harrison HealthPartners Hematology and Oncology-Poulsbo, Poulsbo, Washington, 98370, United States|Peninsula Cancer Center, Poulsbo, Washington, 98370, United States|MultiCare Good Samaritan Hospital, Puyallup, Washington, 98372, United States|Tacoma/Valley Radiation Oncology Centers-Puyallup, Puyallup, Washington, 98372, United States|Valley Medical Center, Renton, Washington, 98055, United States|Virginia Mason Medical Center, Seattle, Washington, 98101, United States|Pacific Gynecology Specialists, Seattle, Washington, 98104, United States|Swedish Medical Center-Ballard Campus, Seattle, Washington, 98107, United States|FHCC South Lake Union, Seattle, Washington, 98109, United States|Kaiser Permanente Washington, Seattle, Washington, 98112, United States|Swedish Medical Center-Cherry Hill, Seattle, Washington, 98122-5711, United States|Swedish Medical Center-First Hill, Seattle, Washington, 98122, United States|University of Washington Medical Center - Montlake, Seattle, Washington, 98195, United States|PeaceHealth United General Medical Center, Sedro-Woolley, Washington, 98284, United States|Providence Regional Cancer System-Shelton, Shelton, Washington, 98584, United States|MultiCare Deaconess Cancer and Blood Specialty Center - Valley, Spokane Valley, Washington, 99216, United States|MultiCare Deaconess Cancer and Blood Specialty Center - Downtown, Spokane, Washington, 99204, United States|MultiCare Deaconess Cancer and Blood Specialty Center - North, Spokane, Washington, 99218, United States|Tacoma/Valley Radiation Oncology Centers-Jackson Hall, Tacoma, Washington, 97405, United States|Franciscan Research Center-Northwest Medical Plaza, Tacoma, Washington, 98405, United States|MultiCare Tacoma General Hospital, Tacoma, Washington, 98405, United States|Northwest Medical Specialties PLLC, Tacoma, Washington, 98405, United States|Tacoma/Valley Radiation Oncology Centers-Saint Joe's, Tacoma, Washington, 98405, United States|PeaceHealth Southwest Medical Center, Vancouver, Washington, 98664, United States|Providence Saint Mary Regional Cancer Center, Walla Walla, Washington, 99362, United States|North Star Lodge Cancer Center at Yakima Valley Memorial Hospital, Yakima, Washington, 98902, United States|Providence Regional Cancer System-Yelm, Yelm, Washington, 98597, United States|Duluth Clinic Ashland, Ashland, Wisconsin, 54806, United States|Bellin Memorial Hospital, Green Bay, Wisconsin, 54301, United States|Mercyhealth

Hospital and Cancer Center - Janesville, Janesville, Wisconsin, 53548, United States|Cancer Center of Western Wisconsin, New Richmond, Wisconsin, 54017, United States|Billings Clinic-Cody, Cody, Wyoming, 82414, United States|Welch Cancer Center, Sheridan, Wyoming, 82801, United States|National Cancer Center-Korea, Goyang-si, Gyeonggi-do, 410-769, Korea, Republic of|Advance Oncology Center, Aguadilla, 00603, Puerto Rico|Doctor's Cancer Center-Arecibo, Arecibo, 00614, Puerto Rico|Cancer Center-Metro Medical Center Bayamon, Bayamon, 00959-5060, Puerto Rico|Hematologia Oncologia San Pablo, Bayamon, 00961, Puerto Rico|HIMA San Pablo Oncologic Hospital, Caguas, 00726, Puerto Rico|Doctors Cancer Center, Manati, 00674, Puerto Rico|Instituto Oncologia Moderna Ponce, Ponce, 00716, Puerto Rico|San Juan Community Oncology Group, San Juan, 00917, Puerto Rico|Primary Care Physician Group, San Juan, 00920, Puerto Rico|San Juan City Hospital, San Juan, 00936, Puerto Rico|Centro de Hematologia y Oncologia del Sur, Santa Isabel, 00757, Puerto Rico|King Faisal Specialist Hospital and Research Centre, Riyadh, 11211, Saudi Arabia
Study Documents:

NCT Number: NCT03505736
Study Title: Stress Test in Detecting Heart Damage in Premenopausal Women With Stage I-III Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03505736
Acronym:
Study Status: COMPLETED
Brief Summary: This pilot trial studies how well a stress test works in detecting heart damage in premenopausal women with stage I-III breast cancer. Giving a stress test with adenosine or regadenoson and cardiovascular magnetic resonance imaging may help doctors detect heart damage caused by breast cancer treatments including chemotherapy and aromatase inhibitors.
Study Results: NO
Conditions: Anatomic Stage I Breast Cancer AJCC v8|Anatomic Stage IA Breast Cancer AJCC v8|Anatomic Stage IB Breast Cancer AJCC v8|Anatomic Stage II Breast Cancer AJCC v8|Anatomic Stage IIA Breast Cancer AJCC v8|Anatomic Stage IIB Breast Cancer AJCC v8|Anatomic Stage III Breast Cancer AJCC v8|Anatomic Stage IIIA Breast Cancer AJCC v8|Anatomic Stage IIIB Breast Cancer AJCC v8|Anatomic Stage IIIC Breast Cancer AJCC v8|Premenopausal|Prognostic Stage I Breast Cancer AJCC v8|Prognostic Stage IA Breast Cancer AJCC v8|Prognostic Stage IB Breast Cancer AJCC v8|Prognostic Stage II Breast Cancer AJCC v8|Prognostic Stage IIA Breast Cancer AJCC v8|Prognostic Stage IIB Breast Cancer AJCC v8|Prognostic Stage III Breast Cancer AJCC v8|Prognostic Stage IIIA Breast Cancer AJCC v8|Prognostic Stage IIIB Breast Cancer AJCC v8|Prognostic Stage IIIC Breast Cancer AJCC v8
Interventions: BIOLOGICAL: Adenosine|PROCEDURE: Magnetic Resonance Imaging|DRUG: Regadenoson|PROCEDURE: Stress Management Therapy
Primary Outcome Measures: Myocardial perfusion reserve index (MPRI), Will first estimate 95% confidence intervals for each group at each time point as well as for the change from baseline to 3-6-months in

each group., Baseline and 3-6 months
Secondary Outcome Measures: Myocardial rest myocardial fibrosis burden (T1) and left ventricular ejection fraction (LVEF), Will be used to correlate myocardial perfusion with T1 and myocardial function (LVEF)., Baseline and 3-6 months|Change in MPRI measures, Change in MPRI measures (overall and within each group) will be compared using 2-sample t-tests for binary variables. Correlations will be estimated between BMI and the change in MPRI measures., Baseline to 3-6 months|Accrual rate defined as based on the number of patients who participate compared to the total number of patients approached, Will capture data for those approached and consenting or declining and any reasons given for declining participation into the study. Will be assessed by estimating counts and percent's and corresponding 95% Clopper-Pearson exact binomial confidence intervals. Will be compared to the total number of patients enrolled., Baseline and 3-6 months|Retention rate defined the number of patients who are enrolled and complete both assessments, Will be assessed by estimating counts and percent's and corresponding 95% Clopper-Pearson exact binomial confidence intervals. Will be compared to the total number of patients enrolled., Baseline and 3-6 months
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators: National Cancer Institute (NCI)
Sex: FEMALE
Age: CHILD, ADULT
Phases:
Enrollment: 25
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IRB00049171|NCI-2018-00588|CCCWFU 98118|P30CA012197
Start Date: 2018-06-21
Primary Completion Date: 2020-03-05
Completion Date: 2020-03-05
First Posted: 2018-04-23
Results First Posted:
Last Update Posted: 2020-03-26
Locations: Wake Forest University Health Sciences, Winston-Salem, North Carolina, 27157, United States
Study Documents:

NCT Number: NCT03949634
Study Title: Cardiac Safety and Efficacy for Early-stage Breast Cancer Patients Treated With Pegylated Liposomal Doxorubicin (PLD)
Study URL: https://beta.clinicaltrials.gov/study/NCT03949634
Acronym:
Study Status: UNKNOWN
Brief Summary: This is a randomized, multicenter, open, controlled Post-Marketing Study. 272 early stage female breast cancer patients who were histopathology confirmed with adjuvant chemotherapy

indications were enrolled in this study .The subjects will be randomly assigned to one of the two treatment groups at a 1: 1 ratio, and stratified by trastuzumab,age,baseline cardiac risk factors.
Study Results: NO
Conditions: Early Breast Cancer
Interventions: DRUG: PLD|DRUG: CTX|DRUG: Docetaxel|DRUG: Paclitaxel|DRUG: Doxorubicin
Primary Outcome Measures: cardiotoxity, Congestive heart failure with clinical symptoms, or no symptoms but an abnormal LVEF, 2 years.
Secondary Outcome Measures: 5-year DFS, 5-year disease-free survival rate, 5 years|5-year OS, 5-year overall survival rate, 5 years|Adverse events (AE), Incidence and Severity of adverse events according to the CTC AE V4.03, 5 years
Other Outcome Measures:
Sponsor: Fudan University
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 272
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CSPC -DMS- BC-08
Start Date: 2017-09-01
Primary Completion Date: 2019-10-31
Completion Date: 2020-10-31
First Posted: 2019-05-14
Results First Posted:
Last Update Posted: 2019-05-14
Locations: Fudan University affiliated cancer hospital, Shanghai, China
Study Documents:

NCT Number: NCT03937934
Study Title: Study Title: Food Rx
Study URL: https://beta.clinicaltrials.gov/study/NCT03937934
Acronym:
Study Status: COMPLETED
Brief Summary: Researchers are trying to determine if subjects with lack of access to healthy food and a long term health problem, are helped by a weekly box of healthy groceries and nutrition education.
Study Results: NO
Conditions: Diabetes|High Blood Pressure|Obesity|Hypertension|Heart Diseases|Stroke|TIA|Osteoarthritis|Cancer
Interventions: BEHAVIORAL: Nutrition Education
Primary Outcome Measures: Change in the number of self-reported fruits per day, Number of self-reported fruits per day, Baseline, 3 months, 6 months|Change in the number of self-reported vegetables per day,

Number of self-reported vegetables per day, Baseline, 3 months, 6 months|Change in number of days a week and minutes per day participants participate in physical activity and sedentary activity, Measured using self-reported Food Rx Pilot survey, Baseline, 3 months, 6 months
Secondary Outcome Measures: Change in A1c, Identified through chart review, 6 months and 12 months|Change in BMI kg/m2 (weight in kg, height in meters), Identified through chart review, 6 months and 12 months|Change in Systolic and/or Diastolic Hypertension mmHg, Identified through chart review, 6 months and 12 months
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 24
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: 18-006630
Start Date: 2019-05-20
Primary Completion Date: 2019-11-20
Completion Date: 2020-05-20
First Posted: 2019-05-06
Results First Posted:
Last Update Posted: 2020-06-09
Locations: Mayo Clinic Health System, Mankato, Minnesota, 56001, United States
Study Documents:

NCT Number: NCT05335928
Study Title: Abatacept in Immune Checkpoint Inhibitor Myocarditis
Study URL: https://beta.clinicaltrials.gov/study/NCT05335928
Acronym: ATRIUM
Study Status: RECRUITING
Brief Summary: The primary aim is to test whether abatacept, as compared to placebo, is associated with a reduction in major adverse cardiac events (MACE) among participants hospitalized with myocarditis secondary to an immune checkpoint inhibitor (ICI). The primary outcome, MACE, is a composite of first occurrence of cardiovascular death, non-fatal sudden cardiac arrest, cardiogenic shock, significant ventricular arrythmias, significant bradyarrythmias, or incident heart failure.
Study Results: NO
Conditions: Myocarditis Acute|Cancer
Interventions: DRUG: Abatacept plus|DRUG: Placebo
Primary Outcome Measures: Major adverse cardiac events, The rates of a composite of cardiovascular death, non-fatal sudden cardiac arrest,

cardiogenic shock, significant ventricular arrhythmias, significant bradyarrhythmias, or incident heart failure., 6 months
Secondary Outcome Measures: The individual components of the primary endpoint., The rates of the following between groups: cardiovascular death, non-fatal sudden cardiac arrest, cardiogenic shock, significant ventricular arrhythmias, significant bradyarrhythmias, or incident heart failure, 6 months|Myocarditis illness severity using a 7-point ordinal severity scale containing each of the individual endpoints in a hierarchical ranking order., The worst score on a 7-point ordinal myocarditis severity scale during the 6 month period from first study treatment. The 7-point ordinal myocarditis severity scale is as follows with more severe outcomes ranked with a higher number:

1. - No component of the primary endpoint;
2. - Incident heart failure;
3. - Significant bradyarrhythmia;
4. - Significant ventricular tachyarrhythmias;
5. - Cardiogenic shock;
6. - Sudden cardiac arrest;
7. - Cardiovascular death;, 6 months|The increase in serum troponin levels, The proportion of participants in each group with a \>50% increase in serum troponin value at any time during the incident hospitalization and following administration of study drug., 6 months|The combination of the rates of the primary outcome plus the proportion of patients with a troponin increase., The rates of a composite of cardiovascular death, non-fatal sudden cardiac arrest, cardiogenic shock, significant ventricular arrhythmias, significant bradyarrhythmias, or incident heart failure plus the proportion of participants in each group with a \>50% increase in serum troponin value at any time during the incident hospitalization and following administration of study drug., 6 months|Clinical status at 90 days after first infusion of study drug, Clinical status at visit 6 (day 90) on an ordinal scale with highest being the worst:

1. - Alive and off corticosteroids for myocarditis;
2. - Alive and on corticosteroids (provide dose) for myocarditis;
3. - Alive and on cellcept (provide dose) for myocarditis;
4. - Alive and on both corticosteroids (provide dose) and cellcept (provide dose) for myocarditis
5. - Dead (cancer, cardiovascular or other)., 6 months|Clinical status at 6 months after first infusion of study drug, Clinical status at visit 7 (6 months) with the highest being the worst:

1. - Alive and off corticosteroids for myocarditis;
2. - Alive and on corticosteroids (provide dose) for myocarditis;
3. - Alive and on cellcept (provide dose) for myocarditis;
4. - Alive and on both corticosteroids (provide dose) and cellcept (provide dose) for myocarditis
5. - Dead (cancer, cardiovascular or other)., 6 months|Fatal and non-fatal DVT and PE, The proportion of patients in each group with a

fatal and non-fatal DVT and PE will be compared., 6 months|Other immune-related adverse events between the two groups, Rates of other immune-related adverse events between the two groups will be compared., 6 months
Other Outcome Measures:
Sponsor: Massachusetts General Hospital
Collaborators: Bristol-Myers Squibb
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 390
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: 2021P003690
Start Date: 2022-06-22
Primary Completion Date: 2026-11
Completion Date: 2027-04
First Posted: 2022-04-20
Results First Posted:
Last Update Posted: 2023-03-17
Locations: Cedars-Sinai Medical Center, Los Angeles, California, 02127, United States|University of California Los Angeles, Los Angeles, California, 90095, United States|University of Chicago, Chicago, Illinois, 60637, United States|Franciscan Health, Indianapolis, Indiana, 46237, United States|University of Kansas Medical Center, Kansas City, Kansas, 66160, United States|University of Kentucky, Lexington, Kentucky, 40536-0200, United States|Maine Health, Portland, Maine, 04102, United States|Massachusetts General Hospital, Boston, Massachusetts, 02114, United States|Beth Israel Deaconess Medical Center, Boston, Massachusetts, 02115, United States|Boston Medical Center, Boston, Massachusetts, 02118, United States|Brigham and Women's Hospital, Boston, Massachusetts, 02215, United States|University of Michigan, Ann Arbor, Michigan, 48109, United States|Mayo Clinic, Rochester, Minnesota, 55905, United States|Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States|University of North Carolina Chapel Hill, Chapel Hill, North Carolina, 27599-7075, United States|Cleveland Clinic, Cleveland, Ohio, 44195, United States|Lehigh Valley Health Network, Bethlehem, Pennsylvania, 18017, United States|University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States|Allegheny-Singer Research Institution, Pittsburgh, Pennsylvania, 15212, United States|University of Texas Southwestern, Dallas, Texas, 72535, United States|MD Anderson Cancer Center, Houston, Texas, 77030, United States|University of Utah, Salt Lake City, Utah, 84132, United States|University of West Virginia, Morgantown, West Virginia, 26506, United States|University of British Colombia, Vancouver, British Colombia, V5Z 1M9, Canada|McMaster University, Hamilton, Ontario, L8V 1C3,

Canada
Study Documents:

NCT Number: NCT03486340
Study Title: Prevention of Chest Pain in Chemo-treated Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT03486340
Acronym: CATCH
Study Status: RECRUITING
Brief Summary: This is a prospective, exploratory, randomised clinical trial. Patients with diagnosed cancer that are to be treated with 5-fluorouracil (5-FU) will be randomised into standard oncological treatment or a cardiological assessment prior to the 5-FU treatment. The investigators hypothesize that aggressive management of ischemic risk factors in asymptomatic patients will reduce the number of hospitalisations and investigations for acute coronary syndrome during and after 5-FU treatment and that patients with high coronary artery calcium scores are more likely to experience chest pain during the treatment with 5-FU.
Study Results: NO
Conditions: Solid Carcinoma|5-Fluorouracil Toxicity|Cardiotoxicity|Chemotherapeutic Toxicity|Acute Coronary Syndrome|Coronary Artery Calcification|Chest Pain
Interventions: PROCEDURE: Cardiologic assessment
Primary Outcome Measures: Acute coronary syndrome, Composite endpoint of the incidence of overall mortality, chest pain requiring hospital admittance, the incidence of coronary angiography intervention and acute coronary syndrome, 6 months
Secondary Outcome Measures: Chest pain, Incidence of chest pain, 6 months
Other Outcome Measures:
Sponsor: Vejle Hospital
Collaborators: Region of Southern Denmark
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: CATCH2018
Start Date: 2018-04-11
Primary Completion Date: 2023-06-30
Completion Date: 2024-06-30
First Posted: 2018-04-03
Results First Posted:
Last Update Posted: 2022-08-09
Locations: Departments of Oncology and Medicine, Vejle Hospital, Vejle, Denmark
Study Documents:

NCT Number: NCT00500734
Study Title: Cardiomyopathy Tissue Bank in a Cancer Population
Study URL: https://beta.clinicaltrials.gov/study/NCT00500734
Acronym:
Study Status: UNKNOWN
Brief Summary: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant.

The goal of this laboratory research study is to collect and store blood and tissue from patients who have a diagnosis of heart disease and may be at a high risk for the development of heart failure. This blood may be used in the future to identify genes that may play a role in developing congestive heart failure (CHF) from chemotherapy or other sources.

This is an investigational study. All will be enrolled at MD Anderson.
Study Results: NO
Conditions: Heart Disease
Interventions: PROCEDURE: Blood Sample
Primary Outcome Measures: Baseline Patient Demographic Information (age, sex, race), One time visit.|Identification biological markers predisposing cancer patients to development of chemotherapy-induced congestive heart failure, One time visit for collection of blood and tissue samples.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 1000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ID02-359
Start Date: 2002-12-10
Primary Completion Date: 2020-12
Completion Date: 2020-12
First Posted: 2007-07-13
Results First Posted:
Last Update Posted: 2020-01-27
Locations: University of Texas MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT04729634
Study Title: Survey Of Mobilisation and Breathing Exercises After Thoracic and Abdominal Surgery

Study URL: https://beta.clinicaltrials.gov/study/NCT04729634
Acronym: SOMBATA
Study Status: COMPLETED
Brief Summary: Background

Thoracic or abdominal surgeries are followed by a shorter or longer period of immobilization and after major surgery there is a higher risk of developing cardiorespiratory complications. To prevent these complications, the patient is encouraged to change position and exercise in bed, get out of bed as early and as much as possible after the operation and to breathe with or without aids. There is no general definition of early mobilization and may start within a few hours to a few days after surgery. There is currently a lack of knowledge nationally and internationally about when the mobilization starts and what it contains.

Many patients also receive breathing training in connection with the surgery. There is currently no consensus on which method is preferable for which groups of patients. There are similarities and differences in practice in the world regarding postoperative breathing training. There are studies that have mapped practice after primarily thoracic surgery but also abdominal surgery. However, there are no studies that have mapped when the prescribed breathing training starts after different types of operations.

The purpose of the study is to map when mobilization and breathing training starts after abdominal and thoracic surgery and what is then performed

Method The study will be carried out as a quality follow-up with mapping of practice. Patients ≥ 18 years of age who are undergoing a planned or acute open, keyhole or robot-assisted surgery, who are extubated and who breathe spontaneously will be included. Exclusion criteria are completed plastic, trauma, orthopedic or transplant surgery.

The material will be recruited from Swedish university hospitals and county hospitals for 20 days of surgery (Monday through Thursday) for five consecutive weeks.

Clinical benefit The study will mean that clinical practice is presented which, with regard to mobilization, is the first study ever that will present when this takes place and what is done and, with regard to breathing training, the first that shows when this training is initiated.
Study Results: NO
Conditions: Abdominal Cancer|Heart Diseases
Interventions: OTHER: Mobilization
Primary Outcome Measures: When mobilization starts after surgery, Time from termination of anaesthesia to when mobilization starts, ie when

the patients are sitting with the legs over the edge of the bed, Within 24 hours after surgery|Mobilization- Content, Content of the mobilization performed i.e. which level of mobilization (sitting on the edge of the bed, standing by the bed, sitting in a chair and walking) which is reached., Within 24 hours after surgery| Mobilization- Duration, Duration of the mobilization performed, minutes, Within 24 hours after surgery|When any intervention with breathing exercises starts after surgery, Time from termination of anesthesia to when the breathing exercise starts, Within 24 hours after surgery|Breathing exercise- Content, Type of breathing exercise, as deep breathing, positive expiratory pressure or incentive spirometry., Within 24 hours after surgery|Breathing exercise- Intensity, Intensity of breathing exercise prescribed, sessions/time., Within 24 hours after surgery
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Göteborg University
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1492
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: OTHER
Other IDs: FoU i VGR: 275327
Start Date: 2021-09-01
Primary Completion Date: 2022-02-28
Completion Date: 2022-06-30
First Posted: 2021-01-28
Results First Posted:
Last Update Posted: 2022-08-16
Locations: Sahlgrenska University Hospital, Göteborg, Västra Götaland, 41345, Sweden
Study Documents:

NCT Number: NCT04755140
Study Title: Endoprosthesis Metal Toxicity Study
Study URL: https://beta.clinicaltrials.gov/study/NCT04755140
Acronym:
Study Status: RECRUITING
Brief Summary: The purpose of this research is to investigate whether patients who previously had endoprosthesis surgery experience memory, thinking, or heart problems. It will also help determine how often these problems occur.
Study Results: NO
Conditions: Bone Tumor|Cancer of Bone|Heart Diseases|Cognitive Impairment|Cognitive Decline|Chemotherapy Effect|Memory Problem
Interventions: BEHAVIORAL: Questionnaires|BEHAVIORAL: Interviews|

DIAGNOSTIC_TEST: Blood Test|DIAGNOSTIC_TEST: Echocardiogram
Primary Outcome Measures: Echo - Left Ventricular Ejection Fraction, The echocardiogram will measure changes in LV ejection fraction as a percent., Echo's will be taken at baseline, 1 year, and 2 years|Echo - Left Ventricular Mass, The echocardiogram will measure changes in LV Mass in grams., Echo's will be taken at baseline, 1 year, and 2 years|Echo - Heart Hypertrophy, The echocardiogram will measure changes in concentric or eccentric hypertrophy in centimeters., Echo's will be taken at baseline, 1 year, and 2 years|Cobalt Metal Levels, The change in cobalt blood ion levels will be measured in ng/mL., Cobalt level will be measured at baseline, 1 year, and 2 years|Chromium Metal Levels, The change in chromium blood ion levels will be measured in ng/mL., Chromium level will be measured at baseline, 1 year, and 2 years|Titanium Metal Levels, The change in titanium blood ion levels will be measured in ng/mL., Titanium level will be measured at baseline, 1 year, and 2 years
Secondary Outcome Measures: Psychometrist Testing - Intelligence Score, The change in participants' intelligence will be measured using the Wechsler Adult Intelligence Scale. The scale is based of scores of 50 to 150. The higher the score the better the outcome. The average outcome will be a score of 100., Testing will occur at baseline, 1 year, and 2 years.|Psychometrist Testing - Memory Score, The change in participants' memory will be measured using the Wechsler Adult Memory Scale. The scale is based of scores of 50 to 150. The higher the score the better the outcome. The average outcome will be a score of 100., Testing will occur at baseline, 1 year, and 2 years.
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators: National Institutes of Health (NIH)|National Heart, Lung, and Blood Institute (NHLBI)|National Institute on Aging (NIA)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 150
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 20-008408|R01AG060920|R01HL147155-02
Start Date: 2021-03-12
Primary Completion Date: 2023-06
Completion Date: 2024-01
First Posted: 2021-02-15
Results First Posted:
Last Update Posted: 2023-02-22
Locations: Mayo Clinic, Rochester, Minnesota, 55905, United States
Study Documents:

NCT Number: NCT03474835
Study Title: Ischemic Heart Disease in Male With Prostate Adenocarcinoma

Study URL: https://beta.clinicaltrials.gov/study/NCT03474835
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of the study: to increase the efficiency of diagnosis, treatment and prediction of the course of coronary heart disease in patients with adenocarcinoma of the prostate gland, depending on the hormonal status by determining the cardiovascular risk factors, factors of angiogenesis, structural and functional state of the heart, coronary vessels, kidney damage and their pharmacological correction.
Study Results: NO
Conditions: Ischemic Heart Disease|Prostate Adenocarcinoma
Interventions: DIAGNOSTIC_TEST: ISCHEMIC HEART DISEASE diagnostic
Primary Outcome Measures: cardiovascular events, cardiovascular events development - myocardial infarction, stroke, 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Dnipropetrovsk State Medical Academy
Collaborators:
Sex:
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: DIAGNOSTIC
Other IDs: 832/18
Start Date: 2018-01-15
Primary Completion Date: 2018-04-15
Completion Date: 2019-01-15
First Posted: 2018-03-23
Results First Posted:
Last Update Posted: 2018-03-23
Locations: SE Dnipropetrovsk medical academy, Dnipro, Ukraine
Study Documents:

NCT Number: NCT00016276
Study Title: Combination Chemotherapy, Surgery, and Radiation Therapy With or Without Dexrazoxane and Trastuzumab in Treating Women With Stage III or Stage IV Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00016276
Acronym:
Study Status: TERMINATED
Brief Summary: Randomized phase III trial to compare the effectiveness of combination chemotherapy, surgery, and radiation therapy with or without dexrazoxane and trastuzumab in treating women who have stage IIIA, stage IIIB or stage IV breast cancer. Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Chemoprotective drugs, such as dexrazoxane, may

protect normal cells from the side effects of chemotherapy. Monoclonal antibodies such as trastuzumab can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Radiation therapy uses high-energy x-rays to damage tumor cells. It is not yet known if chemotherapy combined with surgery and radiation therapy is more effective with or without dexrazoxane and trastuzumab in treating breast cancer
Study Results: NO
Conditions: Cardiac Toxicity|Inflammatory Breast Cancer|Stage IIIA Breast Cancer|Stage IIIB Breast Cancer|Stage IV Breast Cancer
Interventions: DRUG: dexrazoxane hydrochloride|DRUG: doxorubicin hydrochloride|DRUG: cyclophosphamide|DRUG: paclitaxel|BIOLOGICAL: trastuzumab|PROCEDURE: therapeutic conventional surgery|RADIATION: radiation therapy|DRUG: tamoxifen citrate|OTHER: laboratory biomarker analysis
Primary Outcome Measures: Median number of positive axillary lymph nodes, Compared in the Herceptin and no Herceptin groups and in the dexrazoxane versus no dexrazoxane groups using a chi-square test and a two-sample t test, respectively., At 24 weeks|Pathologic complete response (CR) rate in the breast and axilla, Compared in the Herceptin and no Herceptin groups and in the dexrazoxane versus no dexrazoxane groups using a chi-square test and a two-sample t test, respectively., At 24 weeks|Cardiac toxicity, graded according to the National Cancer Institute Common Toxicity Criteria (NCI CTC) v2.0, Assessment will use exact binomial comparison of two proportions., At 24 weeks|Cardiac toxicity, graded according to the National Cancer Institute Common Toxicity Criteria (NCI CTC) v2.0, Assessment will use exact binomial comparison of two proportions., At 78 weeks|Disease-free survival, Proportional hazards regression models will be used., Date of study entry to date of first relapse (local or distant) or death due to any cause, assessed up to 10 years
Secondary Outcome Measures: Occurrence of grade 3 or higher late cardiac or neurological toxicity, or secondary acute myeloid leukemia (AML)/myelodysplastic syndrome (MDS), Up to 10 years|Clinical/ radiographic response in the breast and axilla after doxorubicin hydrochloride and cyclophosphamide with or without dexrazoxane hydrochloride, At 12 weeks|Clinical/radiographic response in the breast and axilla after paclitaxel with or without trastuzumab, At 24 weeks|Time to local/regional recurrence, Up to 10 years|Time to completion of treatment through radiotherapy, Up to 5 years|Rate of breast conservation for patients considered "candidates" prior to treatment, Up to 10 years|Overall survival, Proportional hazards regression models will be used., Date of study entry to date of due to any cause, assessed up to 10 years
Other Outcome Measures:
Sponsor: National Cancer Institute (NCI)
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3

Enrollment: 396
Funder Type: NIH
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: NCI-2012-02380|CLB-49808|U10CA031946|CDR0000068617
Start Date: 2001-05
Primary Completion Date: 2005-03
Completion Date:
First Posted: 2003-09-04
Results First Posted:
Last Update Posted: 2013-01-16
Locations: Cancer and Leukemia Group B, Chicago, Illinois, 60606, United States
Study Documents:

NCT Number: NCT01093235
Study Title: Combination Chemotherapy With or Without Bevacizumab in Treating Patients With Nonmetastatic Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01093235
Acronym:
Study Status: UNKNOWN
Brief Summary: RATIONALE: Drugs used in chemotherapy, such as docetaxel, fluorouracil, epirubicin hydrochloride, and cyclophosphamide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy) may kill more tumor cells. Monoclonal antibodies, such as bevacizumab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. It is not yet known whether giving combination chemotherapy together with or without bevacizumab is more effective in treating patients with nonmetastatic breast cancer.

PURPOSE: This randomized phase III trial is studying how well giving combination chemotherapy works compared with giving combination chemotherapy together with bevacizumab in treating patients with nonmetastatic breast cancer.
Study Results: NO
Conditions: Breast Cancer|Cardiac Toxicity|Perioperative/Postoperative Complications
Interventions: BIOLOGICAL: bevacizumab|DRUG: cyclophosphamide|DRUG: docetaxel|DRUG: epirubicin hydrochloride|DRUG: fluorouracil|PROCEDURE: assessment of therapy complications|PROCEDURE: neoadjuvant therapy|PROCEDURE: quality-of-life assessment|PROCEDURE: therapeutic conventional surgery
Primary Outcome Measures: Complete pathological response rates (tumor and lymph nodes)
Secondary Outcome Measures: Disease-free survival|Overall survival|

Pathological complete response rate in breast alone|Radiological response after 3 and 6 courses of chemotherapy|Rate of breast conservation|Toxicities, including cardiac safety and surgical complications (wound healing, bleeding, and thrombosis)|Quality of life
Other Outcome Measures:
Sponsor: Cambridge University Hospitals NHS Foundation Trust
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 800
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: |Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CDR0000668530|CRCA-CCTC-WCTU-ARTemis|ISRCTN68502941|EUDRACT-2008-002322-11|EU-21017|MREC-08/H1102/104
Start Date: 2009-04
Primary Completion Date: 2012-04
Completion Date:
First Posted: 2010-03-25
Results First Posted:
Last Update Posted: 2010-03-25
Locations: Addenbrooke's Hospital, Cambridge, England, CB2 2QQ, United Kingdom
Study Documents:

NCT Number: NCT05643235
Study Title: Implanted Loop Recorders for Detection and Management of Arrhythmia With Bruton Tyrosine Kinase Inhibitors
Study URL: https://beta.clinicaltrials.gov/study/NCT05643235
Acronym:
Study Status: RECRUITING
Brief Summary: This study will enroll patients initiating Bruton Tyrosine Kinase (BTK) inhibitors without history of documented arrhythmia while on therapy using the Medtronic LINQ-2 insertable cardiac monitor (ILR). The incidence of new onset atrial fibrillation (AF) and other arrhythmia will be determined. Actions taken in response to device detected arrhythmia will be recorded.
Study Results: NO
Conditions: Atrial Fibrillation|Supraventricular Arrhythmia|Ventricular Arrhythmias and Cardiac Arrest|Chronic Lymphocytic Leukemia|Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Interventions: DEVICE: Medtronic LINQ-2 Insertable Cardiac Monitor (ILR)
Primary Outcome Measures: Incidence of device detected atrial fibrillation (AF), Incidence of AF lasting 6 or more minutes at 18 months: each arrhythmic episode detected by the patient's device will be reviewed to determine if it is 1) an actual AF episode, and 2) is

at least 6 minutes in duration., at 18 months after start of BTK inhibitor|Long term Incidence of device detected AF, Incidence of AF lasting 6 or more minutes up to 60 months: each arrhythmic episode detected by the patient's device will be reviewed to determine if it is 1) an actual AF episode, and 2) is at least 6 minutes in duration., up to 60 months after device implantation
Secondary Outcome Measures: Incidence of device detected ventricular arrhythmia (VA), Incidence of VA is defined as follows: greater than or equal to 3 sequential wide complex beats arising from the ventricles, rate \> 100 beats per minute at 18 months after start of BTK inhibitor therapy., at 18 months after start of BTK inhibitor|BTK dose reduction or discontinuation due to device detected arrhythmia, assessed by chart review., Clinical actions including BTK dose reduction, interruption, discontinuation, or change in oncologic treatment by treating oncologist because of device detected arrhythmia., up to 60 months after device implantation|Initiation of anticoagulation for AF detected by device monitoring, assessed by chart review, Prescription of an approved anticoagulant drug (apixaban, dabigatran, rivaroxaban, edoxaban, warfarin, aspirin) for prevention of stroke/systemic embolism based on AF detected by ILR, up to 60 months after device implantation|Long term incidence of device detected ventricular arrhythmia (VA), Incidence of VA is defined as follows: greater than or equal to 3 sequential wide complex beats arising from the ventricles, rate \> 100 beats per minute up to 60 months after device implant., up to 60 months after device implantation
Other Outcome Measures:
Sponsor: Northwell Health
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: OTHER
Other IDs: IRB 22-0256|ERP-2021-12882
Start Date: 2022-11-01
Primary Completion Date: 2024-05-01
Completion Date: 2027-11-01
First Posted: 2022-12-08
Results First Posted:
Last Update Posted: 2022-12-08
Locations: Northwell (Northshore University/Long Island Jewish Hospitals), New Hyde Park, New York, 11040, United States
Study Documents:

NCT Number: NCT01991340
Study Title: H.E.R.O.S. Study: An Observational Study of the Cardiac

Safety of Herceptin (Trastuzumab) in Patients With HER2-Positive Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01991340
Acronym:
Study Status: COMPLETED
Brief Summary: This observational study will assess the safety of Herceptin (trastuzumab) in patients with HER2-positive breast cancer in routine clinical practice. Eligible patients will be followed for up to 4 years.
Study Results: NO
Conditions: Breast Cancer
Interventions:
Primary Outcome Measures: Safety: Incidence of adverse events, up to approximately 4.5 years
Secondary Outcome Measures: Incidence of symptomatic congestive heart failure (NYHA class II, III and IV), up to approximately 4.5 years| Incidence of asymptomatic LVEF decline, up to approximately 4.5 years| Frequency of treatment discontinuations/interruptions, up to approximately 4.5 years
Other Outcome Measures:
Sponsor: Hoffmann-La Roche
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 657
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ML21975
Start Date: 2008-11
Primary Completion Date: 2013-02
Completion Date: 2013-02
First Posted: 2013-11-25
Results First Posted:
Last Update Posted: 2013-11-25
Locations: Algiers, 16000, Algeria|Annaba, 23000, Algeria|Blida, 9000, Algeria|Mascara, 29000, Algeria|Oran, 31000, Algeria|Sidi Belabes, 22000, Algeria|Tizi Ouzou, 15000, Algeria|Agadir, 80000, Morocco| Casablanca, 20000, Morocco|Casablanca, 20052, Morocco|Casablanca, 20100, Morocco|Casablanca, 20502, Morocco|Casablanca, Morocco|Fes, 30000, Morocco|Marrakech, 40000, Morocco|Rabat, 10000, Morocco|Rabat, 21000, Morocco|Rabat, 6213, Morocco|Rabat, Morocco
Study Documents:

NCT Number: NCT03498040
Study Title: Development and Progression of Carcinoid Heart Disease in a Cohort of Adult Patients With Neuroendocrine Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT03498040
Acronym: CRUSOE-NETs

Study Status: NOT_YET_RECRUITING
Brief Summary: Carcinoid Heart Disease (CHD) is a rare form of heart disease, occurring in over 50% of the patients with carcinoid syndrome. Pathophysiology, prognostic factors of development of Carcinoid Heart Disease and progression of disease remain unclear.

This observational multicenter cohort study is designed to study the occurrence of Carcinoid Heart Disease in patients with differentiated carcinoid tumors, to describe numerous factors influencing the occurrence, severity, progression and long-term survival of patients with Carcinoid Heart Disease. Basic informations and detailed diagnosis informations (oncological and cardiac parameters), are collected by professional doctors. Clinical outcomes (onset of Carcinoid Heart Disease, cardiac surgery, related death) will be followed up every year or every six/three months if clinically indicated.
Study Results: NO
Conditions: Carcinoid Heart Disease
Interventions: OTHER: Study of the occurrence of Carcinoid Heart Disease
Primary Outcome Measures: Carcinoid Heart Disease, Percentage of patients with carcinoid heart disease at diagnosis and during follow-up (carcinoid heart disease diagnosis will be assessed by an annual echocardiography)., 10 years (at the end of study)
Secondary Outcome Measures: Cardiac surgery, Percentage of patients requiring cardiac surgery for the cardiac carcinoid heart disease, 10 years (at the end of study)|5HIAA levels, Correlation between urinary 5HIAA levels at diagnosis and occurrence of carcinoid heart disease, 10 years (at the end of study)|Survival, Overall survival in patents with and without carcinoid heart disease, 10 years (at death or at the end of study)
Other Outcome Measures:
Sponsor: Hospices Civils de Lyon
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 600
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 69HCL17_0700
Start Date: 2018-04
Primary Completion Date: 2033-04
Completion Date: 2033-04
First Posted: 2018-04-13
Results First Posted:
Last Update Posted: 2018-04-13
Locations: Hôpital Edouard HERRIOT, Institut du Cancer - Hospices Civils de Lyon, Lyon, 69437, France

Study Documents:

NCT Number: NCT00716898
Study Title: Pharmacokinetics of Low Molecular Weight Heparin in Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT00716898
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of the study is to determine the Pharmacokinetics of Low Molecular Weight Heparin (LMWH) in Cancer patients, and compare it to the Pharmacokinetics of LMWH in Patients without cancer. We also intend to detect any correlation between heparanase blood and urine levels and the Pharmacokinetics of LMWH.
Study Results: NO
Conditions: Cancer|Thrombosis|Angina Pectoris
Interventions:
Primary Outcome Measures: Pharmacokinetics of Low Molecular Weight Heparin (LMWH) in Cancer patients, Interim analysis and at the end of the trial
Secondary Outcome Measures: The role of heparanase on the Pharmacokinetics of Low Molecular Weight Heparin (LMWH) in Cancer patients, End of the study
Other Outcome Measures:
Sponsor: Shaare Zedek Medical Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 25
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Nasser-2008-1CTIL
Start Date: 2009-02
Primary Completion Date: 2011-06
Completion Date: 2011-06
First Posted: 2008-07-16
Results First Posted:
Last Update Posted: 2016-04-15
Locations: Shaare Zedek Medicla Center, Jerusalm, 91031, Israel
Study Documents:

NCT Number: NCT03039140
Study Title: Cardiac Rehabilitation Program in Improving Cardiorespiratory Fitness in Stage 0-III Breast Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT03039140
Acronym:
Study Status: COMPLETED
Brief Summary: This clinical trial studies a cardiac rehabilitation program in improving cardiorespiratory fitness in stage 0-III breast

cancer survivors. Cardiovascular disease is the leading cause of death of women in both the general population and the breast cancer survivor population. There are many risk factors common to both heart disease and breast cancer development, including physical inactivity. A cardiac rehabilitation program may help improve cardiorespiratory fitness, reduce cardiovascular disease risk factors, and improve quality of life among breast cancer survivors.
Study Results: NO
Conditions: Cancer Survivor|Stage 0 Breast Cancer|Stage IA Breast Cancer|Stage IB Breast Cancer|Stage IIA Breast Cancer|Stage IIB Breast Cancer|Stage IIIA Breast Cancer|Stage IIIB Breast Cancer|Stage IIIC Breast Cancer
Interventions: OTHER: Educational Intervention|BEHAVIORAL: Exercise Intervention|OTHER: Quality-of-Life Assessment|OTHER: Questionnaire Administration
Primary Outcome Measures: Feasibility of conducting a 14-week CR program, During the course of the 14-week intervention period, the CR medical director will monitor CR staff adherence to the study protocol. Every 2 weeks, they will review intervention participants' baseline graded exercise test results and subsequent exercise prescriptions to ensure the intervention is targeted at the appropriate level of each participant's VO2 max. Will administer a satisfaction questionnaire to intervention participants. Results from these surveys will be evaluated during the course of the study by the principal investigator and used to improve the study process as appropriate., 14 weeks
Secondary Outcome Measures: Efficacy of CR in improving cardiorespiratory fitness, Analysis of follow-up VO2 max, in units of mL/kg/min, will be done using an analysis of covariance (ANCOVA) approach. If VO2 max values are missing at 14 weeks, will use the Duke Activity Status Index questionnaire responses to approximate VO2 max values., At 14 weeks
Other Outcome Measures:
Sponsor: Ohio State University Comprehensive Cancer Center
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 25
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: OSU-14060|NCI-2015-00810
Start Date: 2015-05-14
Primary Completion Date: 2018-10-23
Completion Date: 2021-12-31
First Posted: 2017-02-01
Results First Posted:
Last Update Posted: 2022-03-10

Locations: Ohio State University Comprehensive Cancer Center, Columbus, Ohio, 43210, United States
Study Documents:

NCT Number: NCT01896440
Study Title: Heart Safety Study of Ondansetron in Children Receiving Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT01896440
Acronym:
Study Status: WITHDRAWN
Brief Summary: We will study the effects of ondansetron on measurements of electrical activity in the heart to make sure doses we are using to prevent nausea and vomiting in children receiving chemotherapy are safe.
Study Results: NO
Conditions: Malignant Childhood Neoplasm
Interventions: DRUG: Ondansetron
Primary Outcome Measures: Change in QTc interval, QTc intervals will be estimated by performing ECGs on patients pre-investigational drug administration and post-investigational drug administration. The change in the QTc interval between the two ECGs for each investigational dose is the primary endpoint., Day 1 to 2 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Oklahoma
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE4
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: Pediatric ondansetron QTc
Start Date: 2013-10
Primary Completion Date: 2013-10
Completion Date: 2013-10
First Posted: 2013-07-11
Results First Posted:
Last Update Posted: 2013-10-08
Locations: University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, 73104, United States
Study Documents:

NCT Number: NCT04939857
Study Title: Effect of Trimetazidine on Radiotherapy-induced Heart Damage.
Study URL: https://beta.clinicaltrials.gov/study/NCT04939857

Acronym:
Study Status: UNKNOWN
Brief Summary: This is a randomized controlled trial. 80 patients with thoracic radiotherapy will be included. Participants will be randomly divided into experimental group or control group. Before radiotherapy, echocardiography, 2D STE, CK, CK-MB, cTnT, NT-proBNP, electrocardiogram (ECG), and hs-CRP will be detected. During subsequent follow-up, echocardiography, 2D STE, CK, CK-MB, cTnT, NT-proBNP, ECG, and hs-CRP will be collected at every follow-up time.
Study Results: NO
Conditions: Cardiotoxicity
Interventions: DRUG: Trimetazidine
Primary Outcome Measures: global longitudinal strain-A parameter of two dimensional speckle tracking echocardiography, The primary outcome of the trial was a decrease in global longitudinal strain ≥10%., pre-radiotherapy, 12 months after radiotherapy
Secondary Outcome Measures: Rate of major adverse cardiovascular events, Proportion of patients with major adverse cardiovascular events (MACE) in total participants. MACE was defined as unstable angina, new arrhythmia, acute myocardial infarction, heart failure, valvular heart disease, acute pericarditis, and cardiac death in this study., pre-radiotherapy, after completion of radiotherapy, 3 months after radiotherapy, 6 months after radiotherapy, and 12 months after radiotherapy
Other Outcome Measures:
Sponsor: Peking University Third Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 80
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: PKU Third Hospital
Start Date: 2021-06-25
Primary Completion Date: 2022-07-30
Completion Date: 2022-08-31
First Posted: 2021-06-25
Results First Posted:
Last Update Posted: 2021-06-25
Locations:
Study Documents:

NCT Number: NCT03459898
Study Title: Assessment of Left-sided Cardiac Sparing Through the Use of 3-dimensional Surface Matching-based Deep Inspiration Breath Hold and Active Breathing Control

Study URL: https://beta.clinicaltrials.gov/study/NCT03459898
Acronym:
Study Status: COMPLETED
Brief Summary: The standard treatment for breast cancer is surgery followed by adjuvant breast radiation therapy in most cases. For left sided breast cancers, the heart dose delivered by the radiation treatment is often of particular concern. In order to spare the heart, different strategies are currently available, including active breathing control (ABC) and voluntary deep in inspiration breath hold (DIBH) (both strategies are currently being used at our centre). To perform accurate heart-sparing treatments, it is important to ensure that patients are positioned consistently. One available approach is through surface imaging which tracks the position of a portion of the skin surface, known as the AlignRT system (VisionRT Ltd, London, UK).
Study Results: NO
Conditions: Left-Sided Breast Cancer
Interventions: DEVICE: AlignRT system (VisionRT Ltd., London, UK)
Primary Outcome Measures: Reproducibility of ABC or vDIBH set-up as measured by Align RT., Reproducibility of set-up will be evaluated by determining discrepancies in patient's surface between treatment and CT simulation which will be acquired with the Align RT system using multiple measures along with daily portal images during treatment and weekly CBCTs., 2 years|Mean heart dose as determined using Align RT., Estimate the change in mean heart dose for each breath-hold/heart sparing strategy by:

i. Converting differences in heart position on 2D portal images acquired during treatment to 3D volumes on Pinnacle plans.

ii. Using the CBCT images (acquired weekly), to recalculate dose to heart based on the patient's position and anatomy that day., 2 years
Secondary Outcome Measures: The impact of Align RT with vDIBH as compared to vDIBH without AlignRT on quality of life as assessed by the EORTC core QoL questionnaire., QoL will be assessed using the EORTC core QoL questionnaire (QLQ-C30) which is a well-validated and widely used QoL questionnaire available in multiple languages (12,13). QLQ-C30 is composed of 30 questions that represent 5 functional scales (physical, role, cognitive, emotional and social), 3 symptom scales (fatigue, nausea and vomiting, and pain), and a global health / QoL scale. The questionnaire will be completed by patients at time of radiation simulation as baseline, at completion of RT (during routine review) and at the 6-8 week follow-up., 2 years
Other Outcome Measures:
Sponsor: Sunnybrook Health Sciences Centre
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 40
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 268-2017
Start Date: 2018-05-19
Primary Completion Date: 2021-12-31
Completion Date: 2022-01-30
First Posted: 2018-03-09
Results First Posted:
Last Update Posted: 2022-05-05
Locations: Sunnybrook Health Sciences Centre, Toronto, Ontario, M4N 3M5, Canada
Study Documents:

NCT Number: NCT03934957
Study Title: Hamburg City Health Study - a German Cohort Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03934957
Acronym: HCHS
Study Status: RECRUITING
Brief Summary: The Hamburg City Health Study (HCHS) is a large, prospective, long-term, population-based cohort study and a unique research platform and network to obtain substantial knowledge about several risk and prognostic factors in major chronic diseases.
Study Results: NO
Conditions: Coronary Heart Disease|Stroke|Dementia|Cancer|Health Care|Vascular Diseases|Periodontal Diseases|Ocular Diseases|Respiratory Disease|Obesity
Interventions:
Primary Outcome Measures: self-reported Information on changes in health in the participants, coronary artery disease atrial fibrillation heart failure dementia stroke cancer such as prostate cancer and skin cancer chronic kidney diseases migraine musculoskeletal diseases such as osteoporosis and bone metastasis ocular diseases such as glaucoma, macular degeneration, fundus hypertonicus, retinal vessel disease and neoplasm oral health including periodontal disease, oropharyngeal cancer and human papillomavirus (HPV)-infection psychiatric and psychosomatic disorders such as mental disorder or late - last depression pulmonary diseases such as obstructive lung disease sexual disorder skin diseases such as psoriasis, chronic wounds and inflammation vascular diseases such as aortic aneurysm, thrombosis and peripheral arterial disease, yearly up to 12 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Universitätsklinikum Hamburg-Eppendorf
Collaborators: Universitäres Herzzentrum Hamburg-Eppendorf|Martini-Klinik am UKE GmbH
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:

Enrollment: 45000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PV5131
Start Date: 2016-02-08
Primary Completion Date: 2022-12-31
Completion Date: 2028-12-31
First Posted: 2019-05-02
Results First Posted:
Last Update Posted: 2019-05-02
Locations: Universitätsklinikum Hamburg-Eppendorf, Hamburg, 20246, Germany
Study Documents:

NCT Number: NCT01772498
Study Title: HRV Biofeedback for Brain Tumour Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT01772498
Acronym:
Study Status: SUSPENDED
Brief Summary: This study is designed to take a first step toward testing the efficacy and acceptability of heart rate variability biofeedback (HRVB) as a means of ameliorating psychological distress in survivors of Primary Brain Tumour (PBT). HRVB is a biofeedback approach that provides clients with real time feedback about their heart rate variability (HRV) as a means of teaching them how to breathe in a specific, therapeutic manner.

More specifically, this study has been designed to test several hypothesises. Each hypothesis is based on the prediction that, in a sample of psychologically distressed PBT survivors, a course of 8 HRVB sessions will demonstrate:

* statistically significant reductions in levels of depression
* statistically significant reductions in levels of anxiety
* statistically significant increases in resting HRV
* that reductions in anxiety and depression will be significantly, negatively correlated with increases in resting HRV
* that the HRVB will be viewed as an acceptable intervention by the participants

In addition to the hypothesises stated above, the study will also investigate in a discovery oriented manner if the HRVB intervention will have positive impacts on the participants:

* levels of sleep impairment
* levels of pain
Study Results: NO
Conditions: Depression|Anxiety|Sleep Impairment
Interventions: BEHAVIORAL: heart rate variability biofeedback

Primary Outcome Measures: Change from baseline in score on Beck Depression Inventory II at 8 weeks, Widely used self report measure to assess for symptoms of depression., comparison of scores immediately pre-intervention and then immediately post-intervention (8 weeks later)|Change from baseline scores on trait form of the State Trait Anxiety Inventory (Spielberger et al., 1983)at 8 weeks, The Trait Anxiety Inventory is a widely used self report measure of anxiety symptoms., comparison of scores immediately pre-intervention and then immediately post-intervention (8 weeks later)|Change from baseline in resting HRV High Frequency Power, Baseline level of High Frequency HRV power (0.15-0.4 Hz) measured in ms2/Hz recorded over 5 minutes of rest at pre-intervention compared to level of High Frequency HRV power (0.15-0.4 Hz) measured in ms2/Hz recorded over 5 minutes of rest recorded aqt post-intervention, comparison of scores immediately pre-intervention and then immediately post-intervention (8 weeks later)|Resting Low Frequency HRV power (0.04-0.15 Hz), Baseline level of Low Frequency HRV power (0.15-0.4 Hz) measured in ms2/Hz recorded over 5 minutes of rest at pre-intervention compared to level of Low Frequency HRV power (0.04-0.15 Hz)measured in ms2/Hz recorded over 5 minutes of rest recorded aqt post-intervention, comparison of scores immediately pre-intervention and then immediately post-intervention (8 weeks later)|Change in the standard deviation of all NN intervals from baseline in resting heart beat, This metric measures the standard deviation of normal beat-to-beat intervals (SDNN) that are present within the heart rythm. it is a time domain measure of HRV and it serves as a marker of overall adaptability of the nervous system., comparison of scores immediately pre-intervention and then immediately post-intervention (8 weeks later)|Subjective Acceptability ratings, This will be a 5 point Likert scale asking how acceptable the participants found the experience of particiapting in the intervention to be , from "not at all acceptable" to "very acceptable"., To be completed immediately post-intervention (8 weeks after the intiation of training)
Secondary Outcome Measures: Change from baseline score on the Short Form McGill Pain Questionnaire (SFMPQ)(Melzack, 1987), The SFMPQ is a widely used measure of pain related experience., comparison of scores immediately pre-intervention and then immediately post-intervention (8 weeks later)|Change from baseline in scores on the Pittsburgh Sleep Quality Index (Buysse et al., 1989), The Pittsburgh Sleep Quality Index (Buysse et al., 1989)is a widely used self report measure of sleep quality., comparison of scores immediately pre-intervention and then immediately post-intervention (8 weeks later)
Other Outcome Measures:
Sponsor: British Columbia Cancer Agency
Collaborators: University of British Columbia
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 15
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: HRVB-123
Start Date: 2013-01
Primary Completion Date: 2015-08
Completion Date: 2016-06
First Posted: 2013-01-21
Results First Posted:
Last Update Posted: 2015-05-06
Locations: BC Cancer Agency, Vancouver, British Columbia, V2L-5L6, Canada
Study Documents:

NCT Number: NCT05132998
Study Title: Impact of a Comprehensive Cardiac Rehabilitation Program Framework Among High Cardiovascular Risk Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT05132998
Acronym:
Study Status: COMPLETED
Brief Summary: Many cancer survivors are at risk for cardiovascular disease (CVD); it is therefore important to identify patients at increased risk for cardiotoxicity, especially in the setting of CVRF or pre-existing CVD, and to design personalized interventions to prevent cardiovascular morbidity. In this background, cardio-oncology rehabilitation frameworks for specific cancer patients have been proposed. Given potential beneficial effects of exercise among cancer patients (including those at higher risk of CVD), data pertaining to optimal program designs are of paramount contemporary importance.

Thus, the aim of this study is to compare the impact of a Cardiac Rehabilitation Program (CRP) model versus a community-based exercise intervention plus usual care on cardiorespiratory fitness (CRF), physical function domains and CVRF control in adult cancer survivors who have been exposed to cardiotoxic cancer treatment and/or with cardiovascular medical background. Study outcomes will be assessed at baseline (M0) and after an 8 weeks-intervention (M1), comprising maximal aerobic capacity (peak oxygen uptake), muscular strength, neuromuscular function, single CVRF control including physical activity measurements and psychosocial parameters, health-related quality of life, fatigue, health literacy, inflammatory response and feasibility metrics; an economic evaluation will provide quantitative comparison, for a cost-effectiveness analysis
Study Results: NO
Conditions: Oncologic Disorders|Cardiovascular Diseases
Interventions: OTHER: Cardiac Rehabilitation Program|OTHER: Community exercise intervention
Primary Outcome Measures: Cardiorespiratory fitness, VO2peak measured by CPET, Change from baseline to 2 months
Secondary Outcome Measures: Ventilatory efficiency, minute ventilation

to carbon dioxide production slope (VE/VCO2 slope) assessed by CPET, Change from baseline to 2 months|Sit-to-stand test, Sit-to-stand test during 60 seconds, Change from baseline to 2 months|Handgrip maximal isometric muscle strength, muscle strength measured with manual dynamometers (Kgf), Change from baseline to 2 months|Body composition, Changes in body composition assessed by bioelectrical impedance analysis, Change from baseline to 2 months|Resting diastolic blood pressure, Measured with an average of 3 readings by an automated measurement device as per the ESC guidelines (mmHg), Change from baseline to 2 months|Resting systolic blood pressure, Measured with an average of 3 readings by an automated measurement device as per the ESC guidelines (mmHg), Change from baseline to 2 months|Resting heart rate, Measured with an average of 3 readings by an automated measurement device (bpm), Change from baseline to 2 months| Hyperlipidemia, Measured through fasting Blood biochemistry including total cholesterol (TC), low-density lipoprotein-cholesterol (LDL-C), high-density-lipoprotein cholesterol (HDL-C), triglycerides (TG), Change from baseline to 2 months|Diabetes control, Measured through glycated haemoglobin (%) in fasting state, Change from baseline to 2 months|Physical Activity, Self-reported through the International Physical Activity Questionnaire, classifying the activity in three categories (low activity levels, moderate activity levels or high activity levels), Change from baseline to 2 months|Physical Activity, objectively assessed by accelerometer, to wear for seven consecutive days, Change from baseline to 2 months|Smoking Cessation, Cigarette smoking habits quantified in pack-year and cigarettes per day, to measure exposure to tobacco, Change from baseline to 2 months| Depression and anxiety, Psychosocial parameters assessed through the Hospital Anxiety and Depression Score questionnaire. Scores 0-14. A sub-scale score \> 8 denotes anxiety or depression symptoms, Change from baseline to 2 months|Health Related Quality of Life, Evaluated using the EuroQuol Five- Dimensional questionnaire (EQ-5D-5L). It consists in five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. The EQ - Visual Analog Scale records the patient's self-rated health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'., Change from baseline to 2 months|Fatigue, Fatigue score evaluated by the specific item on the EORTC QLQ-C30 questionnaire (high score representing high level of symptomatology), Change from baseline to 2 months|Health Literacy, Assessed by the Newest Vital Sign questionnaire; range score 0-6 (high score corresponding to high health literacy), Change from baseline to 2 months|Inflammatory markers- Interleukin-6 (IL-6), Blood samples

collected to access plasma levels of IL-6, Change from baseline to 2 months|Inflammatory markers - High-sensitivity C-reactive protein, Blood samples collected to access plasma levels of high-sensitivity C-reactive protein, Change from baseline to 2 months|Feasibility - Consent rate, number of patients who met inclusion criteria divided by the number who consented in writing to participate. Reasons for not participating in the study will be registered., Through study recruitment, up to 2 years|Testing and Intervention Adverse events, all the events will be recorded and registered as "related" or "unrelated" to the intervention itself, as well as the impact for exercise concerns or other health intervention required, Change from baseline to 2 months|Feasibility - Retention rate, number of participants who remained in the study (without formally drop out during intervention)., Change from baseline to 2 months|Feasibility - Intervention adherence, total number of exercise sessions attended by participants allocated to this intervention group. Reasons for dropping out will be registered., Change from baseline to 2 months|Feasibility - Completion rate, number of patients that completed all the evaluations during the defined timeline., Change from baseline to 2 months|Cost-effectiveness analysis, Incremental cost per quality-adjusted life. Costs will be calculated from the provider perspective, which includes the costs incurred by the health institution providing health services; and from the societal perspective, From baseline assessment up to 2 years
Other Outcome Measures:
Sponsor: Associacao de Investigacao de Cuidados de Suporte em Oncologia
Collaborators: Centro Hospitalar de Vila Nova de Gaia/Espinho, E.P.E.|University Institute of Maia
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 80
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: CORE Trial
Start Date: 2021-09-30
Primary Completion Date: 2022-06-23
Completion Date: 2022-07-05
First Posted: 2021-11-24
Results First Posted:
Last Update Posted: 2022-10-04
Locations: Centro Hospitalar Vila Nova de Gaia Espinho, E.P.E., Vila Nova De Gaia, Porto, 4434-502, Portugal
Study Documents:

NCT Number: NCT05403736
Study Title: Cardiac Aggressive Risk Mitigation in Thoracic

Radiotherapy (CARMA) Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT05403736
Acronym: CARMA
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The purpose of this study is to examine adherence to cardio-oncology consultation.
Study Results: NO
Conditions: Cancer
Interventions: OTHER: Cardiac Aggressive Risk MitigAtion Plan
Primary Outcome Measures: Number of participants who complete the cardio-oncology consultation visit, Adherence is defined as 70% of the participants completing the cardio-oncology consultation visit prior to or during radiotherapy., From baseline to 3 months
Secondary Outcome Measures: Number of participants who wear the FitBit device at least 10 hours per day for 4 out of the 7 days prior to each study visit, Proportion of participants who wear the FitBit device at least 10 hours per day for 4 out of the 7 days prior to each study visit, From baseline to 3 months|Number of participants who obtain blood pressure readings for at least 4 timepoints, Proportion of participants who obtain blood pressure readings for at least 4 timepoints.

-The Omron blood pressure monitor will be used to obtain blood pressure readings., From baseline to 3 months|Number of participants who obtain electrocardiogram (EKG) readings for at least 4 timepoints, Proportion of participants who obtain EKG readings for at least 4 timepoints.

-The AliveCor KardiaMobile EKG monitor will be used to obtain EKG readings, From baseline to 3 months|Rate of cardiovascular therapeutic medication intervention recommendations by the cardio-oncologist, Number of participants provided recommendation to either initiate, or modify the dose of, a cardiovascular risk-reducing medication (anti-lipid, anti-platelet, anti-coagulation, anti-hypertensive). Expressed as the number of participants as a fraction of the total number of participants., From baseline to 3 months|Rate of compliance with cardiovascular therapeutic medication intervention, Compliance will be assessed by self-reporting of medication usage at the 3-month follow-up and defined as yes or no for all recommended cardiovascular therapeutic medication interventions. Expressed as the number of participants as a fraction of the total number of participants., From baseline to 3 months|Evaluate participant intervention perspectives at the end of the study., * Analyze participate attitudes and perspectives on implementation and impact of the cardiovascular intervention plan. Participants will be asked to complete a survey at the 3-month visit.
* Each question is either answered on a scale of 1-4 or strongly agree-strongly disagree, where higher scores indicate the highest level of burden or disagreement, respectively., At 3 months
Other Outcome Measures:

Sponsor: Cedars-Sinai Medical Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IIT2021-07-Atkins-CARMA
Start Date: 2022-10-07
Primary Completion Date: 2023-08-31
Completion Date: 2024-08-31
First Posted: 2022-06-03
Results First Posted:
Last Update Posted: 2023-04-06
Locations: Cancer Clinical Trials Office, Los Angeles, California, 90048, United States
Study Documents:

NCT Number: NCT04047901
Study Title: Effect of Physical Training in Patients With Heart Failure Caused by Chemotherapy for Cancer Treatment
Study URL: https://beta.clinicaltrials.gov/study/NCT04047901
Acronym:
Study Status: UNKNOWN
Brief Summary: New therapies for cancer increased patient survival, but led to the recognition of adverse effects associated with cancer treatment, such as the use of chemotherapy. Cardiotoxicity is the most significant adverse effect, which affect the functional capacity and quality of life and is associated with high morbidity and mortality, regardless of the oncological prognosis. One of the manifestations of cardiotoxicity is ventricular dysfunction that can lead to heart failure. Neuro humoral hyperactivation with increased sympathetic nerve activity is a typical manifestation of heart failure and is associated with worse prognosis. Studies have shown that physical training significantly reduces sympathetic nerve activity in addition to improving muscle blood flow, reversing effects on skeletal muscle and improving quality of life. The hypothesis is that physical training may reduce sympathetic nerve activity and vasoconstrictor status in patients with heart failure caused by anthracyclines, as well as improving baroreflex and chemoreflex sensibility, mechanoreflex and metaborreflex control and skeletal myopathy.
Study Results: NO
Conditions: Insufficiency;Cardiac|Cancer|Cardiotoxicity|Heart Failure
Interventions: OTHER: exercise training
Primary Outcome Measures: Measure muscular sympathetic nervous activity, The sympathetic nervous activity is assessed by the microneurography technique, 16 weeks

Secondary Outcome Measures: Evaluate baroreflex activity, Evaluation of muscular sympathetic nervous activity at rest by the technique of microneurography, evaluation of the muscular blood flow by venous occlusion plethysmography technique, 16 weeks|Evaluate quimiorreflex sensibility, Evaluation of muscular sympathetic nervous activity at rest by the technique of microneurography, evaluation of the muscular blood flow by venous occlusion plethysmography technique, 16 weeks|Evaluate Mecanorreflex control, Evaluation of muscular sympathetic nervous activity at rest by the technique of microneurography, evaluation of the muscular blood flow by venous occlusion plethysmography technique, 16 weeks|Evaluate metaborreflex control, Evaluation of muscular sympathetic nervous activity at rest by the technique of microneurography, evaluation of the muscular blood flow by venous occlusion plethysmography technique, 16 weeks|Evaluation of skeletal myopathy, muscle biopsy, 16 weeks
Other Outcome Measures:
Sponsor: University of Sao Paulo General Hospital
Collaborators: InCor Heart Institute|Cancer Institute of Sao Paulo|Hospital Sirio-Libanes
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: SDC COP 002/15/002
Start Date: 2016-11-07
Primary Completion Date: 2021-02
Completion Date: 2021-02
First Posted: 2019-08-07
Results First Posted:
Last Update Posted: 2019-08-07
Locations: Heart Institute of University of São Paulo, São Paulo, Sao Paulo, 05403-900, Brazil
Study Documents:

NCT Number: NCT00960401
Study Title: A Study of Atherosclerosis in Patients After Radiation Treatment for Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00960401
Acronym: ABCART
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to compare plaque burden in the coronary and carotid arteries 5 years after adjuvant radiotherapy in women with right sided breast cancer vs left sided breast cancer.
Study Results: NO
Conditions: Atherosclerosis

Interventions:
Primary Outcome Measures: to compare plaque burden in the coronary and carotid arteries after radiotherapy for breast cancer, after 5 years of radiotherapy
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Alexander Hindenburg, MD
Collaborators: Winthrop University Hospital
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 20
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 05018
Start Date: 2005-08
Primary Completion Date: 2007-05
Completion Date: 2012-12
First Posted: 2009-08-17
Results First Posted:
Last Update Posted: 2012-08-15
Locations: Winthrop University Hospital, Mineola, New York, 11501, United States
Study Documents:

NCT Number: NCT02984124
Study Title: Communication During Hospitalization About Resuscitation Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT02984124
Acronym: CHART
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This multicenter RCT of 200 hospitalized patients and their family members evaluates an "informed assent" approach to discussing cardiopulmonary resuscitation, compared to usual care, in older seriously ill hospitalized patients with severe life-limiting illness or severe functional impairment.
Study Results: NO
Conditions: Severe Life-limiting COPD|Severe Life-limiting Heart Failure|Severe Life-limiting Cirrhosis|Severe Life-limiting Malignancy|Severe Functional Impairment|End Stage Renal Disease
Interventions: BEHAVIORAL: Informed Assent Discussion|BEHAVIORAL: Usual Care with Attention Control
Primary Outcome Measures: Quality of Communication Questionnaire (QOCQ), slightly modified to focus on communication about cardiopulmonary resuscitation, Patient-Assessed Quality of Communication about CPR, Study day 5 +/- 1 or hospital discharge, whichever is earlier
Secondary Outcome Measures: Quality of Communication Questionnaire (QOCQ), slightly modified to focus on communication about

cardiopulmonary resuscitation, Family-Assessed Quality of Communication about CPR, Study day 5 +/- 1 or hospital discharge, whichever is earlier|5-question communication domain of the CANHELP Questionnaire, slightly modified to focus on communication about cardiopulmonary resuscitation, Patient-Assessed Satisfaction with Communication about CPR, Study day 5 +/- 1 or hospital discharge, whichever is earlier|5-question communication domain of the CANHELP Questionnaire, slightly modified to focus on communication about cardiopulmonary resuscitation, Family-Assessed Satisfaction with Communication about CPR, Study day 5 +/- 1 or hospital discharge, whichever is earlier|Hospital Anxiety and Depression Survey (HADS), Patient Depressive and Anxiety Symptoms, Study day 5 +/- 1 or hospital discharge (whichever is earlier), 3 months, and 6 months|Hospital Anxiety and Depression Survey (HADS), Family Depressive and Anxiety Symptoms, Study day 5 +/- 1 or hospital discharge (whichever is earlier), 3 months, and 6 months|Do-Not-Resuscitate Orders (yes/no), Study day 5 +/- 1 or hospital discharge (whichever is earlier), 3 months, and 6 months|Time to Do-Not-Resuscitate Orders, To 6 months post-randomization|Admission to the intensive care unit (ICU) 9yes/no), Measured at the time hospital discharge, which will likely occur at an average of 6 days after admission, but will be assessed for up to 6 months.|ICU length of stay (days), Measured at the time hospital discharge, which will likely occur at an average of 6 days after admission, but will be assessed for up to 6 months.|Tracheostomy placement (yes/no), Measured at the time hospital discharge, which will likely occur at an average of 6 days after admission, but will be assessed for up to 6 months.|Gastrostomy tube placement (yes/no), Measured at the time hospital discharge, which will likely occur at an average of 6 days after admission, but will be assessed for up to 6 months.|Receipt of mechanical ventilation (yes/no), Measured at the time hospital discharge, which will likely occur at an average of 6 days after admission, but will be assessed for up to 6 months.|Receipt of renal replacement therapy (yes/no), Measured at the time hospital discharge, which will likely occur at an average of 6 days after admission, but will be assessed for up to 6 months.|Receipt of cardiopulmonary resuscitation (yes/no), Measured at the time hospital discharge, which will likely occur at an average of 6 days after admission, but will be assessed for up to 6 months.|Cost of health care after initial hospitalization, Repeat hospital admissions, ICU admissions, nursing home says, hospice care stays, and use of home health care will be assessed, and if they occurred, duration will be recorded. A standardized value (costs, not charges) will be applied to these measures to determine overall cost., 3 months and 6 months post-randomization|Mortality (dead or alive), To 6 months post-randomization
Other Outcome Measures:
Sponsor: University of Vermont
Collaborators: University of Washington|Medical University of South Carolina|University of North Carolina, Chapel Hill
Sex: ALL

Age: OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 182
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: OTHER
Other IDs: CHRMS 16-227
Start Date: 2016-12
Primary Completion Date: 2023-02
Completion Date: 2024-12
First Posted: 2016-12-06
Results First Posted:
Last Update Posted: 2023-05-15
Locations: University of North Carolina, Chapel Hill, North Carolina, 27599, United States|Medical University of South Carolina, Charleston, South Carolina, 29425, United States|University of Vermont, Burlington, Vermont, 05405, United States|University of Washington, Seattle, Washington, 98104, United States
Study Documents:

NCT Number: NCT03692624
Study Title: Use of Heart Rate Variability (HRV) Biofeedback for Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT03692624
Acronym:
Study Status: COMPLETED
Brief Summary: Heart rate variability biofeedback (HRV-B) is a complementary, non-pharmacologic therapy that is being tested to see if it can help cancer survivors reduce their symptoms of pain, stress, insomnia, fatigue, or depression. HRV-B is an interactive procedure in which participants relax and breathe regularly while watching the a computer screen. The computer screen provides feedback that helps people increase their heart rate variability.
Study Results: NO
Conditions: Cancer
Interventions: BEHAVIORAL: Biofeedback
Primary Outcome Measures: Reduced Pain, Participants will attend an HRV-B training session once a week for up to 6 weeks. They will complete a questionnaire which includes a symptom cluster assessment related to pain using the Brief Pain Inventory (BPI)., Weekly for 4 to 6 weeks|Reduced Stress, Participants will attend an HRV-B training session once a week for up to 6 weeks. They will complete a SUSCRO Distress Inventory which includes a symptom cluster inventory related to distress. The inventory includes 12 questions which are self-rated from 0 (not at all) to 4 (most of the time). Lower scores indicate less distress and higher scores indicate severe distress., Weekly for 4 to 6 weeks|Reduced Fatigue, Participants will attend an HRV-B training session once a week for up to 6 weeks. They will complete a questionnaire which includes a symptom cluster inventory related to

fatigue using the Multi-Dimensional Fatigue Inventory (MFI)., Weekly for 4 to 6 weeks|Reduced Depression, Participants will attend an HRV-B training session once a week for up to 6 weeks. They will complete a questionnaire which includes a symptom cluster inventory related to depression using the Beck Depression Inventory II (BDI-II)., Weekly for 4 to 6 weeks|Reduced Insomnia, Participants will attend an HRV-B training session once a week for up to 6 weeks. They will complete the Insomnia Symptom Questionnaire (ISQ) which includes a symptom cluster inventory related to sleep patterns. The inventory includes 13 self-rated questions. Questions 1, 2 or 5 are used to determine the presence, frequency and duration of sleep symptom criteria. Questions 6 through 13 are used to identify significant daytime consequences of sleep disturbance., Weekly for 4 to 6 weeks.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Prisma Health-Upstate
Collaborators: University of South Carolina
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 34
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: Pro00042898
Start Date: 2015-05-10
Primary Completion Date: 2017-04-19
Completion Date: 2020-02-07
First Posted: 2018-10-02
Results First Posted:
Last Update Posted: 2020-03-06
Locations: Greenville Health System Cancer Institute, Greenville, South Carolina, 29605, United States
Study Documents:

NCT Number: NCT04351880
Study Title: Meals MATTER: A Trial of Medically Tailored Meals 2 Weeks vs. 4 Weeks Post Hospital Discharge
Study URL: https://beta.clinicaltrials.gov/study/NCT04351880
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine if medically tailored meals provided for either 2 weeks or 4 weeks (1 meal per day) to a Kaiser Permanente Colorado (KPCO) member after hospital discharge will improve their health. Medically tailored meals (MTM) are meals that are approved by a dietitian and shown to help people with certain health conditions.
Study Results: NO
Conditions: Heart Failure|Copd|Liver Failure|Diabetes Mellitus|Cancer|

End Stage Renal Disease
Interventions: OTHER: Medically Tailored Meals
Primary Outcome Measures: Anxiety and Depression measured through the Hospital Anxiety and Depression Scale, Measured through the Hospital Anxiety and Depression Scale. 0 = Minimum. 21 = Maximum. Higher score is worse outcome., A change in score from baseline to 60 days
Secondary Outcome Measures: Functional Status measured through the Katz Activities of Daily Living Scale, Measured through the Katz Activities of Daily Living. Minimum = 0, Maximum = 6. Higher score is better outcome., A change in score from baseline to 60 days|Re-hospitalization and Emergency Department Visits, Measured through time of discharge through re-hospitalization or Emergency Department visit, 60 days from hospital discharge
Other Outcome Measures:
Sponsor: Kaiser Permanente
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 650
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: OTHER
Other IDs: IRB-1556587
Start Date: 2020-04-16
Primary Completion Date: 2021-09-08
Completion Date: 2021-12-31
First Posted: 2020-04-17
Results First Posted:
Last Update Posted: 2022-02-17
Locations: St Joseph's Hospital, Denver, Colorado, 80218, United States|Good Samaritan Medical Center, Lafayette, Colorado, 80026, United States
Study Documents:

NCT Number: NCT00827801
Study Title: M. D. Anderson Symptom Inventory - Heart Failure (MDASI-HF) Symptom Management Program
Study URL: https://beta.clinicaltrials.gov/study/NCT00827801
Acronym:
Study Status: COMPLETED
Brief Summary: Primary Objective:

To determine if there is a reduction in the mean symptom severity scores for the heart failure specific symptom items between baseline and at the end of three months between patients whose symptoms are managed using the MDASI-HF symptom assessment scores (treatment group) as a decision making guide, as compared to patients managed without using the MDASI-HF symptom assessment scores (control group).

Secondary Objectives:

1. Examine the correlation between mean symptom severity scores and the secondary endpoints of: a) exercise tolerance (6-minute walk), b) NYHA (New York Heart Association) functional classification, c) B-type natriuretic peptide (a biomarker for heart failure), and d) dose titration of HF (heart failure) medications.
2. Define symptom severity critical values in cancer patients with concurrent heart failure that trigger clinical intervention
3. Identify symptom clusters which may occur in cancer patients with concurrent heart failure.
Study Results: NO
Conditions: Heart Failure|Cancer
Interventions: BEHAVIORAL: MDASI-HF Questionnaire
Primary Outcome Measures: Mean Symptom Severity Scores (MDASI-HF Symptom Assessment Scores), Baseline and at end of 3 Months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 26
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2007-0722
Start Date: 2009-01
Primary Completion Date: 2011-08
Completion Date: 2011-08
First Posted: 2009-01-23
Results First Posted:
Last Update Posted: 2012-07-23
Locations: UT MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT03183180
Study Title: Prevalence of Secondary Cardiac Damage in Rheumatic Fever Patients and Penicillin Secondary Prophylaxis
Study URL: https://beta.clinicaltrials.gov/study/NCT03183180
Acronym:
Study Status: UNKNOWN
Brief Summary: According to American Heart Association criteria, patients who have had Rheumatic Fever (RF) should be treated with antibiotic prophylaxis. Continuous prophylaxis is recommended in patients with well-documented histories of RF and in those with evidence of rheumatic heart disease.

There is a limited data regarding adherence of patients to treatment and efficacy of treatment.

In this study, patients with RF who are older than 21 years will be collected from a computerized database of 'Maccabi Healthcare Services', one of the biggest Israeli Health Funds. Patients will be assigned to the study after obtaining informed consent.

Previous adherence to antibiotic prophylaxis will be examined according to computerized database of drugs which were issued to the patient since RF diagnosis.

Past history of cardiac involvement, including past Echocardiograms, will be collected from computerized database. In addition, the current cardiac state will be assessed by an experienced cardiologist, including a full new Echocardiogram examination.
Study Results: NO
Conditions: Secondary Cardiac Damage in Rheumatic Fever
Interventions: DIAGNOSTIC_TEST: Echocardiogram
Primary Outcome Measures: Cardiac function including vulvar involvement, Cardiac morphology and function measured by echocardiography, 60 days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Assuta Hospital Systems
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 0137-16-ASMC
Start Date: 2017-06
Primary Completion Date: 2017-12
Completion Date: 2019-05
First Posted: 2017-06-09
Results First Posted:
Last Update Posted: 2017-06-09
Locations:
Study Documents:

NCT Number: NCT02920580
Study Title: The NEUROlogically-impaired Extubation Timing Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT02920580
Acronym: NEURO-ETT
Study Status: UNKNOWN
Brief Summary: This randomized controlled trial will enrol patients

with acute severe brain injury who pass a spontaneous breathing trial but have decreased level of consciousness. It will directly compare (1) prompt extubation vs. (2) usual care, with extubation or tracheostomy timed according to physicians' discretion. The primary outcome will be ICU free days (days spent alive and outside an ICU).
Study Results: NO
Conditions: Acute Brain Injury
Interventions: PROCEDURE: Extubation|PROCEDURE: Usual Care
Primary Outcome Measures: ICU Free Days, The primary outcome is number of ICU free days to day 60, defined as the number of days spent alive and outside of an ICU until day 60.

The primary outcome will be measured to answer the following primary question: Among patients receiving minimal mechanical ventilatory support for severe and persistent brain injury, which of the following airway management strategies increase ICU-free days to day 60: (1) prompt extubation vs. (2) usual care, which may include extubation or tracheostomy timed according to physicians' discretion?, 60 days
Secondary Outcome Measures: Mortality,, Mortality at ICU discharge, mortality at hospital discharge, mortality at 3 months, mortality at 6 months, up to 6 months|Ventilator-Free Days, Days free of mechanical ventilation, total duration (days) of ventilation among survivors, up to 60 days|Airway Complications, Presence versus absence of airway complication, up to 60 days|Nutrition Intake, Time to normal oral nutrition intake, up to 6 months|Antibiotic Days, Injection or infusion of antibiotics given intravenously, up to day 14|Delirium, Presence versus absence of delirium experienced, up to day 14|Rate of Tracheostomy Insertion, Presence versus absence of tracheostomy insertion, up to 6 months|Rate of ICU Readmission, ICU readmission rates to hospital discharge, up to hospital discharge|Hospital Discharge Destination, Destination of the patient post hospitalization - home, rehabilitation facility, retirement home, long-term care/ nursing home, no fixed address or shelter, continuing complex care, acute care hospital, other, at hospital discharge|Extended Glasgow Outcome Score, Functional outcome (scoring 1 to 8), up to 6 months|EQ-5D, Health related quality of life (scoring 1 to 5), up to 6 months
Other Outcome Measures:
Sponsor: Sunnybrook Health Sciences Centre
Collaborators: Canadian Institutes of Health Research (CIHR)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 27
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: NEURO-ETT (Vanguard)
Start Date: 2017-02-01

Primary Completion Date: 2019-06-19
Completion Date: 2022-01-31
First Posted: 2016-09-30
Results First Posted:
Last Update Posted: 2020-02-05
Locations: University of Alberta Hospital, Edmonton, Alberta, T6G 2B7, Canada|Royal Columbian Hospital, New Westminster, British Columbia, V3L 3W7, Canada|Vancouver General Hospital, Vancouver, British Columbia, V5Z 1M9, Canada|Hamilton General Hospital, Hamilton, Ontario, L8N 3Z5, Canada|Kingston General Hospital, Kingston, Ontario, K7L 2V7, Canada|London Health Sciences Centre, London, Ontario, N6A 5A5, Canada|Ottawa Hospital, Ottawa, Ontario, K1H 8L6, Canada|Sunnybrook Health Sciences Centre, Toronto, Ontario, M4N 3M5, Canada|St. Michael's Hospital, Toronto, Ontario, M5B 1W8, Canada|Toronto Western Hospital, Toronto, Ontario, M5G 2N2, Canada|Centre hospitalier de l'Université de Montréal, Montreal, Quebec, H2X 2H8, Canada|Hôpital du Sacré-Cœur de Montréal, Montreal, Quebec, H4J 1C5, Canada|L'Hôpital de l'Enfant-Jésus, Quebec City, Quebec, G1J 1Z4, Canada
Study Documents:

NCT Number: NCT04073524
Study Title: The Wild Man Programme - a Nature-based Rehabilitation Enhancing Quality of Life for Men on Long-term Sick Leave
Study URL: https://beta.clinicaltrials.gov/study/NCT04073524
Acronym:
Study Status: UNKNOWN
Brief Summary: The aim of the present study is to examine whether the nature based 'Wild man Programme' can help to increase quality of life among men on sick leave compared to treatment as usual. Additionally, the study examines which natural environments best work as supportive environments in the rehabilitation.
Study Results: NO
Conditions: Stress|Anxiety|Depression|Cardiac Disease|Cancer|Diabetes|Copd
Interventions: OTHER: Nature-Body-Mind-Community|OTHER: Treatment as usual
Primary Outcome Measures: Level of quality of life - total score, The primary outcome is self-experienced quality of life. The World Health Organization's brief quality of life questionnaire (WHOQOL-BREF) will be used. The questionnaire examines four domains on a five-point Likert scale: Physical health, mental health, social relationships and health-related environments e.g. instant access to medical care. The global quality of life is based on the participants' scores on the four domains and they range from 0-100, with a high score indicating high quality of life., 9 weeks
Secondary Outcome Measures: Level of quality of life - physical health, The WHOQOL-BREF will be used. The domain of physical health is measured on a five-point Likert scale with five questions., 9 weeks|Level of quality of life - mental health, The WHOQOL-BREF will be used. The domain of mental health is measured on a five-point Likert

scale with five questions., 9 weeks|Level of quality of life - social relationships, The WHOQOL-BREF will be used. The domain of social relationships is measured on a five-point Likert scale with five questions., 9 weeks|Level of quality of life - health related environments, The WHOQOL-BREF will be used. The domain of health related environments is measured on a five-point Likert scale with five questions., 9 weeks|Level of self-experienced restitution, Self-experienced restitution. The Perceived Restorativeness Scale-11 (PRS-11) will be used., 9 weeks|Level of self perceived stress, Self perceived stress. The Cohen's Perceived Stress Scale (PSS) will be used. The scale consists of 14 items measured on a five-point Likert scale., 9 weeks
Other Outcome Measures:
Sponsor: University of Southern Denmark
Collaborators: TrygFonden, Denmark
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 76
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SEQUENTIAL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: USouthernDenmarkpsychology
Start Date: 2018-06-01
Primary Completion Date: 2021-06-01
Completion Date: 2021-06-01
First Posted: 2019-08-29
Results First Posted:
Last Update Posted: 2020-11-04
Locations: Southern Danish University, Odense, Fyn, 5230, Denmark
Study Documents:

NCT Number: NCT03234101
Study Title: Meta-Analyses of Low-risk Lifestyle Behaviours and Patient Important Outcomes
Study URL: https://beta.clinicaltrials.gov/study/NCT03234101
Acronym:
Study Status: UNKNOWN
Brief Summary: Public health policy is universal in recommending the adoption of low risk low-risk lifestyle behaviors for health promotion and prevention of chronic or non-communicable diseases (NCDs).These behaviors generally include achieving and maintaining a healthy body weight, healthy diet, regular physical activity, smoking cessation, moderate alcohol intake, and adequate sleep. While there is a general consensus that adherence to any one of these low-risk lifestyle behaviors is associated with benefit, it is not clear if adherence to multiple behaviors would result in a larger benefit across different groups of people, conditions, and chronic disease outcomes. The Canadian Cardiovascular Society (CCS), as part of the Dyslipidemia

Guidelines Update, commissioned a series of systematic reviews and meta-analyses (a type of knowledge synthesis) using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to quantify the benefit of adherence to multiple low-risk lifestyle behaviors in relation to patient-important chronic disease outcomes (risk of cardiovascular disease, diabetes, cancer, and death) and assesses the quality and strength of the evidence for this benefit.
Study Results: NO
Conditions: Cardiovascular Disease|Diabetes|Cancer|Mortality
Interventions: BEHAVIORAL: Low-risk lifestyle behaviours
Primary Outcome Measures: Cardiovascular disease, Cardiovascular disease incidence and mortality, coronary heart disease incidence and mortality, stroke incidence and mortality, Up to 20 years|Diabetes, Diabetes incidence, Up to 20 years|Cancer, Cancer incidence and mortality, Up to 20 years|All-cause mortality, Up to 20 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Toronto
Collaborators: Canadian Institutes of Health Research (CIHR)|The Physicians' Services Incorporated Foundation|Canadian Diabetes Association|Canadian Cardiovascular Society|Banting & Best Diabetes Centre
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 1
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CCS-Low risk lifestyle-2017
Start Date: 2016-06
Primary Completion Date: 2017-12
Completion Date: 2017-12
First Posted: 2017-07-31
Results First Posted:
Last Update Posted: 2017-08-03
Locations: The Toronto 3D (Diet, Digestive tract and Disease) Knowledge Synthesis and Clinical Trials Unit, Clinical Nutrition and Risk Factor Modification Centre, St. Michael's Hospital, Toronto, Ontario, M5C 2T2, Canada
Study Documents:

NCT Number: NCT04407780
Study Title: Cardio-Oncology Registry
Study URL: https://beta.clinicaltrials.gov/study/NCT04407780
Acronym: CONFUCIUS
Study Status: RECRUITING
Brief Summary: Cardio-oncology is an emerging field. Most of the data available have been issued from either retrospective analysis,

industry data or pharmacovigilance data. These data sources include a number of bias.

CONFUCIUS is a single tertiary centre prospective registry including all patients who have been referred for cardio-oncology assessemnt.

The objectives are to provide a comprehensive vue of cardoi-oncology, enable to detect early signals of cardiotoxicity and enhance ancillary projetcts aiming at specific populations (e.g., type of cancer) and/or drugs.
Study Results: NO
Conditions: Cancer|Cardiac Disease|Metabolic Syndrome|Arrhythmia|Heart Diseases
Interventions: OTHER: No interventions are planned
Primary Outcome Measures: Incidence of cardio-toxicty, Number of patients with cardiotoxicity in a cohort of patients referred to a cardio-oncology clinic, 5 years
Secondary Outcome Measures: Analysis of cardiotoxicity, Correlation of cardio-toxicity overall, and in predefined subgroups; statistical associatoin with outcomes., 5 years|Analysis of cardioprotective strategies, Correlation between the use of cardiovascular drugs and the number of patients with cardiotoxicity., 5 years|Analysis of underlying cardiovacsular profile, Correlation between underlying cardioascular profile and the number of patients with cardiotoxicity., 5 years|Analysis of arrhythmias, Correlation between incident arrhythmias and cancer drugs, 5 years|Precision medicine, Correlation between biomarkers with use of artificial intelligence and the number of patients with cardiotoxicity., 5 years|Oncology, Adherence to oncology treatment plan as stated in the multidisciplinary team meeting in patients with cardio-oncology assessment compared to matched patients with no cardio-oncology assessment within our institution; outcomes., 5 years|Cardiovascular outcomes, Assess cardiovascular outcomes (cardiovascular death, admission for heart failure, acute coronary syndrome, stroke)., 10 years|Any advserse event, Correlation between any adverse event, oncology treatment, and outcomes., 5 years|Behaviour, Correlation of any behaviour treatment (exercice, rehabilitation, nutrition consultation) and the number of patents with cardiotoxocity., 5 years|Metabolic, Correlation between oncology treatments, cardiovascular therapies, behaviour therapies and the number of patients with metabolic disorders (diabetes or dyslipidemia)., 5 years
Other Outcome Measures:
Sponsor: European Georges Pompidou Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 5000
Funder Type: OTHER
Study Type: OBSERVATIONAL

Study Design: Observational Model: |Time Perspective: p
Other IDs: 00011928
Start Date: 2017-01-01
Primary Completion Date: 2022-06-01
Completion Date: 2027-06-01
First Posted: 2020-05-29
Results First Posted:
Last Update Posted: 2020-05-29
Locations: Assistance Publique Hôpitaux de Paris - Centre Université de Paris, Paris, 75015, France
Study Documents:

NCT Number: NCT00002624
Study Title: Video-Assisted Surgery Followed by Radiation Therapy in Treating Patients With Stage I Non-small Cell Lung Cancer and Poor Heart and Lung Function
Study URL: https://beta.clinicaltrials.gov/study/NCT00002624
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Video-assisted surgery followed by radiation therapy may be an effective treatment in patients whose poor heart and lung function make them high risk for standard surgery.

PURPOSE: Phase II trial to study the effectiveness of video-assisted surgery followed by radiation therapy in treating patients with stage I non-small cell lung cancer and poor heart and lung function.
Study Results: NO
Conditions: Lung Cancer
Interventions: PROCEDURE: adjuvant therapy|PROCEDURE: diagnostic thoracoscopy|PROCEDURE: therapeutic thoracoscopy|PROCEDURE: video-assisted surgery|RADIATION: radiation therapy
Primary Outcome Measures: Determine the feasibility of video-assisted thoracoscopic wedge resection (VAR), Up to 10 years|Determine the incidence of locoregional recurrence in patients treated with this regimen, Up to 10 years|Determine the overall and disease-free survival, Up to 10 years|Determine the short- and long-term complications associated with VAR in these patients, Up to 10 years|Determine the technical feasibility of ipsilateral lymph node sampling and complete resection with VAR in these patients, Up to 10 years|Determine the toxicity of adjuvant radiotherapy after VAR in these patients, Up to 10 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Alliance for Clinical Trials in Oncology
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 66
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CALGB-9335|U10CA031946|CDR0000063987
Start Date: 1994-12
Primary Completion Date: 2005-04
Completion Date: 2005-08
First Posted: 2003-01-27
Results First Posted:
Last Update Posted: 2016-07-14
Locations: CCOP - Colorado Cancer Research Program, Incorporated, Denver, Colorado, 80224, United States|John Stoddard Cancer Center at Iowa Methodist Medical Center, Des Moines, Iowa, 50309, United States|Mercy Cancer Center at Mercy Medical Center-Des Moines, Des Moines, Iowa, 50314, United States|Iowa Lutheran Hospital, Des Moines, Iowa, 50316-2301, United States|Beth Israel Deaconess Medical Center, Boston, Massachusetts, 02215, United States|CCOP - Metro-Minnesota, Saint Louis Park, Minnesota, 55416, United States|Midlands Cancer Center at Midlands Community Hospital, Papillion, Nebraska, 68128-4157, United States|MBCCOP - University of New Mexico HSC, Albuquerque, New Mexico, 87131, United States|Penn State Cancer Institute at Milton S. Hershey Medical Center, Hershey, Pennsylvania, 17033-0850, United States|Drexel University Hospital, Philadelphia, Pennsylvania, 19102-1192, United States|Hillman Cancer Center at University of Pittsburgh Cancer Institute, Pittsburgh, Pennsylvania, 15236, United States|CCOP - MainLine Health, Wynnewood, Pennsylvania, 19096, United States|CCOP - St. Vincent Hospital Cancer Center, Green Bay, Green Bay, Wisconsin, 54307-3453, United States|Westmead Hospital, Westmead, New South Wales, 2145, Australia|Instituto de Enfermedades Neoplasicas, Lima, 34, Peru|San Juan City Hospital, San Juan, 00936-7344, Puerto Rico
Study Documents:

NCT Number: NCT03923036
Study Title: Anticancer Vigilance Of Cardiac Events (AVOCETTE) in Metastatic Colorectal Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03923036
Acronym: AVOCETTE
Study Status: UNKNOWN
Brief Summary: This study is a retrospective observational study that evaluates the rate of cardiovascular adverse events leading to hospitalization in metastatic colorectal cancer in the French county Calvados by drug exposure.
Study Results: NO
Conditions: Colorectal Cancer Metastatic
Interventions: DRUG: Antineoplastic Agents
Primary Outcome Measures: Difference in rates of cardiovascular adverse events leading to hospitalization between chemotherapy treated patients and chemotherapy-free patients., Any cardiovascular adverse event (e.g. the non limitative list: ischaemic heart disease, heart

failure, hypertension, ischaemic stroke, embolic or thrombotic events, arrhythmias, conductive disorders) that was the primary diagnosis of a hospital admission.

Any anticancer drug (chemotherapy) intake will be considered for the primary analysis.

We will use a competing risk statistical model., Between 2004 and 2017
Secondary Outcome Measures: Risk of cardiovascular adverse events (any) for each individual anticancer drug., Drug exposure will be defined as a binary variable for each drug. (intakes/no intakes). A competing risk model will be used., Between 2004 and 2017|Risk of cardiovascular adverse events (any) for each anticancer drugs combination/protocol, Drugs combination will be defined as a binary variable for each protocol. (intakes/no intakes)., Between 2004 and 2017|Risk of individual cardiovascular adverse events of chemotherapy treated patients versus chemotherapy-free patients, Several individual cardiovascular adverse events will be assessed in separate analyses: ischaemic heart disease, heart failure, hypertension, ischaemic stroke, embolic or thrombotic events, arrhythmias, conductive disorders). A competing risk model will be used, Between 2004 and 2017|Dose-effect relation ship between individual anticancer drugs and cardiovascular adverse events, Dose will be approached by the number of cycles of the anticancer drug and by the cumulative dose (in milligram) received., Between 2004 and 2017|Dose-effect relation ship between individual anticancer drugs combination/protocol and cardiovascular adverse events, Dose will be approached by the number of cycles of the anticancer drugs combination/protocol., Between 2004 and 2017
Other Outcome Measures:
Sponsor: University Hospital, Caen
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 2000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: TPS 68479
Start Date: 2019-04
Primary Completion Date: 2019-06
Completion Date: 2019-06
First Posted: 2019-04-22
Results First Posted:
Last Update Posted: 2019-04-22
Locations: CHU Caen, Caen, Normandy, 14000, France
Study Documents:

NCT Number: NCT04562636

Study Title: Evaluating a Messaging Campaign in the United States
Study URL: https://beta.clinicaltrials.gov/study/NCT04562636
Acronym:
Study Status: COMPLETED
Brief Summary: Purpose: To evaluate reactions to and opinions of a messaging campaign.

Participants: Participants will be recruited through Prime Panels and will be US-based adults (18 years old and older) who consumed red meat in the past 30 days.

Procedures (methods): After completing a screening question about meat consumption, participants will review a consent form. If they select to participate in the study, participants will be randomly assigned to view control messages, red meat-related environment messages, or red meat-related health messages. They will be asked a series of questions about these messages.

Participants will also be asked about grocery shopping preferences and standard demographics questions.
Study Results: NO
Conditions: Obesity|Heart Diseases|Cancer
Interventions: OTHER: Environmental message|OTHER: Health message|OTHER: Neutral Message
Primary Outcome Measures: Perceived Message Effectiveness (PME), Perceived effectiveness of the messages will be measured during the message using 4 items adapted from Baig et al. (2018): concern, unpleasantness, and discouragement. The averaged responses on the 4 items will be used to create a PME score. All 4 items are measured using a a 1 to 5 likert scale, with higher scores representing a higher amount of the construct.

Questions: How much do these messages...

* make you concerned about the health effects of eating red meat?
* make you concerned about the environmental effects of eating red meat?
* discourage you from wanting to eat red meat?
* make eating red meat seem unpleasant to you?

1. Not at all, 2=Very little, 3=Somewhat, 4=Quite a bit, 5=A great deal)., ~10 minute computer survey immediately after seeing messages
Secondary Outcome Measures: Attention, How much the message grabs one's attention. Measured using a a 1 to 5 likert scale, with higher scores representing a higher amount of the construct., ~10 minute computer survey immediately after seeing messages|Negative affect, How much the messages make one feel scared. Measured using a a 1 to 5 likert scale, with higher scores representing a higher amount of the construct., ~10 minute computer survey immediately after seeing messages|Cognitive elaboration, How much the messages make one think

about the environmental/health harms caused by eating meat. Measured using a a 1 to 5 likert scale, with higher scores representing a higher amount of the construct., ~10 minute computer survey immediately after seeing messages|Social interactions, How much one is likely to talk about the message with others in the next week. Measured using a 1 to 5 likert scale, with higher scores representing a higher amount of the construct., ~10 minute computer survey immediately after seeing messages|Intention to reduce meat consumption, How much one intends to reduce red meat consumption in the next 30 days. Measured using a a 1 to 5 likert scale, with higher scores representing a higher amount of the construct., ~10 minute computer survey immediately after seeing messages
Other Outcome Measures:
Sponsor: University of North Carolina, Chapel Hill
Collaborators: Wellcome Trust
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1244
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 20-2552|14380
Start Date: 2020-09-29
Primary Completion Date: 2020-10-01
Completion Date: 2020-10-01
First Posted: 2020-09-24
Results First Posted:
Last Update Posted: 2020-10-05
Locations: Carolina Population Center, Chapel Hill, North Carolina, 27599, United States
Study Documents: Statistical Analysis Plan

NCT Number: NCT05718128
Study Title: Clinical Study of Endocardial Myocardial Biopsy
Study URL: https://beta.clinicaltrials.gov/study/NCT05718128
Acronym:
Study Status: RECRUITING
Brief Summary: In this study, patients with endocardial myocardial biopsy were selected to observe the safety of the operation, and pathological examination was performed. If necessary, special tests such as viral examination, mass spectrometry and molecular biology were performed to confirm the diagnosis, and follow-up was performed.
Study Results: NO
Conditions: Myocarditis|Cardiomyopathies|Heart Failure|Cardiac Tumor|Endocardiomyocardial Biopsy
Interventions: PROCEDURE: Endocardiomyocardial biopsy
Primary Outcome Measures: Incidence of MACE-4, incidences of MACE-4(cardiovascular death, myocardial infarction, stroke and

hospitalized unstable angina), 10 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Second Affiliated Hospital, School of Medicine, Zhejiang University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 2021-0131
Start Date: 2021-06-01
Primary Completion Date: 2031-06-01
Completion Date: 2031-06-01
First Posted: 2023-02-08
Results First Posted:
Last Update Posted: 2023-03-28
Locations: 2nd Affiliated Hospital, School of Medicine, Zhejiang University, China, Hangzhou, Zhejiang, China
Study Documents:

NCT Number: NCT04674501
Study Title: Radiotherapy for Thoracic and Breast Cancer and the Related Cardiotoxicity Following Treatment (RACCOON)
Study URL: https://beta.clinicaltrials.gov/study/NCT04674501
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to investigate the risk factors and mechanisms of cardiotoxicity following thoracic radiotherapy and to provide insights in preventing radiation-related cardiotoxicity.

-Condition or disease : Thoracic irradiation -Intervention/treatment : Cardiac evaluation, Blood sampling
Study Results: NO
Conditions: Patients Who Receive Thoracic Irradiation
Interventions: PROCEDURE: Cardiac evaluation and blood sampling
Primary Outcome Measures: Cardiotoxicity rate, 2 years
Secondary Outcome Measures: Overall survival, 2 years|Cancer-specific survival, 2 years|Progression-free survival, 2 years|Other toxicity rates, 2 years
Other Outcome Measures:
Sponsor: Yonsei University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases:
Enrollment: 200
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 4-2020-1093
Start Date: 2020-12-22
Primary Completion Date: 2022-12
Completion Date: 2022-12
First Posted: 2020-12-19
Results First Posted:
Last Update Posted: 2020-12-24
Locations: Yonsei Cancer Center, Yonsei University College of Medicine, Yonsei University Health System, Seoul, Korea, Republic of
Study Documents:

NCT Number: NCT05068180
Study Title: Low-dose Neuroleptanalgesia for Postoperative Delirium in Elderly Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05068180
Acronym:
Study Status: RECRUITING
Brief Summary: Postoperative delirium (POD) is a common complication that can directly affect important clinical outcomes, and exert an enormous burden on patients, their families, hospitals, and public resources. In order to evaluate whether an intraoperative administration of low-dose neuroleptanalgesia reduces postoperative delirium, droperidol 1.25 mg and fentanyl 0.025 mg or normal saline is used by intravenous injection 30 minutes before the end of the operation, in elderly patients with non-cardiac major surgery under general anesthesia. The efficiency and safety of neuroleptanalgesia on the incidence of POD would be evaluated in elderly patients.
Study Results: NO
Conditions: Stomach Neoplasms|Colonic Neoplasms|Rectal Neoplasms|Sigmoid Neoplasms|Liver Neoplasms|Kidney Neoplasms|Urinary Bladder Neoplasms|Prostatic Neoplasms|Osteoarthropathy|Fractures, Bone|Gynecologic Cancer
Interventions: DRUG: low-dose neuroleptanalgesia|DRUG: Placebo
Primary Outcome Measures: Incidences of POD after general anesthesia in elderly patients undergoing non-cardiac major surgery, Up to 7 days after surgery (or leaving hospital)
Secondary Outcome Measures: Length of hospital stay, Participants will be followed for the duration of hospital stay, an expected average of 7 days|Incidence of postoperative nausea and vomiting, Up to 7 days after surgery (or leaving hospital) |Patients' satisfaction, This outcome will be measured using a numeric rating scale from 1 (dissatisfaction) to 3 (very satisfied), Up to 7 days after surgery (or leaving hospital) |Incidence of postoperative hypoxia, Up to 1 day after surgery|Incidence of major serious complications and serious

arrhythmia, Up to 7 days after surgery (or leaving hospital) |Duration of postoperative delirium, Up to 7 days after surgery (or leaving hospital)
Other Outcome Measures:
Sponsor: RenJi Hospital
Collaborators: Shanghai 8th People's Hospital
Sex: ALL
Age: OLDER_ADULT
Phases: PHASE4
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: KY2020-125
Start Date: 2021-10-05
Primary Completion Date: 2022-04-10
Completion Date: 2022-04-10
First Posted: 2021-10-05
Results First Posted:
Last Update Posted: 2021-10-06
Locations: Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, Shanghai, 200127, China|Shanghai Eighth People's Hospital, Shanghai, Shanghai, China
Study Documents:

NCT Number: NCT01446224
Study Title: Cardiovascular and Torsades de Pointes Monitoring for Pazopanib
Study URL: https://beta.clinicaltrials.gov/study/NCT01446224
Acronym:
Study Status: COMPLETED
Brief Summary: This observational study is conducted as part of a systematic pharmacovigilance activity, to provide a population-based context for Pazopanib use outside of the clinical trial setting. The aims of the study are to examine the incidence of cardiovascular ischemia (including myocardial infarction, unstable angina, transient ischemic attack, and cerebrovascular accident) and cardiac arrhythmia (Torsades de Pointes) in renal cell carcinoma patients treated with marketed anti-VEGF agents \[Pazopanib (VOTRIENT), Bevacizumab (AVASTIN), Sorafenib (NEXAVAR), and Sunitinib (SUTENT)\].

Two databases will be utilized for this study: a large healthcare claims database in the U.S. and the Dutch linked medical registries (PHARMO RLS). The databases will provide large, geographically varied, non-trial populations in which to examine the incidence of the stated cardiovascular ischemic events and Torsades des Pointes.
Study Results: NO
Conditions: Carcinoma, Renal Cell

Interventions: DRUG: Pazopanib|DRUG: Other anti-VEGFs
Primary Outcome Measures: Cardiovascular ischemia, Cardiovascular ischemia including myocardial infarction, unstable angina, transient ischemic attack, and cerebrovascular accident, Over four years from approval of pazopanib
Secondary Outcome Measures: Torsades de Pointes, Torsades de Pointes, Over four years from approval of pazopanib
Other Outcome Measures:
Sponsor: GlaxoSmithKline
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 114428|WEUKSTV4602
Start Date: 2010-12
Primary Completion Date: 2013-12
Completion Date: 2013-12
First Posted: 2011-10-05
Results First Posted:
Last Update Posted: 2015-03-27
Locations:
Study Documents:

NCT Number: NCT05718401
Study Title: The Diagnostic Pattern and Prognosis of Multiple Myeloma Patients With Myocardial Amyloidosis Were Evaluated by NMR Based Metabolomics
Study URL: https://beta.clinicaltrials.gov/study/NCT05718401
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: In this clinical study, a single-center retrospective cohort study was used to explore the clinical characteristics and risk factors of patients with multiple myeloma myocardial amyloidosis. An exploratory study was conducted to compare the effects of various sublayer factors (M protein, electrocardiogram, echocardiography, CD138, chromosome abnormalities, etc.) on patients' survival. On this basis, a hierarchical diagnostic model (1-2-3-4) for patients with multiple myeloma complicated with myocardial amyloidosis was established based on the phenoomics of NMR and mass spectrometry, and the prognosis was evaluated simultaneously, in order to create an early, non-invasive, sensitive and quantitative diagnostic model for multiple myeloma complicated with myocardial amyloidosis, and lay a foundation for the early application of effective treatment.
Study Results: NO
Conditions: Multiple Myeloma|Amyloidosis Cardiac
Interventions: DEVICE: NMR

Primary Outcome Measures: The long axial strain of echocardiography, The long axial strain of echocardiography was in the normal range （18%-22%）, From date of randomization until the date of first documented progression or date of death from any cause, whichever came first, assessed up to 36 mouths
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: First Affiliated Hospital Xi'an Jiaotong University
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 500
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: XJTU1AF-CRF-2022-033
Start Date: 2022-11-01
Primary Completion Date: 2024-12-31
Completion Date: 2024-12-31
First Posted: 2023-02-08
Results First Posted:
Last Update Posted: 2023-02-08
Locations: First Affiliated Hospital of Xian Jiaotong University, Xi'an, Shanxi, 710061, China
Study Documents:

NCT Number: NCT02274480
Study Title: Diffusion Weighted Imaging as a Biomarker for Detection of Chemotherapy Induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT02274480
Acronym:
Study Status: COMPLETED
Brief Summary: The goal of this study is to see if a special type of heart scan called a diffusion weighted magnetic resonance imaging (DW-MRI) that uses extra measurements, can be used to find early signs of heart damage from chemotherapy.
Study Results: NO
Conditions: Chemotherapy Induced Cardiotoxicity in Breast Cancer Patients
Interventions: DEVICE: cardiac MRI with DWI
Primary Outcome Measures: presence of edema, associated with cardiotoxicity as visualized on DWI by the attending cardiac imagers we may explore the association of the presence of edema on DWI with a drop in LVEF \> 10% using exact logistic regression, 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators:
Sex: ALL

Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 28
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 14-191
Start Date: 2014-10-22
Primary Completion Date: 2020-09-02
Completion Date: 2020-09-02
First Posted: 2014-10-24
Results First Posted:
Last Update Posted: 2020-09-04
Locations: Memorial Sloan Kettering Westchester, Harrison, New York, 10604, United States|Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States
Study Documents:

NCT Number: NCT05209880
Study Title: Advance Care Planning in the Emergency Department
Study URL: https://beta.clinicaltrials.gov/study/NCT05209880
Acronym:
Study Status: RECRUITING
Brief Summary: This is a two-armed, parallel-design, pre-/post-intervention assessment study. The investigators will conduct a randomized controlled trial for ED GOAL on a cohort of 120 older adults with serious illness to collect patient-centered outcomes and determine preliminary efficacy on increasing advance care planning engagement (self-reported and/or in the electronic medical record) one month after leaving the emergency department. The investigators will also conduct qualitative interviews with participants of ED GOAL.
Study Results: NO
Conditions: Congestive Heart Failure|Metastatic Cancer|Chronic Kidney Disease Requiring Chronic Dialysis|Chronic Obstructive Pulmonary Disease
Interventions: BEHAVIORAL: ED GOAL
Primary Outcome Measures: Change in advance care planning (ACP) engagement with clinicians at one month, ACP engagement is a one-item question from the validated ACP engagement survey that measures participants' self-reported readiness to discuss their values and preferences with their doctors. The instrument is a 5-point Likert scale ranging from "I have never thought about it (1)" to "I have already done it (5)." A higher score indicates a better outcome.

Sudore RL, Heyland DK, Barnes DE, Howard M, Fassbender K, Robinson CA, Boscardin J, You JJ. Measuring Advance Care Planning: Optimizing the Advance Care Planning Engagement Survey. J Pain Symptom Manage. 2017 Apr;53(4):669-681.e8. doi: 10.1016/j.jpainsymman.2016.10.367. Epub 2016 Dec 29. PMID: 28042072; PMCID: PMC5730058., Change from baseline ACP engagement at one month

Secondary Outcome Measures: Feeling heard and understood survey, A validated instrument for seriously ill patients to report how well they feel heard and understood about their wishes for end-of-life care. This instrument is a 5-point Likert scale: "not at all (1)," "slightly (2)," "moderately (3)," "quite a bit (4)," and "completely (5)." A higher score indicates a better outcome.

Gramling R, Stanek S, Ladwig S, Gajary-Coots E, Cimino J, Anderson W, Norton SA; AAHPM Research Committee Writing Group, Aslakson RA, Ast K, Elk R, Garner KK, Gramling R, Grudzen C, Kamal AH, Lamba S, LeBlanc TW, Rhodes RL, Roeland E, Schulman-Green D, Unroe KT. Feeling Heard and Understood: A Patient-Reported Quality Measure for the Inpatient Palliative Care Setting. J Pain Symptom Manage. 2016 Feb;51(2):150-4. doi: 10.1016/j.jpainsymman.2015.10.018. Epub 2015 Nov 17. PMID: 26596879., Baseline & 1, 3, and 6 months|Quality of communication survey, A validated instrument to measure the quality of communication about end-of-life care. This instrument is a 10-point Likert scale ranging from "the very worse I could imagine (0)" to "the very best I could imagine (10)". A higher score indicates a better outcome.

Engelberg RA, Downey L, Curtis JR. Psychometric characteristics of a quality of communication questionnaire assessing communication about end-of-life care. J Palliat Med. 2006 Oct;9(5):1086-98., Baseline & at 1, 3, and 6 months|Healthcare utilization, Electronic medical records will be reviewed to find the number of urgent care visits, ED visits, hospitalizations, hospice visits, and outpatient visits., At 6 and 12 months before and 1, 6, 12 months after enrollment|Mortality, The electronic medical records will be reviewed to find the patients' vital status., At 1, 3, and 6 months|Qualitative benefits and obstacles of advance care planning (ACP) conversations after ED GOAL, Semi-structured interviews to assess the benefits of ED GOAL and obstacles participants faced in completing more ACP conversations with their outpatient clinicians and loved ones after ED GOAL., At 1, 3, and/or 6 months|Electronic medical record documentation of advance care planning (ACP) conversations, The electronic medical record will be reviewed to find clinician documentation of ACP conversations., At 1, 3, and 6 months|Change in advance care planning (ACP) engagement with clinicians at three months, ACP engagement is a one-item question from the validated ACP engagement survey that measures participants' self-reported readiness to discuss their values and preferences with their doctors. The instrument is a 5-point Likert scale ranging from "I have never thought about it (1)" to "I have already done it (5)." A higher score indicates a better outcome.

Sudore RL, Heyland DK, Barnes DE, Howard M, Fassbender K, Robinson CA, Boscardin J, You JJ. Measuring Advance Care Planning: Optimizing the Advance Care Planning Engagement Survey. J Pain Symptom Manage. 2017 Apr;53(4):669-681.e8. doi: 10.1016/j.jpainsymman.2016.10.367. Epub 2016 Dec 29. PMID: 28042072; PMCID: PMC5730058., Change from baseline ACP engagement at three months|Change in advance care planning (ACP)

engagement with clinicians at six months, ACP engagement is a one-item question from the validated ACP engagement survey that measures participants' self-reported readiness to discuss their values and preferences with their doctors. The instrument is a 5-point Likert scale ranging from "I have never thought about it (1)" to "I have already done it (5)." A higher score indicates a better outcome.

Sudore RL, Heyland DK, Barnes DE, Howard M, Fassbender K, Robinson CA, Boscardin J, You JJ. Measuring Advance Care Planning: Optimizing the Advance Care Planning Engagement Survey. J Pain Symptom Manage. 2017 Apr;53(4):669-681.e8. doi: 10.1016/j.jpainsymman.2016.10.367. Epub 2016 Dec 29. PMID: 28042072; PMCID: PMC5730058., Change from baseline ACP engagement at six months|Participant-reported completion of advance care planning (ACP) conversations, Participants are asked if they had completed ACP conversations with their loved ones and clinicians., At 1, 3, and 6 months
Other Outcome Measures:
Sponsor: Brigham and Women's Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 2021P003093
Start Date: 2022-03-01
Primary Completion Date: 2023-12-31
Completion Date: 2024-06-30
First Posted: 2022-01-27
Results First Posted:
Last Update Posted: 2023-06-22
Locations: Brigham and Women's Hospital, Boston, Massachusetts, 02115, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT01741480
Study Title: Early Warning System
Study URL: https://beta.clinicaltrials.gov/study/NCT01741480
Acronym:
Study Status: COMPLETED
Brief Summary: The study will begin in 2013 whereby patients having an early warning system (EWS) alert will be randomized to be seen by the rapid response team (RRT) for triage versus usual care. A RRT is usually made up of a nurse and/or a physician who respond to a requested activation of the RRT (called an "ACT"). The intervention will occur as follows:
Study Results: YES

Conditions: Congestive Heart Failure|Chronic Obstructive Pulmonary Disease|Cancer|Diabetes Mellitus|Obstructive Sleep Apnea
Interventions: OTHER: Early warning system monitoring.|OTHER: routine care
Primary Outcome Measures: ICU Transfer, Patients transferred to the ICU from a general hospital ward will be assessed as having met the outcome., Patients will be assessed for the primary outcome measure during their hospital with an average of 14 days.
Secondary Outcome Measures: Mortality, Death during hospitalization will be used to determine the presence of this outcome., Patients will be asessed for the secondary outcome measure during an average of 28 days..
Other Outcome Measures:
Sponsor: Washington University School of Medicine
Collaborators: The Foundation for Barnes-Jewish Hospital|American College of Chest Physicians
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 571
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: PREVENTION
Other IDs: 201210003
Start Date: 2013-02
Primary Completion Date: 2013-05
Completion Date: 2013-05
First Posted: 2012-12-05
Results First Posted: 2015-01-26
Last Update Posted: 2022-05-11
Locations: Barnes-Jewish Hospital, Saint Louis, Missouri, 63110, United States
Study Documents:

NCT Number: NCT04826601
Study Title: The Physical and Psychologic Effects of Aromatherapy in Cancer Patients During Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04826601
Acronym:
Study Status: UNKNOWN
Brief Summary: Background: Stress is the critical method for survive of reacting to a condition including a threat, challenge or physical and psychological challenge. Stress either physiological or biological is an organism's response to a stressor such as an environmental condition. Stimuli that alter an organism's environment are responded to by multiple systems in the body. The hypothalamic-pituitary-adrenal (HPA) axis and autonomic nervous system are major systems which the body reacts to the stress. It has been reported that cancer patients receiving chemotherapy perceived a lot of stress. It has been believed

and well known that stress-related illness is one of the reasons contributing to the increase in long-term sick leave during the last decade in many countries.

Purpose: The aims of this study are to evaluate the effects of aromatherapy on cancer patient receiving chemotherapy: 1) for physical effects by meridian electrical conductance, heart rate variability (HRV), vital sign, visual analogue scale (VAS) for pain; 2) for psychologic effects by State-Trait Anxiety Inventory (STAI).

Materials and methods: This is a prospective, pre post comparison study. A total of 40 cancer patients receiving chemotherapy will be recruited as participants in this study. The characteristics data will be collected in all participants. Blood orange and rosewood will be chosen as the essential oils for aromatherapy in this study. Essential oils will be applied to all participants by inhalation for 30 minutes. Meridian electrical conductance, HRV, vital sign, VAS for pain, and STAI were evaluated and compared before and after aromatherapy.

Expected outcomes: It is expected to understand more about the effects of aromatherapy on the meridian system, HRV and emotional status by undertaking 30 minutes session aromatherapy intervention for cancer patients receiving chemotherapy. The results may suggest aromatherapy as one of the affiliated programs of chemotherapy.
Study Results: NO
Conditions: Pain|Heart Rate Variability|Anxiety
Interventions: OTHER: essential oils
Primary Outcome Measures: pain score, Visual analogue scale for pain. Scores are recorded between 0 for "no pain" and 10 for "worst pain". A higher score indicates greater pain intensity., immediately after aromatherapy
Secondary Outcome Measures: Anxiety, State-Trait Anxiety Inventory (STAI), immediately after aromatherapy
Other Outcome Measures:
Sponsor: Show Chwan Memorial Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: SRD-109037
Start Date: 2021-05-12
Primary Completion Date: 2021-12
Completion Date: 2022-03
First Posted: 2021-04-01
Results First Posted:

Last Update Posted: 2021-07-01
Locations: Show Chwan Memorial Hospital, Changhua, 500, Taiwan
Study Documents:

NCT Number: NCT01627080
Study Title: Cardiac Biomarker Study in Esophageal Cancer Patients Treated With Chemotherapy and Radiation
Study URL: https://beta.clinicaltrials.gov/study/NCT01627080
Acronym:
Study Status: WITHDRAWN
Brief Summary: The goal of this clinical research study is to learn if the radiation that you will receive for esophageal cancer may cause the heart to create more proteins called cardiac biomarkers.

When cardiac biomarkers are above normal levels, there may be heart damage. The relationship between cardiac biomarkers and radiation therapy has not been well studied. Learning more about this relationship may lead to better ways to check the heart during radiation therapy and predict heart problems.
Study Results: NO
Conditions: Esophageal Cancer
Interventions: OTHER: Cardiac Biomarker Blood Draws
Primary Outcome Measures: Evaluation of Cardiac Biomarker Elevation with Radiation Therapy, Descriptive statistics used to summarize change from baseline in enzyme levels at each time point (beyond baseline). Each enzyme examined separately. Pearson or Spearman correlation coefficient used to examine correlation between changes in cardiac biomarkers from baseline in enzyme level at each time point and mean radiotherapy dose or cumulative dose to heart. Linear mixed effects regression model used to model longitudinal change in cardiac biomarker from baseline as a function of cumulative radiation to the heart, radiation modality (Protons vs Photons), and time., Within 24 hours after first fraction of radiation therapy (RT), during 3rd week of RT (fraction 11-15), within 48 hours of RT completion (fraction 26-28).
Secondary Outcome Measures: Incidence of Adverse Cardiac Outcomes, Incidence of adverse cardiac outcomes tabulated including myocardial infarction, heart failure, arrhythmias, all-cause and cardiac-specific mortality at same time points used to analyze cardiac biomarker levels., Within 24 hours after first fraction of radiation therapy (RT), during 3rd week of RT (fraction 11-15), within 48 hours of RT completion (fraction 26-28).
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 0
Funder Type: OTHER

Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2012-0004
Start Date: 2014-04
Primary Completion Date: 2024-04
Completion Date:
First Posted: 2012-06-25
Results First Posted:
Last Update Posted: 2014-07-28
Locations:
Study Documents:

NCT Number: NCT02794324
Study Title: The HeartSpare Study (Stage I)
Study URL: https://beta.clinicaltrials.gov/study/NCT02794324
Acronym:
Study Status: COMPLETED
Brief Summary: Radiotherapy (RT) has a major curative role in women with early breast cancer, and is recommended routinely after lumpectomy and selectively after mastectomy. It has contributed to a halving of breast cancer mortality in the UK over the last 2 decades despite ever-rising cancer incidence. RT in women with left-sided tumours often exposes the underlying heart to a damaging dose. The heart is very sensitive to RT, and there were 1-2 deaths from heart disease for every 100 breast cancer patients treated during the 1960s-70s. The situation has improved in recent years, but standard RT techniques still deliver significant radiation doses to heart tissue.

Two potentially simple techniques reduce heart dose. In one, women are taught to breathe in deeply and to hold their breath for about 20 seconds while RT is given. The downward movement of the diaphragm pulls the heart away from the RT beam. In the other technique, women lie on their fronts, instead of on their backs as they normally do for breast RT. In this position, the breast falls away from the rib cage and reduces exposure of the heart. Neither technique is routinely available to women receiving breast RT in the UK for reasons that this research aims to address. The investigators need to: 1) confirm that patient position can be reproduced with millimetre precision every day using these techniques, 2) minimise costs of equipment, time and personnel required to support such techniques, 3) select the most appropriate technique for different patients and 4) train staff in centres across the UK to deliver techniques safely and effectively. By addressing all of these issues, the study aims ultimately to make heart-sparing RT available to all UK women that might benefit from treatment, thereby significantly reducing the burden of heart disease in breast cancer survivors.
Study Results: NO
Conditions: Breast Cancer
Interventions: PROCEDURE: Voluntary deep-inspiratory breath hold|
PROCEDURE: Active-breathing-controlled deep-inspiratory breathhold|

PROCEDURE: Prone treatment|DEVICE: Active-breathing-controlled deep-inspiratory breathhold
Primary Outcome Measures: Interfraction reproducibility of chest wall position (group A), The position of ipsilateral chest wall will be compared between the digitally reconstructed radiographs (derived from the planning CT) and the on-treatment electronic portal images and mean daily displacements calculated., End of radiotherapy (3-4 weeks)|Difference in mean left anterior descending coronary artery (LAD) mean normal tissue dose (NTDmean) (group B), Using dose-volume histograms (DVHs) based on the planning scan and on-treatment CBCT imaging, mean LAD NTDmean will be compared for ABC_DIBH versus prone positioning., End of radiotherapy (3-4 weeks)
Secondary Outcome Measures: Difference in NTDmean for heart, LAD, ipsilateral and whole lungs (group A), End of radiotherapy (3-4 weeks)|Comparison of standard deviation in mean LAD NTDmean over a treatment course (group B), End of radiotherapy (3-4 weeks)|Comparison of individual patient heart NTDmean differences by anatomical factors (group B), End of radiotherapy (3-4 weeks)|Difference in mean normal tissue doses (NTDmean) to heart, ipsilateral and whole lungs (group B), End of radiotherapy (3-4 weeks)|Difference in volumes of chest wall receiving 20Gy (Groups A and B), End of radiotherapy (3-4 weeks)|Interfraction reproducibility of chest wall position (groups A and B), End of radiotherapy (3-4 weeks)|Interfraction reproducibility of tumour bed position (groups A and B), End of radiotherapy (3-4 weeks)|Time and equipment costs (groups A and B), End of study (2 years)|Patient and radiographer satisfaction with positioning technique (groups A and B), Weekly questionnaire
Other Outcome Measures:
Sponsor: Royal Marsden NHS Foundation Trust
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 57
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CCR3593
Start Date: 2012-02
Primary Completion Date: 2014-05
Completion Date: 2014-05
First Posted: 2016-06-09
Results First Posted:
Last Update Posted: 2016-06-09
Locations: The Royal Marsden NHS Foundation Trust, Sutton, SM2 5PT, United Kingdom
Study Documents:

NCT Number: NCT03333824

Study Title: Effects of AZD1775 on the PK Substrates for CYP3A, CYP2C19, CYP1A2 and on QT Interval in Patients With Advanced Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03333824
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine whether AZD1775 has any effect on the pharmacokinetics (PK) of three compounds (caffeine, omeprazole, and midazolam) that are probes for common drug-metabolizing enzymes (caffeine-CYP1A2, omeprazole-CYP2C19, midazolam-CYP3A). The study also seeks to determine the effect of AZD1775 on the QTc interval, which is a common measure of cardiac (heart) function.
Study Results: NO
Conditions: Solid Tumours
Interventions: DRUG: CYP1A2 (caffeine)|DRUG: CYP2C19 (omeprazole)|DRUG: CYP3A (midazolam)|DRUG: Kytril (granisetron)|DRUG: Wee-1 kinase inhibitor AZD1775
Primary Outcome Measures: Part A: Area under the plasma concentration-time curve from zero to infinity for cocktail parent compounds (midazolam, omeprazole and caffeine), To assess the effect of AZD1775 on the PK of probe substrates for CYP1A2 (caffeine), CYP2C19 (omeprazole), and CYP3A (midazolam), Blood samples are collected on Day -8 and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post cocktail dose|Part A: Area under the plasma concentration-time curve from time zero to the time "t" of the last quantifiable concentration for cocktail parent compounds (midazolam, omeprazole and caffeine), To assess the effect of AZD1775 on the PK of probe substrates for CYP1A2 (caffeine), CYP2C19 (omeprazole), and CYP3A (midazolam), Blood samples are collected on Day -8 and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post cocktail dose|Part A: maximum plasma drug concentration for cocktail parent compounds (midazolam, omeprazole and caffeine), To assess the effect of AZD1775 on the PK of probe substrates for CYP1A2 (caffeine), CYP2C19 (omeprazole), and CYP3A (midazolam), Blood samples are collected on Day -8 and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post cocktail dose|Part B: dECG intervals (QTcF) for absolute values and time-matched change from baseline, To assess the effect on QT interval corrected for heart rate (QTc) following multiple oral doses of AZD1775, dECGs are measured on Day -1, Day 1 and Day 3 of Part B at pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12 and 24 hours post AZD1775 dose
Secondary Outcome Measures: Time to reach maximum plasma concentration for cocktail parent compounds (midazolam, omeprazole and caffeine), To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Terminal half-life for cocktail parent compounds (midazolam, omeprazole and caffeine), To describe the PK of midazolam, omeprazole and caffeine

and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Elimination rate constant for cocktail parent compounds (midazolam, omeprazole and caffeine), To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Apparent clearance following oral administration for cocktail parent compounds (midazolam, omeprazole and caffeine), To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Apparent volume of distribution for cocktail parent compounds (midazolam, omeprazole and caffeine), To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Area under the plasma concentration-time curve from zero to infinity for cocktail metabolites, To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Area under the plasma concentration-time curve from time zero to the time "t" of the last quantifiable concentration for cocktail metabolites, To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Time to reach maximum plasma concentration for cocktail metabolites, To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Maximum plasma drug concentration for cocktail metabolites, To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Terminal half-life for cocktail metabolites, To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day

-8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Elimination rate constant for cocktail metabolites, To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Day 1, Part B Only: Area under the plasma concentration-time curve from time zero to 12 hours for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 1 of Part B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10 and 12 hours post dose|Day 1, Part B only: Time to reach maximum plasma concentration for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 1 of Part B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10 and 12 hours post dose|Day 1, Part B only: Maximum plasma drug concentration for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 1 of Part B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10 and 12 hours post dose|Day 3, Parts A & B: Area under the plasma concentration-time curve from time zero to 12 hours for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 3 of Part A and B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10 and 12 hours post dose|Day 3, Parts A & B: Time to reach maximum plasma concentration for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 3 of Part A and B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Day 3, Parts A & B: Maximum plasma drug concentration for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 3 of Part A and B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Day 3, Parts A & B: Minimum plasma drug concentration for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 3 of Part A and B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Day 3, Parts A & B: Average concentration over a dosing interval for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 3 of Part A and B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Day 3, Parts A & B: Apparent clearance at steady state for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 3 of Part A and B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Day 3, Parts A & B: Fluctuation index (FI) over a dosing interval for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 3 of Part A and B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Part B only: Accumulation ratio for area under the plasma

concentration-time curve from time zero to twelve hours for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 1 and 3 of Part B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Part B only: Accumulation ratio for maximum plasma drug concentration for AZD1775, To describe the PK of AZD1775 following single and multiple dose administration, Blood samples are collected on Day 1 and 3 of Part B at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|dECG intervals (heart rate, RR, PR, QRS, QTcB, QTcF and QT) for absolute values and time-matched change from baseline, To evaluate the effect of single and multiple doses of AZD1775 on cardiac (ECG) parameters, dECG intervals are performed on Day -1, Day 1, and Day 3 of Part B at pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12 and 24 hours post dose|Changes in dECG morphology, To evaluate the effect of single and multiple doses of AZD1775 on cardiac (ECG) parameters, dECG intervals are performed on Day -1, Day 1, and Day 3 of Part B at pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12 and 24 hours post dose|Area under the plasma concentration-time curve from time zero to infinity ratios in relation to parent compound, To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose|Maximum plasma drug concentration ratios in relation to parent compound, To describe the PK of midazolam, omeprazole and caffeine and their metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) in the absence and presence of AZD1775, Blood samples are collected on Day -8, and Day 3 of Part A at pre-dose, 0.25, 0.5, 0.75, 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours post dose
Other Outcome Measures:
Sponsor: AstraZeneca
Collaborators: Quintiles, Inc.
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 33
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: D6014C00006
Start Date: 2017-12-01
Primary Completion Date: 2019-01-22
Completion Date: 2019-01-22
First Posted: 2017-11-07
Results First Posted:
Last Update Posted: 2019-03-25
Locations: Research Site, Bingham Farms, Michigan, 48025, United States|Research Site, Detroit, Michigan, 48202, United States|Research

Site, Lebanon, New Hampshire, 03756, United States|Research Site, Cincinnati, Ohio, 45229, United States|Research Site, Providence, Rhode Island, 02903, United States|Research Site, Greenville, South Carolina, 29605, United States|Research Site, Dallas, Texas, 75251, United States
Study Documents:

NCT Number: NCT01110824
Study Title: Prevention of Left Ventricular Dysfunction During Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT01110824
Acronym: OVERCOME
Study Status: COMPLETED
Brief Summary: The investigators' objective is to assess the efficacy of the combined treatment with enalapril and carvedilol in the prevention of left ventricular systolic dysfunction in patients with hematological malignancies submitted to intensive chemotherapy with potential cardiotoxicity.

The hypothesis is that these drugs administered during chemotherapy may prevent left ventricular systolic dysfunction.
Study Results: NO
Conditions: Acute Myeloid Leukemia|Precursor-cell Lymphoblastic Leukemia-Lymphoma|Lymphoid Neoplasm|Multiple Myeloma|Lymphoma|Autologous Hematopoietic Stem Cell Transplantation
Interventions: DRUG: Enalapril and carvedilol
Primary Outcome Measures: Change from baseline in left ventricular ejection fraction (LVEF) measured by echocardiography and by cardiac magnetic resonance imaging (CMR)., 6 months after randomization
Secondary Outcome Measures: Incidence of death, heart failure or LV systolic disfunction (LVEF<45%), 6 months after randomization|Assessment of genetic polymorphisms involved in chemotherapy-induced cardiotoxicity, Baseline|Prognostic value for cardiac toxicity of troponin I and BNP, up to 3 months|Right and left ventricular volumes measured by CMR, 6 months after randomization|Subgroup analysis by diagnosis (acute leukemia vs. other malignant hemopathies submitted to autologous peripheral blood stem cell transplantation), and positive biomarkers (TnI, BNP)., 6 months after randomization|Incidence of an absolute decrease in LVEF>10 percent units associated with a decline below its normal limit of 50%, 6 months after randomization|Serious adverse events, 6 months after randomization|the incidence of LV dysfunction as assessed by the measurement of the LV strain, and of diastolic dysfunction measured by echo-Doppler, 6 months after randomization
Other Outcome Measures:
Sponsor: Hospital Clinic of Barcelona
Collaborators: Instituto de Salud Carlos III|European Union
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3

Enrollment: 90
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: PREVENTION
Other IDs: OVERCOME|2007-006604-38|FIS EC07/90211
Start Date: 2008-04
Primary Completion Date: 2011-12
Completion Date: 2012-03
First Posted: 2010-04-27
Results First Posted:
Last Update Posted: 2013-11-15
Locations: Hospital Clinic, Barcelona, Catalunya, 08035, Spain|
Hospital Clinic, Barcelona, Catalunya, 08036, Spain
Study Documents:

NCT Number: NCT03930680
Study Title: Prevention of Heart Failure Induced by Doxorubicin With
Early Administration of Dexrazoxane
Study URL: https://beta.clinicaltrials.gov/study/NCT03930680
Acronym: PHOENIX1
Study Status: RECRUITING
Brief Summary: The purpose of this research study is to determine
whether early administration of Dexrazoxane prevents Doxorubicin
induced cardiotoxicity.
Study Results: NO
Conditions: Healthy
Interventions: DRUG: Dexrazoxane
Primary Outcome Measures: Degradation of Topoisomerase 2 b,
Topoisomerase 2 b degradation to less than 15 percent of baseline
level in human blood of 5 volunteers., 48 hours after administration
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Arkansas
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 25
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 262180
Start Date: 2021-09-14
Primary Completion Date: 2024-06
Completion Date: 2025-06
First Posted: 2019-04-29
Results First Posted:
Last Update Posted: 2023-04-03

Locations: University of Arkansas for Medical Sciences, Little Rock, Arkansas, 72205, United States
Study Documents:

NCT Number: NCT02955524
Study Title: Topical Anesthesia and Intra-arterial Chemotherapy for Retinoblastoma
Study URL: https://beta.clinicaltrials.gov/study/NCT02955524
Acronym: TOPIAC
Study Status: WITHDRAWN
Brief Summary: The objective of this study is to use local topical anesthesia to numb the sensory input, captured by branches of the Trigeminal nerve found on the skin in and around the eye, to decrease a hemodynamic reflex seen during placement of a catheter for intra-arterial chemotherapy (IAC) for eye tumors in children. This Trigeminal-cardiac reflex brings about hemodynamic instability during general anesthesia.

Normally, one could block this sensorial input with ophthalmic peribulbar placement of local anesthetics, but these eyes have malignant growth and invasive procedures may cause more harm. The investigators are aiming to numb the sensory branches of the trigeminal nerve non-invasively and observe for any decrease in these events.
Study Results: NO
Conditions: Hemodynamic Instability
Interventions: DRUG: Tetracaine 0.5%|DRUG: Lidocaine hydrochloride ophthalmic gel 3.5%
Primary Outcome Measures: Decrease in systolic Blood Pressure, Interventionalist will communicate to the investigator of the catheter placement and our outcome measure will be recorded soon after., 5 seconds|Drop in end-tidal C02, Interventionalist will communicate to the investigator of the catheter placement and our outcome measure will be recorded soon after., 5 seconds|Decrease in lung compliance, Interventionalist will communicate to the investigator of the catheter placement and our outcome measure will be recorded soon after., 5 seconds|Decrease in oxygen saturation, Interventionalist will communicate to the investigator of the catheter placement and our outcome measure will be recorded soon after., 5 seconds|Cardiac arrythmia, Interventionalist will communicate to the investigator of the catheter placement and our outcome measure will be recorded soon after., 5 seconds
Secondary Outcome Measures: Recovery from Trigeminal-cardiac event, Investigator will communicate when the event is over or rescue drugs given., 2 minutes
Other Outcome Measures:
Sponsor: University of Miami
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT

Phases: EARLY_PHASE1
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 20161001
Start Date: 2018-03
Primary Completion Date: 2020-06
Completion Date: 2020-12
First Posted: 2016-11-04
Results First Posted:
Last Update Posted: 2018-04-20
Locations:
Study Documents:

NCT Number: NCT00530101
Study Title: The Magnetic Resonance Imaging Evaluation of Doxorubicin Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT00530101
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this research study is to evaluate MR imaging in subjects receiving doxorubicin chemotherapy to see if MR can detect heart damage as well as or better than MUGA scans.

This research study is expected to enroll approximately 10 subjects over 12 months at the University of Miami / Miller School of Medicine.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Doxorubicin
Primary Outcome Measures: The purpose of this research study is to evaluate MR imaging in subjects receiving doxorubicin chemotherapy to see if MR can detect heart damage as well as or better than MUGA scans., Over a period of 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Miami
Collaborators: Mallinckrodt
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 3
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 1177-04-806|20043031 and 20050866
Start Date: 2004-07
Primary Completion Date: 2008-03

Completion Date: 2008-03
First Posted: 2007-09-17
Results First Posted:
Last Update Posted: 2008-06-04
Locations: University of Miami Dept of Hematology/Oncology, Miami, Florida, 33136, United States|University of Miami Dept of Radiology, Miami, Florida, 33136, United States
Study Documents:

NCT Number: NCT05150080
Study Title: Early Identification and Evaluation of Cyclophosphamide Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT05150080
Acronym: EIECC
Study Status: RECRUITING
Brief Summary: Hematopoietic stem cell transplantation is an important method for the treatment of hematological diseases and cyclophosphamide is a commonly used chemotherapeutic agent for transplant pretreatment. The incidence of severe cardiovascular events after high-dose cyclophosphamide exposure ranges from 7% to 28% with mortality from 11% to 43%. Thus, an non-invasive, sensitive and reliable method in detecting cardiac function is significant to balance the cardiac risk and the potential cancer treatment benefits. In previous studies, we demonstrated that strain values analyzed by speckle tracking echocardiography decreased significantly after high-dose cyclophosphamide exposure, even though left ventricular ejection fraction remained stable and within normal range. We follow up the hematopoietic cell transplantation patients with cyclophosphamide: to analyze the cut-off values of the parameters of speckle tracking multilayer analysis in predicting early cardiotoxicity induced by cyclophosphamide; to detect the cut-off values of the plasma miRNAs levels in predicting early cardiotoxicity induced by anthracycline.

The purpose of our study is to find out non-invasive, reliable and sensitive echocardiographic parameters and plasma biomarkers for early detection and prediction cyclophosphamide -induced cardiac toxicity and to be helpful to target patients at high risk of cardiotoxicity, who could benefit from closer monitoring or earlier initiation of cardioprotective therapy.
Study Results: NO
Conditions: Cardio-oncology|Hematopoietic Stem Cell Transplantation|Cardiotoxicity|Cyclophosphamide|Echocardiography
Interventions:
Primary Outcome Measures: changes of global longitudinal strain value between cardiotoxicity group and No cardiotoxicity, changes of global longitudinal strain value between cardiotoxicity group and No cardiotoxicity at the follow-up point, From the start of cyclophosphamide injection to1 month after the completion of injection
Secondary Outcome Measures: changes of miRNA between cardiotoxicity group and No cardiotoxicity, changes of miRNA between cardiotoxicity

group and No cardiotoxicity, From the start of cyclophosphamide injection to1 month after the completion of injection
Other Outcome Measures:
Sponsor: Kai Mu
Collaborators:
Sex: ALL
Age: CHILD
Phases:
Enrollment: 40
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: QianfoshanH-210118
Start Date: 2021-07-10
Primary Completion Date: 2022-04-01
Completion Date: 2022-06-01
First Posted: 2021-12-08
Results First Posted:
Last Update Posted: 2021-12-08
Locations: Qianfoshan Hospital (The First Affiliated Hospital of Shandong First Medical University), Jinan, Shandong, 251400, China
Study Documents:

NCT Number: NCT03389724
Study Title: Prevention of Chemotherapy Induced Cardiotoxicity in Children With Bone Tumors and Acute Myeloid Leukemia
Study URL: https://beta.clinicaltrials.gov/study/NCT03389724
Acronym:
Study Status: COMPLETED
Brief Summary: Prevention and early detection of chemotherapy-induced cardiotoxicity in children with bone tumors and Acute Myeloid Leukemia by giving capoten
Study Results: NO
Conditions: Cardiotoxicity|Acute Myeloid Leukemia in Children|Bone Tumor
Interventions: DRUG: Capoten®
Primary Outcome Measures: To determine the effect of ACE-I in preventing chemotherapy-related cardiotoxicity using both investigation techniques: Troponin I level and cardiac imaging (TTE, TDI, STE)., ALL patients will be subjected to the following cardiac imaging (TTE, TDI, STE) at the each time intervals of the study.

Plasma troponin I (TnI) concentration will be measured for all the patients at the each time intervals of the study., 3 years|To determine the role of Troponin I (TnI) as an early marker of cardiac toxicity, Troponin I (TnI) concentration is to be determined by a fluorometric enzyme immunoassay analyzer (Stratus CS, Dade Behring, Miami, Fla) with a functional sensitivity of 0.03 g/L; the cutoff level was 0.08 ng/mL.

Plasma troponin I (TnI) concentration will be measured in both groupsas follows :

* Early TnI: TnI concentration will be measured before and soon after each cycle of HDC. Determination of early TnI consists of a curve of assays (2ml blood sample): baseline initially, before \& after immediately, and 12 and 24 hours after the end of Anthracycline chemotherapy infusion.This sequence will be repeated with each cycle of therapy containing Anthracycline. For each patient, the highest TnI value will be considered for each chemotherapy cycle.
* Late TnI: TnI value also is to be determined at the end of treatment and 2, 3, 6, and 12 months after end of treatment in both groups., 3 years|To measure the accuracy of other radiological techniques for early detection of cardiotoxicity like Tissue Doppler Imaging (TDI) and Speckle-tracking Echo (STE)., Patients will be evaluated Clinically for cardiac functions using ECG , conventional echo, Tissue Doppler Imaging (TDI) and SpeckelTracking Echocardiography STE , before each chemotherapy cycle maximum one week given, 3 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Children's Cancer Hospital Egypt 57357
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE3
Enrollment: 245
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: CCHE -AML0001
Start Date: 2017-11-14
Primary Completion Date: 2021-11-01
Completion Date: 2021-11-01
First Posted: 2018-01-04
Results First Posted:
Last Update Posted: 2022-11-08
Locations: Children's Cancer Hospital Egypt 57357 Cairo, Egypt, Cairo, Egypt
Study Documents:

NCT Number: NCT01434134
Study Title: Prevention of Cardiac Dysfunction During Adjuvant Breast Cancer Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT01434134
Acronym: PRADA
Study Status: COMPLETED
Brief Summary: Women treated for breast cancer are at increased risk for cardiovascular disease, including heart failure. In this study, by using magnetic resonance imaging (MRI), the investigators want to

assess if heart failure medications such as beta blockers and angiotensin receptor blockers can prevent cardiac dysfunction during early breast cancer therapy.
Study Results: NO
Conditions: Breast Cancer|Heart Failure
Interventions: DRUG: Metoprolol|DRUG: Placebo|DRUG: Candesartan|DRUG: Placebo
Primary Outcome Measures: Change in left ventricular ejection fraction, as assessed by cardiac MRI, Baseline and end of study (up to 72 weeks)
Secondary Outcome Measures: Change in contrast enhancement by MRI, Baseline and approximately 4 weeks|Change in left 2D global strain, as assessed by echocardiography, Baseline and end of study (up to 72 weeks)|Incidence of clinical of heart failure or objective left ventricular dysfunction, Left ventricular dysfunction defined as ejection fraction \< 55% by cardiac MRI, Up to 72 weeks|Change in biochemical markers of cardiac injury, i.e. hs-cTnT, Baseline and end of study (up to 72 weeks)|Change in left ventricular diastolic function, as assessed by echocardiography, Diastolic function assessed by e/e', Baseline and end of study (up to 72 weeks)|Change in biochemical markers of cardiac function, i.e. NT-proBNP, Baseline and end of study (up to 72 weeks)|Change in contrast enhancement, as assessed by cardiac MRI, Baseline and end of study (up to 72 weeks)
Other Outcome Measures:
Sponsor: University Hospital, Akershus
Collaborators: University of Oslo|Norwegian Cancer Society|AstraZeneca
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 130
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: FACTORIAL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 2709001/90005
Start Date: 2011-09
Primary Completion Date: 2014-09
Completion Date: 2014-09
First Posted: 2011-09-14
Results First Posted:
Last Update Posted: 2014-10-22
Locations: Akershus University Hospital, Lørenskog, 1478, Norway
Study Documents:

NCT Number: NCT03177928
Study Title: Cardiac Changes in Myeloproliferative Neoplasms
Study URL: https://beta.clinicaltrials.gov/study/NCT03177928
Acronym:
Study Status: UNKNOWN

Brief Summary: Myeloproliferative neoplasms are heterogeneous group of clonal hematopoietic stem cell neoplasms with excessive proliferation of one or more of the erythroid, megakaryocytic, or myeloid lineages and relatively normal maturation resulting in increased numbers of red cells, platelets, and/or granulocytes in the peripheral blood. Constitutive tyrosine kinase activation appears to be a common pathogenetic mechanism.
Study Results: NO
Conditions: Myeloproliferative Neoplasm
Interventions: DEVICE: Transthorathic echocardiogram
Primary Outcome Measures: number of patients with cardiac complications in myeloproliferative diseases., cardiac complications as valvular changes, ejection fraction changes, pulmonary hypertension, 30 minutes
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Assiut University
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: OTHER
Other IDs: CCMPNS
Start Date: 2017-09-01
Primary Completion Date: 2018-08-31
Completion Date: 2019-02-28
First Posted: 2017-06-06
Results First Posted:
Last Update Posted: 2017-06-06
Locations:
Study Documents:

NCT Number: NCT01857141
Study Title: Comparative Study on the Effects of Epidural Dexmedetomidine on Heart Rate Variability During General Anesthesia in Patients Undergoing Gastrectomy
Study URL: https://beta.clinicaltrials.gov/study/NCT01857141
Acronym:
Study Status: COMPLETED
Brief Summary: The use of epidural dexmedetomidine decreases the anaesthetic requirements and improved postoperative pain. Dexmedetomidine is a potent and highly selective a2-adrenoceptor agonist and has sympatholytic effect. Power spectral analysis of heart rate variability(HRV) is a useful tool to assess cardiac autonomic activity. We investigated whether preemptive epidural dexmedetomidine can develop hemodynamic change and it could be identify patients by

HRV.
Study Results: NO
Conditions: Gastric Cancer
Interventions: DRUG: preemptive dexmedetomidine epidural bolus injection(1.5 mcg/kg)|DRUG: normal saline
Primary Outcome Measures: Heart rate variability analysis, Heart rate variability analysis was performed according to the Task Force recommendations.

Frequency domain analysis was based on fast Fourier transformation. Power spectrum densities were calculated for low frequencies (LF: 0.04–0.15 Hz) and high frequencies (HF: 0.15–0.4 Hz) informalized units, defined as the LF or HF proportional part of the total power.

Baseline and 30min after the injection of the study drug., 5min perioids after fluid resuscitation.
Secondary Outcome Measures: Epidural injection, And secondary data collection was done at 30 min after the epidural injection of the study drug.

All of the HRV analysis was done before anaesthesia induction., at 30 min after the epidural injection of the study drug
Other Outcome Measures:
Sponsor: Yonsei University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 38
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 4-2011-0904
Start Date: 2012-02
Primary Completion Date: 2013-06
Completion Date: 2013-08
First Posted: 2013-05-20
Results First Posted:
Last Update Posted: 2014-02-05
Locations: Department of Anesthesiology and Pain Medicine, and Anesthesia and Pain Research Institute, Yonsei University College of Medicine, Seoul, Korea, Seoul, 120-752, Korea, Republic of
Study Documents:

NCT Number: NCT02921828
Study Title: A Safety and Efficacy of Pomalyst® Capsules Under the Actual Use in All Patients Who Are Treated With Pomalyst at a Dose of 1 mg, 2 mg, 3 mg, or 4 mg

Study URL: https://beta.clinicaltrials.gov/study/NCT02921828
Acronym:
Study Status: COMPLETED
Brief Summary: 1. Planned enrollment period One year (The planned number of patients to be enrolled is set to 400 patients.) Since all patients who are prescribed with Pomalyst are registered in RevMate®, enrollment using the Registration Form of the surveillance will be completed at the time when the planned number of patients to be enrolled is reached. During a period until conditions for approval are removed, a system enabling to retrospectively collect appropriate information based on patient data from RevMate® will be, as necessary, maintained.
2. Planned duration of the surveillance Anticipated to be 2 years and 6 months from the start date of release of Pomalyst
Study Results: NO
Conditions: Multiple Myeloma
Interventions:
Primary Outcome Measures: Adverse event (AE), Number of participants with adverse events, 3 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Celgene
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1149
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NIS-Celgene-JP-PMS-002
Start Date: 2015-04-30
Primary Completion Date: 2015-12-10
Completion Date: 2015-12-10
First Posted: 2016-10-03
Results First Posted:
Last Update Posted: 2022-07-05
Locations: Local Institution - Japan, No City Provided, New Jersey, 00000, United States|Shinko Hospital, Kobe, Hyogo, 651-0072, Japan
Study Documents:

NCT Number: NCT01805778
Study Title: Preventing Cardiac Sequelae in Pediatric Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT01805778
Acronym: PCS2
Study Status: COMPLETED
Brief Summary: Cancer therapy can place childhood cancer survivors at increased risk for heart disease which can lead to significant illness or early death. Interventions that occur late in the evolution of treatment-related heart disease are usually ineffective at preventing

its progression to death or heart transplant. Our team will work in several research cores to test new imaging and biomarker methods that will lead to earlier detection of heart disease before clinical symptoms develop or it become apparent on standard imaging tests. We will evaluate the importance of genetic differences between individuals in determining who is at greatest risk of developing heart disease as a result of exposure to cardiotoxic agents. We will combine this genetic information with the novel imaging and biomarker methods to predict which children are at particular risk. These vulnerable children can then be targeted by modifying their cancer therapy to reduce their exposure to cardiac toxins, or introducing medications that protect the heart from chemotherapy damage. This team brings together the expertise of clinicians and scientists in pediatric oncology, pediatric and adult cardiology, radiation oncology, genetics, and biostatistics. This is a cross-Canada initiative that will leverage the latest knowledge about cardiac toxicity and create a resource for ongoing research into this important cause of morbidity and mortality in childhood cancer survivors.
Study Results: NO
Conditions: Anthracycline-induced Cardiotoxicity
Interventions:
Primary Outcome Measures: Cardiac Remodeling, The presence of one or more of the following:

1. Cardiac Remodeling defined as Left Ventricular Posterior Wall Thickness (LVPWT) or Thickness to Dimension Ratio (TDR) z-score \<-2.0 or a reduction in LVPWT or TDR z-score by at least 1 standard deviation compared to baseline; or
2. Reduced left ventricular ejection fraction (LV EF) (\<55%); or
3. Symptomatic heart failure graded using New York Heart Association (NYHA) classification (or Ross heart failure class at least 2 in infants less than 2 years old), one year after last dose of anthracycline therapy in Acute Cohort; anytime during 2 year follow up in Survivor Cohort
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: The Hospital for Sick Children
Collaborators: Canadian Institutes of Health Research (CIHR)|Ontario Institute for Cancer Research|Pediatric Oncology Group of Ontario|C17 Council|Ottawa Heart Institute Research Corporation|Montreal Heart Institute|McMaster Children's Hospital|Children's Hospital of Eastern Ontario|London Health Sciences Centre|Children's Hospital of Orange County|Princess Margaret Hospital, Canada
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 1128
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p

Other IDs: 1000032746
Start Date: 2012-12
Primary Completion Date: 2018-09
Completion Date: 2018-09
First Posted: 2013-03-06
Results First Posted:
Last Update Posted: 2019-07-08
Locations: Children's Hospital of Orange County, Orange, California, 92868, United States|McMaster Children's Hospital, Hamilton, Ontario, Canada|London Health Sciences Centre, London, Ontario, Canada|Children's Hospital of Eastern Ontario, Ottawa, Ontario, Canada|SickKids, Toronto, Ontario, M5G1XE, Canada|Princess Margaret Hospital, Toronto, Ontario, M5T2M9, Canada
Study Documents:

NCT Number: NCT03727958
Study Title: Simultaneous Coronary Artery Evaluation and Lung Cancer CT Screening
Study URL: https://beta.clinicaltrials.gov/study/NCT03727958
Acronym: SIMULTANEOUS
Study Status: UNKNOWN
Brief Summary: Cardiac computed tomography (CT) is often performed in patients who are at high risk for lung cancer in whom screening is currently recommended. This pilot randomized study will test the feasibility, safety and diagnostic ability of a novel ultra-low-dose CT protocol that allows concomitant coronary artery evaluation and lung screening. Current or former heavy smoker subjects with suspected or known coronary artery disease will be randomized to undergo CT assessment of either thoracic area only or both coronary arteries and thoracic area. Primary end-points will be the effective contrast and radiation doses.
Study Results: NO
Conditions: HEAVY SMOKING
Interventions: DIAGNOSTIC_TEST: Lung and coronary CT assessment|DIAGNOSTIC_TEST: Coronary CT assessment
Primary Outcome Measures: Safety of computed tomography as measured by effective radiation dose (as measured in mSv), Measurement of the effective radiation dose (as measured in mSv) at time of computed tomography, Through study completion, an average of 2 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Roma La Sapienza
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|

Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 2018/D/789
Start Date: 2018-11-01
Primary Completion Date: 2018-12-31
Completion Date: 2018-12-31
First Posted: 2018-11-01
Results First Posted:
Last Update Posted: 2018-11-01
Locations:
Study Documents:

NCT Number: NCT04291378
Study Title: The DBCG Proton Trial: Photon Versus Proton Radiation Therapy for Early Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT04291378
Acronym:
Study Status: RECRUITING
Brief Summary: The majority of early breast cancer patients are treated with adjuvant radiation therapy (RT) as part of their multimodal therapy. The aim of the RT is to lower the risk of local, regional and distant failure and improve survival. Modern RT is been provided with photon therapy. Now, more proton therapy facilities are opened, including in Denmark. Proton RT may have the potential to cause lower dose to heart and lung during breast RT. This trial will randomise patients between standard photon RT versus experimental proton RT. The primary endpoint is 10 year risk of heart disease.
Study Results: NO
Conditions: Early Breast Cancer|Radiation Associated Cardiac Failure
Interventions: RADIATION: Proton versus photon radiation therapy
Primary Outcome Measures: Radiation associated ischaemic and valvular heart disease, The following incidences heart diseases according to ICD10: ischaemic heart disease codes I20-25 and valvular heart disease codes I00-09, I01.0, I09.2, I34-39, 10 years after RT
Secondary Outcome Measures: Radiation associated second cancer, Incidences of second cancer associated with the RT: lung, esophagus, thyroid, sarcoma, contralateral breast, 10 years after RT|Distant failure, Incidences of distant failures, i.e. cancer recurrence outside the loco-regional region, 10 years after RT|Acute radiation associated morbidity, According to CTC version 4.0: Incidences of radiation dermatitis, itching, pain, fatigue, dyspnea, cough, pneumonitis, dysphagia, increased sensation of tightness of the shoulder and lymphedema, within 6 months after RT|Late radiation associated morbidity, Incidences of fibrosis, dyspigmentation, telangiectasia, edema, arm lymph edema, range of motion of the shoulder, pain, rib fractures, pneumonitis, 10 years after RT|Patient reported outcome measures, Rates of patient satisfaction with cosmetic outcome, body image scale, rates of depression and fear of cancer recurrence, 10 years after RT|Translational research, Incidences of cardiac disease detected on heart CT scans, PET CT scans, and concentration of early markers of late cardiac events measured in

blood samples, 10 years after RT
Other Outcome Measures:
Sponsor: Danish Breast Cancer Cooperative Group
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1502
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: DBCG Proton trial
Start Date: 2020-06-01
Primary Completion Date: 2027-06-01
Completion Date: 2037-06-01
First Posted: 2020-03-02
Results First Posted:
Last Update Posted: 2020-10-08
Locations: Aalborg University Hospital, Aalborg, Denmark|Aarhus University Hospital, Aarhus, Denmark|The Danish Breast Cancer Cooperative Group, Copenhagen, DK-2100 Ø, Denmark|Rigshospitalet, Copenhagen, Denmark|Herlev Hospital, Herlev, Denmark|Naestved Hospital, Naestved, Denmark|Odense University Hospital, Odense, Denmark|Vejle Hospital, Vejle, Denmark
Study Documents:

NCT Number: NCT04461223
Study Title: Evaluation of Myocardial Injury After Anthracycline Chemotherapy in Osteosarcoma Patients Using CMR
Study URL: https://beta.clinicaltrials.gov/study/NCT04461223
Acronym:
Study Status: UNKNOWN
Brief Summary: using a contrast-enhanced (CE) cardiac magnetic resonance imaging(CMR) which included the measurement of T1 mapping, T2 mapping, T2* mapping and late gadolinium enhancement(LGE) sequences, as well as LVEF and extracellular volume(ECV) to evaluate the respective changes before and after anthracycline chemotherapy.
Study Results: NO
Conditions: Cardiotoxicity|Osteosarcoma|Myocardial Injury|Chemotherapy Induced Systolic Dysfunction|Doxorubicin Induced Cardiomyopathy
Interventions: DIAGNOSTIC_TEST: contrast-enhanced cardiac magnetic resonance imaging(MAGNETOM Aera 1.5T)
Primary Outcome Measures: Completion of chemotherapy with anthracycline drugs, Chemotherapy regimen completed., Through study completion, an average of 6 months.
Secondary Outcome Measures: Incidence of Cancer therapy-related cardiac dysfunction, Cancer therapy-related cardiac dysfunction was defined as an LVEF reduction \>10% from baseline, or LVEF \<53%, From start of anthracycline therapy up to 6 months of anthracycline

completion
Other Outcome Measures: Changes of T1 mapping values, Change in T1 mapping values before and after anthracyclin chemotherapy, At timepoints 0 months, 2 months and 6 months (corresponding to the chemotherapy regimen controls)|Changes of T2 mapping values, Change in T2 mapping values before and after anthracyclin chemotherapy, At timepoints 0 months, 2 months and 6 months (corresponding to the chemotherapy regimen controls)|Changes of T2* mapping values, Change in T2* mapping values before and after anthracyclin chemotherapy, At timepoints 0 months, 2 months and 6 months (corresponding to the chemotherapy regimen controls)
Sponsor: Second Affiliated Hospital, School of Medicine, Zhejiang University
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 55
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2019-523
Start Date: 2019-12-01
Primary Completion Date: 2021-12-01
Completion Date: 2021-12-01
First Posted: 2020-07-08
Results First Posted:
Last Update Posted: 2020-07-08
Locations: 2nd Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou, Zhejiang, 310000, China
Study Documents:

NCT Number: NCT00164658
Study Title: Evaluating Tools for Health Promotion and Disease Prevention
Study URL: https://beta.clinicaltrials.gov/study/NCT00164658
Acronym:
Study Status: COMPLETED
Brief Summary: The study will evaluate the effect of familial risk assessment and prevention prompts tailored to familial risk on health behaviors and use of preventive services among adults who are members of primary care practices in the U.S.
Study Results: NO
Conditions: Coronary Heart Disease|Stroke|Diabetes|Breast Cancer|Ovarian Cancer|Colorectal Cancer
Interventions: BEHAVIORAL: Familial risk assessment and personalized prevention messages
Primary Outcome Measures: Change in stage of adoption of health behaviors and referral for additional screening and follow up for high risk participants at 6 month post evaluation

Secondary Outcome Measures: Primary care physicians' provision of preventive services in response to family medical history.
Other Outcome Measures:
Sponsor: Centers for Disease Control and Prevention
Collaborators: Case Western Reserve University|American Academy of Family Physicians National Research Network|Evanston Northwestern Healthcare Research Institute|University of Michigan
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 8400
Funder Type: FED
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE|Primary Purpose: PREVENTION
Other IDs: CDC-OGDP-4444|U36/CCU319276-MM-0630|U50/CCU300860-TS-1216|U36/CCU319276-MM-0789
Start Date: 2005-09
Primary Completion Date:
Completion Date: 2007-10
First Posted: 2005-09-14
Results First Posted:
Last Update Posted: 2010-01-07
Locations: Evanston Northwestern Healthcare (ENH) internal medicine, family practice, and OB/GYN practices, Evanston, Illinois, 60201, United States|American Academy of Family Physicians National Research Network (AAFP-NRN)., Leawood, Kansas, 66211, United States|Great Lakes Research into Practice Network (GRIN), Ann Arbor, Michigan, 48109, United States
Study Documents:

NCT Number: NCT00005578
Study Title: Combination Chemotherapy With or Without Dexrazoxane in Treating Children With Hodgkin's Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT00005578
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Chemoprotective drugs, such as dexrazoxane, may protect normal cells from the side effects of chemotherapy.

PURPOSE: Randomized phase III trial to compare the effectiveness of combination chemotherapy with or without dexrazoxane in treating children who have Hodgkin's disease.
Study Results: NO
Conditions: Cardiac Toxicity|Lymphoma
Interventions: BIOLOGICAL: bleomycin sulfate|BIOLOGICAL: filgrastim|DRUG: cyclophosphamide|DRUG: dexrazoxane hydrochloride|DRUG: doxorubicin hydrochloride|DRUG: etoposide|DRUG: prednisone|DRUG:

vincristine sulfate|RADIATION: radiation therapy
Primary Outcome Measures: Diffusing capacity of the lungs for carbon monoxide (DLCO), The Wilcoxon test will be used to evaluate whether DLCO values differ between the two arms., One year post therapy
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Children's Oncology Group
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE3
Enrollment: 219
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: SINGLE|Primary Purpose: TREATMENT
Other IDs: 9425|COG-9425|CDR0000065359|P9425
Start Date: 1997-03
Primary Completion Date: 2004-10
Completion Date: 2008-06
First Posted: 2004-05-26
Results First Posted:
Last Update Posted: 2014-07-24
Locations: University of Alabama Comprehensive Cancer Center, Birmingham, Alabama, 35294, United States|MBCCOP - University of South Alabama, Mobile, Alabama, 36688, United States|University of Arkansas for Medical Sciences, Little Rock, Arkansas, 72205, United States|University of California San Diego Cancer Center, La Jolla, California, 92093-0658, United States|Lucile Packard Children's Hospital at Stanford, Palo Alto, California, 94304, United States|University of California Davis Medical Center, Sacramento, California, 95817, United States|Yale Comprehensive Cancer Center, New Haven, Connecticut, 06520-8028, United States|Walter Reed Army Medical Center, Washington, District of Columbia, 20307-5000, United States|Shands Hospital and Clinics, University of Florida, Gainesville, Florida, 32610-100277, United States|Sylvester Cancer Center, University of Miami, Miami, Florida, 33136, United States|Miami Children's Hospital, Miami, Florida, 33155, United States|CCOP - Florida Pediatric, Tampa, Florida, 33682-7757, United States|Emory University Hospital - Atlanta, Atlanta, Georgia, 30322, United States|Cancer Research Center of Hawaii, Honolulu, Hawaii, 96813, United States|Children's Memorial Hospital, Chicago, Chicago, Illinois, 60614, United States|University of Kansas Medical Center, Kansas City, Kansas, 66160-7357, United States|CCOP - Wichita, Wichita, Kansas, 67214-3882, United States|MBCCOP - LSU Medical Center, New Orleans, Louisiana, 70112, United States|CCOP - Ochsner, New Orleans, Louisiana, 70121, United States|Ochsner Clinic, New Orleans, Louisiana, 70121, United States|Marlene & Stewart Greenebaum Cancer Center, University of Maryland, Baltimore, Maryland, 21201, United States|Johns Hopkins Oncology Center, Baltimore, Maryland, 21231,

United States|Boston Floating Hospital Infants and Children, Boston, Massachusetts, 02111, United States|Dana-Farber Cancer Institute, Boston, Massachusetts, 02115, United States|University of Massachusetts Memorial Medical Center, Worcester, Massachusetts, 01655, United States|Children's Hospital of Michigan, Detroit, Michigan, 48201, United States|University of Mississippi Medical Center, Jackson, Mississippi, 39216-4505, United States|Cardinal Glennon Children's Hospital, Saint Louis, Missouri, 63104, United States|Washington University School of Medicine, Saint Louis, Missouri, 63110, United States|CCOP - Northern New Jersey, Hackensack, New Jersey, 07601, United States|Hackensack University Medical Center, Hackensack, New Jersey, 07601, United States|Roswell Park Cancer Institute, Buffalo, New York, 14263-0001, United States|Schneider Children's Hospital, New Hyde Park, New York, 11042, United States|Mount Sinai School of Medicine, New York, New York, 10029, United States|University of Rochester Cancer Center, Rochester, New York, 14642, United States|State University of New York - Upstate Medical University, Syracuse, New York, 13210, United States|Memorial Mission Hospital, Asheville, North Carolina, 28801, United States|Carolinas Medical Center, Charlotte, North Carolina, 28232-2861, United States|Presbyterian Healthcare, Charlotte, North Carolina, 28233-3549, United States|Duke Comprehensive Cancer Center, Durham, North Carolina, 27710, United States|East Carolina University School of Medicine, Greenville, North Carolina, 27858-4354, United States|Comprehensive Cancer Center of Wake Forest University Baptist Medical Center, Winston-Salem, North Carolina, 27157-1082, United States|Oklahoma Memorial Hospital, Oklahoma City, Oklahoma, 73126-0307, United States|CCOP - Columbia River Program, Portland, Oregon, 97213, United States|St. Christopher's Hospital for Children, Philadelphia, Pennsylvania, 19134-1095, United States|Rhode Island Hospital, Providence, Rhode Island, 02903, United States|Medical University of South Carolina, Charleston, South Carolina, 29425-0721, United States|Children's Hospital of Greenville Hospital System, Greenville, South Carolina, 29605, United States|Saint Jude Children's Research Hospital, Memphis, Tennessee, 38105-2794, United States|Simmons Cancer Center - Dallas, Dallas, Texas, 75235-9154, United States|Baylor College of Medicine, Houston, Texas, 77030, United States|MBCCOP - South Texas Pediatric, San Antonio, Texas, 78284-7810, United States|University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78284-7811, United States|Cancer Center, University of Virginia HSC, Charlottesville, Virginia, 22908, United States|Naval Medical Center, Portsmouth, Portsmouth, Virginia, 23708-2197, United States|Massey Cancer Center, Richmond, Virginia, 23298-0037, United States|Midwest Children's Cancer Center, Milwaukee, Wisconsin, 53226, United States|Cross Cancer Institute, Edmonton, Alberta, T6G 1Z2, Canada|McMaster Division, Hamilton, Ontario, L8N 3Z5, Canada|Hospital for Sick Children, Toronto, Ontario, M5G 1X8, Canada|Montreal Children's Hospital, Montreal, Quebec, H3H 1P3, Canada|Hopital Sainte Justine, Montreal, Quebec, H3T 1C5, Canada|Swiss Pediatric Oncology Group Bern, Bern, CH 3010, Switzerland

Study Documents:

NCT Number: NCT05454878
Study Title: Atrial Fibrillation Monitoring on Patients With Lymphoma After Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT05454878
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: This prospective cohort study is to investigate the incidence of atrial fibrillation after chemotherapy by aplying wearable ECG recoder and the risk factors on patients with newly diagonsed lymphoma
Study Results: NO
Conditions: Atrial Fibrillation
Interventions:
Primary Outcome Measures: Incidence, Incidence of atrial fibrillation after chemotherapy, 1 year after the first course of chemotherapy
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Chinese PLA General Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: LAF-20220523
Start Date: 2022-07-15
Primary Completion Date: 2023-07-01
Completion Date: 2023-12-01
First Posted: 2022-07-12
Results First Posted:
Last Update Posted: 2022-07-12
Locations: General hospital of PLA, Beijing, Beijing, 100853, China
Study Documents:

NCT Number: NCT04939558
Study Title: Cardiorespiratory Diagnostic Study
Study URL: https://beta.clinicaltrials.gov/study/NCT04939558
Acronym: CARES
Study Status: COMPLETED
Brief Summary: This study uses a new breathing device called 'N-Tidal C' handset which measures breathing patterns. Investigators have found that people with cardiac and respiratory illnesses breathe out a gas, called carbon dioxide (CO2), in a different way to healthy people. The pattern of breathed out CO2 (the waveform) varies according to the underlying health of the user's lungs. Monitoring these changes may help doctors to more accurately diagnose and monitor the most common

and serious respiratory conditions.
Study Results: NO
Conditions: COPD|Asthma|Lung Cancer|Anemia|Congestive Cardiac Failure|Bronchiectasis|Interstitial Lung Disease|Long COVID|Upper Respiratory Disease|Healthy
Interventions: DEVICE: N-Tidal C handset
Primary Outcome Measures: Breath records from participants with Chronic Obstructive Pulmonary Disease (COPD), Tidal Breathing CO2 waveform data from 245 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 6860 records, 12 months from First Patient First Visit (FPFV)
Secondary Outcome Measures: Breath records from Healthy volunteers (no previous or current cardiorespiratory diagnoses), Tidal Breathing CO2 waveform data from 55 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)|Breath records from participants with Asthma, Tidal Breathing CO2 waveform data from 55 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)|Breath records from participants with Congestive cardiac failure, Tidal Breathing CO2 waveform data from 55 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)|Breath records from participants with Anaemia, Tidal Breathing CO2 waveform data from 55 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)|Breath records from participants with Bronchiectasis, Tidal Breathing CO2 waveform data from 55 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)|Breath records from participants with Lung cancer, Tidal Breathing CO2 waveform data from 55 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)|Breath records from participants with Interstitial Lung Disease, Tidal Breathing CO2 waveform data from 55 participants collected using the

N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)|Breath records from participants with Long COVID, Tidal Breathing CO2 waveform data from 55 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)|Breath records from participants with Upper airway obstruction disorder, Tidal Breathing CO2 waveform data from 55 participants collected using the N-Tidal C Handset.

Each participant delivering 2 x breath records per day for 14 days = 1540 records, 12 months from First Patient First Visit (FPFV)
Other Outcome Measures:
Sponsor: TidalSense
Collaborators: Innovate UK|National Institute for Health Research, United Kingdom
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 744
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: G001-21
Start Date: 2021-06-02
Primary Completion Date: 2022-11-02
Completion Date: 2022-11-30
First Posted: 2021-06-25
Results First Posted:
Last Update Posted: 2023-06-02
Locations: Modality Partnership, Birmingham, West Midlands, B19 1BP, United Kingdom
Study Documents:

NCT Number: NCT04894123
Study Title: Cardiovascular Events From Trifluridine/Tipiracil +/- Oxaliplatin in Colorectal/Oesogastric Adenocarcinoma Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04894123
Acronym:
Study Status: RECRUITING
Brief Summary: The purpose of this study is to assess the incidence of cardiovascular events in patients with esophageal/stomach or colorectal cancer treated by trifluridine/tipiracil +/- oxaliplatin after an episode of cardiac angina-related thoracic pain due to fluoropyrimidines in the adjuvant or metastatic setting .
Study Results: NO

Conditions: Colorectal Adenocarcinoma|Oesogastric
Interventions: DRUG: Trifluridine/Tipiracil|DRUG: Oxaliplatin
Primary Outcome Measures: Rate of cardiovascular events at 3 months., Assessment of the rate of cardiovascular events in patients treated by trifluridine/tipiracil +/- oxaliplatin over a 3-month period., At 3 months
Secondary Outcome Measures: Number of patients with treatment-related adverse events by CTCAE 5.0, Safety profile of the trifluridine/ tipiracil and oxaliplatin combination, Assessed up to 48 months|Number of patients with disease control rate (DCR), DCR defined as partial response, complete response (CR), or stable disease (SD)., Assessed up to 48 months|The 3-month drop-out rate of limiting toxicity, Drop-out rate defined as the number of patients who left the study due to limiting toxicity between treatment initiation and 3 months., At 3 months
Other Outcome Measures:
Sponsor: GERCOR - Multidisciplinary Oncology Cooperative Group
Collaborators: Servier
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 49
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: ACOTAS G-098
Start Date: 2022-01-27
Primary Completion Date: 2025-01
Completion Date: 2025-01
First Posted: 2021-05-20
Results First Posted:
Last Update Posted: 2022-02-11
Locations: CHU Jean Minjoz, Besançon, France|Centre Hospitalier Boulogne/ Mer, Boulogne-sur-Mer, France|Hôptial Henri Mondor, Créteil, France|Chu Dijon, Dijon, France|Hôpital Privé Jean Mermoz, Lyon, France|GH Pitié Salpêtrière, Paris, France|Hôpital Saint Antoine, Paris, France|CHU Poitiers, Poitiers, France|Hôpital Robert Debré, Reims, France|CHU Pontchaillou, Rennes, France|CHU Tours Hôpital Trousseau, Tours, France
Study Documents:

NCT Number: NCT05338723
Study Title: Possible Protective Effect of Rosuvastatin in Chemotherapy-induced Cardiotoxicity in HER2 Positive Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05338723
Acronym:
Study Status: RECRUITING
Brief Summary: This study aims to investigate the possible role of

rosuvastatin in protection against cardiotoxicity in HER2 positive breast cancer patients receiving doxorubicin sequential with trastuzumab.
Study Results: NO
Conditions: Chemotherapy-induced Cardiotoxicity|Breast Cancer
Interventions: DRUG: Rosuvastatin 20mg
Primary Outcome Measures: change in left ventricular ejection fraction(LVEF) detected by electrocardiography transthoracic echocardiography, Patients will undergo transthoracic echocardiography 24 hours prior to the initiation of chemotherapy, after 3 months and after 6 months to detect change in LVEF, 6 months
Secondary Outcome Measures: change of serum level of High sensitivity troponin I (hs-TnI)., Blood samples will be collected at baseline, after 3 months and after 6 months to evaluate High sensitivity troponin I (hs-TnI)., 6 months|change of serum level of Myeloperoxidase (MPO)., Blood samples will be collected at baseline, after 3 months and after 6 months to evaluate Myeloperoxidase (MPO)., 6 months|change of serum level of Interleukin-6 (IL-6). > Liver function test (ALT)., Blood samples will be collected at baseline, after 3 months and after 6 months to evaluate Interleukin-6 (IL-6)., 6 months|change of serum level of Liver function test (ALT)., Blood samples will be collected at baseline, after 3 months and after 6 months to evaluate Liver function test (ALT)., 6 months
Other Outcome Measures:
Sponsor: Tanta University
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: rosuva2020
Start Date: 2020-09-15
Primary Completion Date: 2023-09-15
Completion Date: 2023-09-15
First Posted: 2022-04-21
Results First Posted:
Last Update Posted: 2023-06-15
Locations: The Department of Clinical Oncology, Tanta University Hospital, Tanta, Egypt
Study Documents:

NCT Number: NCT00575523
Study Title: Atropine for Prevention of Dysrhythmias Caused by Percutaneous Ethanol Instillation for Hepatoma Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT00575523
Acronym: atropinePEI

Study Status: COMPLETED
Brief Summary: Ultrasound guided percutaneous ethanol injection (PEI) is an established method in the treatment of hepatocellular carcinoma (HCC) and considered a safe procedure with severe complications occurring rarely. Previous studies revealed, that the occurrence of bradycardia and sinuatrial blockage is quite frequent during ethanol instillation sometimes accompanied by clinical complications such as unconsciousness, respiratory arrest or seizure like symptoms. Study purpose is to evaluate whether the use of i.v. Atropine before starting ethanol instillation can prevent dysrhythmias during instillation. Study design: randomized, placebo controlled, double blinded study. Atropine or saline solution will be administered intravenously to 40 patients immediately before starting percutaneous ethanol instillation. A 6 line ECG with limb leads will be recorded at rest and during ethanol instillation to reveal possibly occurring dysrhythmias.
Study Results: NO
Conditions: Arrhythmia|Respiratory Arrest
Interventions: DRUG: Atropine|DRUG: Placebo
Primary Outcome Measures: Occurrence of dysrhythmias, during percutaneous ethanol instillation
Secondary Outcome Measures: Clinical complications, during percutaneous ethanol instillation and consecutive 24 hours
Other Outcome Measures:
Sponsor: Medical University of Vienna
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 31
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: atropinePEI
Start Date: 2003-10
Primary Completion Date:
Completion Date: 2008-01
First Posted: 2007-12-18
Results First Posted:
Last Update Posted: 2008-01-25
Locations: Div. of Gastroenterology and Hepatology, Medical University of Vienna, Vienna, 1090, Austria
Study Documents:

NCT Number: NCT05718284
Study Title: High Flow Nasal Cannula After Esophagectomy
Study URL: https://beta.clinicaltrials.gov/study/NCT05718284
Acronym: OSSIGENA1V

Study Status: RECRUITING
Brief Summary: This study will compare the effect of HFNC versus standard oxygen administration after elective esophagectomy for cancer.
Study Results: NO
Conditions: Esophageal Cancer|Postoperative Pulmonary Atelectasis|Postoperative Pneumonia|Postoperative Pneumothorax|Postoperative Infection of Incision|Postoperative Acute Myocardial Infarction
Interventions: DEVICE: AIRVO2|OTHER: STANDARD CARE
Primary Outcome Measures: POST-OPERATIVE PULMONARY COMPLICATIONS, Describe the frequency of PPC that include: pneumonia, pleural effusion, pneumothorax, atelectasis, ARDS, aspiration pneumonia, trachea-bronchial lesion, air leak, within 30 days after surgery
Secondary Outcome Measures: CARDIO-VASCULAR COMPLICATIONS, Describe the frequency of myocardial infarction, pulmonary edema, cardiac arrest, pulmonary embolism, deep venous thrombosis, stroke, pericardtis, within 30 days after surgery
Other Outcome Measures:
Sponsor: Cristian Deana
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 320
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: OSSIGENA
Start Date: 2023-04-01
Primary Completion Date: 2024-10
Completion Date: 2025-01
First Posted: 2023-02-08
Results First Posted:
Last Update Posted: 2023-04-25
Locations: Azienda Sanitaria Universitaria Friuli Centrale, Udine, 33100, Italy
Study Documents:

NCT Number: NCT02348684
Study Title: Evaluate Cardiac Function Using Cardiac MRI and Dosimetric Correlation
Study URL: https://beta.clinicaltrials.gov/study/NCT02348684
Acronym:
Study Status: COMPLETED
Brief Summary: The association between radiation exposure and cardiac disease is well recognized, it is not fully understood if there exists an optimal or "safe" radiation dose-volume relationship.
Study Results: YES
Conditions: Node Positive Breast Cancer

Interventions: RADIATION: Radiation therapy groups
Primary Outcome Measures: Cardiac MRI Parameters, Cardiac MRI parameters include Left Ventricular (LV) ejection fraction, LV mass (indexed), LV dimensions, extracellular volume (ECV), and late gadolinium enhancement (LGE)., day of MRI scan
Secondary Outcome Measures: Correlate Cardiac MRI Parameters, Correlate cardiac MRI parameters with pre-treatment heart imaging and cardiac dose volume constraints as a measure of cardiac injury after partial heart irradiation in women with node positive breast cancer treated with surgery, anthracycline-based chemotherapy and regional nodal irradiation., the day of MRI
Other Outcome Measures: Dose-volume Constraints for the Heart During Radiation Therapy for Breast Cancer., Trial data will improve the understanding of cardiac function after radiotherapy and allow oncologists to start to define safe dose-volume constraints for the heart in women treated with regional nodal irradiation for breast cancer., The day of the MRI
Sponsor: Medical College of Wisconsin
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 20
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Cardiac MRI post RT Breast Ca
Start Date: 2012-03
Primary Completion Date: 2014-11
Completion Date: 2014-12
First Posted: 2015-01-28
Results First Posted: 2018-08-23
Last Update Posted: 2021-03-03
Locations: Froedtert Hospital, Milwaukee, Wisconsin, 53226, United States
Study Documents:

NCT Number: NCT04281784
Study Title: Project to Improve Communication About Serious Illness--Hospital Study: Pragmatic Trial (Trial 1)
Study URL: https://beta.clinicaltrials.gov/study/NCT04281784
Acronym: PICSI-H
Study Status: COMPLETED
Brief Summary: The objective of this protocol is to test the effectiveness of a Jumpstart intervention on patient-centered outcomes for patients with chronic illness by ensuring that they receive care that is concordant with their goals over time, and across settings and providers. This study will examine the effect of the EHR-based intervention to improve quality of palliative care for patients 55 years or older with chronic, life-limiting illness with a particular

emphasis on Alzheimer's disease and related dementias (ADRD). The specific aims are:

1. To evaluate the effectiveness of a novel EHR-based (electronic health record) clinician Jumpstart guide, compared with usual care, for improving the quality of care; the primary outcome is documentation of a goals-of-care discussion in the period between randomization and 30 days following randomization. Secondary outcomes focus on intensity of care: ICU use, ICU and hospital length of stay, costs of care during the hospitalization, and 7 and 30-day hospital readmissions.
2. To conduct a mixed-methods evaluation of the implementation of the intervention, guided by the RE-AIM framework for implementation science, incorporating quantitative evaluation of the intervention's reach and adoption, as well as qualitative analyses of interviews with participants, to explore barriers and facilitators to future implementation and dissemination.

Study Results: YES

Conditions: Dementia|Chronic Disease|Neoplasm Metastasis|Lung Neoplasm|Pulmonary Disease, Chronic Obstructive|Heart Failure, Congestive|Liver Cirrhosis|Kidney Failure, Chronic|Lung Diseases, Interstitial|Peripheral Vascular Disease|Diabetes With End Organ Injury|Palliative Care, Patient Care|Health Care Quality, Access, and Evaluation|Patient Care|Inpatients|Health Communication|Patient Care Planning

Interventions: BEHAVIORAL: EHR-based Clinician Jumpstart

Primary Outcome Measures: Proportion of Patients With EHR Documentation of Goals of Care Discussions, The primary outcome is the proportion of patients who have a goals-of-care (GOC) discussion that has been documented in the EHR in the period between randomization and 30 days following randomization The proportion is the number of patients with GOC documentation over the number of patients in each study arm. Documentation of goals-of-care discussions will be evaluated using our NLP/ML methods., Assessed for the period between randomization and 30 days following randomization

Secondary Outcome Measures: Intensity of Care/ICU Use: ICU Admissions, Secondary outcomes include measures of intensity of care, including utilization metrics: Number of ICU admissions during the patient's (index) hospital stay will be collected from the EHR., Assessed for the period between randomization and 30 days following randomization|Intensity of Care/ICU Use: ICU Length of Stay, Secondary outcomes include measures of intensity of care, including utilization metrics: Number of days alive and out of the ICU within 30 days from randomization will be collected from the EHR., Assessed for the period between randomization and 30 days following randomization|Intensity of Care/Hospital Use: Hospital Length of Stay, Secondary outcomes include measures of intensity of care, including utilization metrics: Number of days alive and out of the hospital within 30 days from randomization will be collected from the EHR., Assessed for the period between randomization and 30 days following randomization|Intensity of

Care: Hospital Readmissions 30 Days, Secondary outcomes include measures of intensity of care, including utilization metrics: Proportion of patients readmitted to the hospital following index hospitalization., Assessed for the period between randomization and 30 days following randomization|Intensity of Care: ICU Readmissions 30 Days, Secondary outcomes include measures of intensity of care, including utilization metrics: Proportion of patients who received ICU care., Assessed for the period between randomization and 30 days following randomization|Intensity of Care: Healthcare Costs, Costs for intervention vs. control will be reported in US dollars and identified from UW Medicine administrative financial databases. Costs will be reported for total hospital costs and disaggregated costs (direct-variable, direct fixed, indirect costs). Direct-variable costs will include supply and drug costs. Direct-fixed costs will include labor, clinical department administration, and overhead fees. Indirect costs represent services provided by cost centers not directly linked to patient care such as information technology and environmental services. Costs for ED (emergency department) days and ICU days will be similarly assessed., Assessed for the period between randomization and 30 days following randomization|All-cause Mortality at 1 Year (Safety Outcome), From Washington State death certificates., 1 year after randomization
Other Outcome Measures:
Sponsor: University of Washington
Collaborators: National Institute on Aging (NIA)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 2512
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: STUDY00007031-A|1R01AG006244
Start Date: 2020-04-23
Primary Completion Date: 2021-04-26
Completion Date: 2022-09-26
First Posted: 2020-02-24
Results First Posted: 2022-04-26
Last Update Posted: 2022-11-29
Locations: Harborview Medical Center, Seattle, Washington, 98104, United States|UW Medical Center - Northwest, Seattle, Washington, 98133, United States|UW Medical Center - Montlake (UWMC), Seattle, Washington, 98195, United States
Study Documents: Study Protocol|Statistical Analysis Plan

NCT Number: NCT03737084
Study Title: Effects of Compassion Training to Patients Undergoing HSCT on Biological and Psychosocial Parameters
Study URL: https://beta.clinicaltrials.gov/study/NCT03737084

Acronym:
Study Status: COMPLETED
Brief Summary: The hematopoietic stem cell transplant (HSCT) experience is emotionally and physically stressful for cancer patients who undergo this procedure. This study aims to evaluate the effects of Cognitively-Based Compassion Training (CBCT) on depression and anxiety symptoms, levels of resilience, hope and self-compassion in patients undergoing HSCT and their caregivers. As well as assessing the effects of CBCT on clinical conditions in patients and cortical activity and heart rate variability in caregivers.
Study Results: NO
Conditions: Hematopoietic Stem Cell Transplant
Interventions: BEHAVIORAL: CBCT Intervention
Primary Outcome Measures: Change from Baseline Anxiety and Depression symptoms at 1 week after intervention, Hospital Anxiety and Depression Scale (HADS). The scale consists of 14 items, 7 for anxiety (HADS-A) and 7 items for depression (HADS-D). The final score ranges from 0 to 21 points in each subscale, the higher the score, the greater the symptoms of anxiety or depression (Zigmond and Snaith, 1983)., baseline,1 week after intervention|Change from Baseline Resilience level at 1 week after intervention, Resilience Scale (RS). Developed by Wagnild and Young (Wagnild and Young, 1993). Composed of 25 items. The Resilience Scale was applied to measure the degree of resilience. It measures two main factors: 'personal competence' (17 items) and 'acceptance of self and life' (8 items). The response scale ranges from 1 ('totally disagree') to 7 ('totally agree'). The total score ranges from 26 to 175 points. The higher the score the higher the level of resilience., baseline; 1 week after intervention.|Change from Baseline Self-Compassion level at 1 week after intervention, Self-Compassion Scale. This is a 26-item scale that measures how one typically acts toward oneself in difficult times. These items were designed to assess how respondents perceive their actions toward themselves in difficult times and are rated using a Likert-type scale anchored from 1 (almost never) to 5 (almost always). The scale ranges from 26 to 130 points. The higher the score the higher the level of Self-Compassion. Developed by Kristin Neff., baseline; 1 week after intervention.|Change from Baseline Perceived Stress level at 1 week after intervention, Perceived Stress Scale (PSS). This scale measures the degree to which individuals perceive situations as stressful. Composed of 14 items related to sensation. PSS scores are obtained by reversing the scores on the seven positive items, e.g., 0=4, 1=3, 2=2, etc., and then summing across all 14 items. Items 4, 5, 6, 7, 9, 10, and 13 are the positively stated items. A higher score indicates a higher level of Perceived Stress. The final score ranges from 0 to 56 points. Developed by Luft, 2007., baseline; 1 week after intervention.
Secondary Outcome Measures:
Other Outcome Measures: Cortical activity, Measured by Near-Infrared Spectroscopy (NIRS), in an experiment using a paradigm of autobiographical events, remembering stressful and positive memories., baseline, 1 week after intervention|Heart rate variability (HRV),

Measured from the cardiac activity record through a Polar® V800 heart monitor., baseline, 1 week after intervention
Sponsor: Hospital Israelita Albert Einstein
Collaborators:
Sex: ALL
Age: ADULT
Phases: NA
Enrollment: 80
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, CARE_PROVIDER)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: CEP 2.373.269
Start Date: 2018-04-03
Primary Completion Date: 2020-04-03
Completion Date: 2020-07-01
First Posted: 2018-11-09
Results First Posted:
Last Update Posted: 2020-09-25
Locations: Instituto Israelita de Ensino e Pesquisa Albert Einstein, São Paulo, SP, 05652901, Brazil|Hospital Israelita Albert Einstein, Sao Paulo, 05652901, Brazil
Study Documents:

NCT Number: NCT02132884
Study Title: Genetic Sequencing-Informed Targeted Therapy in Treating Patients With Stage IIIB-IV Non-small Cell Lung Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02132884
Acronym:
Study Status: TERMINATED
Brief Summary: This randomized clinical trial studies how well genetic sequencing-informed targeted therapy works in treating patients with stage IIIB-IV non-small cell lung cancer. Targeted therapy is a type of treatment that uses drugs or other substances to identify and attack specific types of tumor cells that may have less harm to normal cells. Genetic sequencing may help identify these specific types of tumor cells in patients with non-small cell lung cancer.
Study Results: YES
Conditions: Malignant Pericardial Effusion|Malignant Pleural Effusion|Recurrent Non-small Cell Lung Cancer|Stage IIIB Non-small Cell Lung Cancer|Stage IV Non-small Cell Lung Cancer
Interventions: OTHER: cytology specimen collection procedure|PROCEDURE: therapeutic procedure|DRUG: targeted therapy|OTHER: laboratory biomarker analysis
Primary Outcome Measures: Progression Free Survival, A chi-square test (one-sided; alpha = .1) will be used to assess the efficacy of treating patients with targeted agents based in the Cancer-Code-50 in the second line setting. For each patient "success" will be defined as being progression free for at least 3 months following initiation of

second line therapy. Progression free survival times will be characterized separately by arm using the method of Kaplan and Meier., Time from start of second line treatment to time of progression or death, whichever occurs first, assessed at 3 months
Secondary Outcome Measures: Response Rate Defined by RECIST 1.1, The response rate (with 95% two-sided confidence intervals) will be computed separately by arm. One-sided chi-square or Fisher's exact tests (alpha = .1) will be used to evaluate differences in response rates between arms., Up to 2 years|Proportion of Arm B Patients Whose Second Line Therapy is Changed as a Result of Physician Access to CancerCode-50 Results, To assess the effect of sequencing on clinical practice and decision making the proportion of Arm B patients whose second line therapy is changed as a result of physician access to CancerCode-50 results will be computed. This comparison will be based on information provided by the treating physician before being exposed to the sequencing results, and information obtained from a from post-treatment chart review., Up to 2 years
Other Outcome Measures: Concordance of Variants (Arm B), The concordance of variants identified when sequencing will be performed on samples from the same patient collected at baseline and follow-up time points will also be measured., Up to 2 years|Incidence of Non-protocol Testing (Arm A), The incidence of non-protocol testing of those patients in Arm A who undergo molecular testing (by any method) at the discretion of the treating physician will be estimated., Up to 2 years|Response Rate Defined by RECIST 1.1 (Arm A), The response rate of those patients in Arm A who undergo molecular testing (by any method) at the discretion of the treating physician will be estimated., Up to 2 years|Progression Free Survival (Arm A), The progression free survival of those patients in Arm A who undergo molecular testing (by any method) at the discretion of the treating physician will be estimated., Time from start of second line treatment to time of progression or death, whichever occurs first, assessed up to 2 year
Sponsor: Fox Chase Cancer Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CGI-068|NCI-2014-00717|CGI-068|P30CA006927
Start Date: 2015-03
Primary Completion Date: 2016-08
Completion Date: 2016-08
First Posted: 2014-05-07
Results First Posted: 2017-12-13
Last Update Posted: 2019-09-04

Locations: Fox Chase Cancer Center, Philadelphia, Pennsylvania, 19111, United States
Study Documents:

NCT Number: NCT01259284
Study Title: Fish Oil Versus Statins Versus Placebos in Reducing Atrial Fibrillation in Patients Undergoing Thoracic Surgery for Lung Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01259284
Acronym:
Study Status: TERMINATED
Brief Summary: The goal of this clinical research study is to learn if Lipitor (atorvastatin) or fish oil supplements can help to control side effects of the heart that are commonly seen after lung surgery (such as irregular heartbeat). Researchers also want to learn if one of these drugs is more effective than the other at controlling side effects.
Study Results: YES
Conditions: Advanced Cancers
Interventions: DRUG: Atorvastatin|DIETARY_SUPPLEMENT: Fish Oil Supplement|OTHER: Placebo
Primary Outcome Measures: Incidences of Atrial Fibrillation During First 4 Days After Lung Resection, New onset of sustained (15 min or \>) or clinically significant (requiring intervention) atrial fibrillation (AF) during first 4 days post surgery as defined by on American College of Cardiology and American Heart Association Physician Consortium., Baseline to 4 days post surgery
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 2
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR)|Primary Purpose: TREATMENT
Other IDs: 2009-0591
Start Date: 2011-01
Primary Completion Date: 2011-09
Completion Date: 2011-09
First Posted: 2010-12-14
Results First Posted: 2012-04-24
Last Update Posted: 2012-08-07
Locations: UT MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT01671696
Study Title: Defining Late Onset Occult Asymptomatic Cardiotoxicity in Childhood Cancer Survivors Exposed to Anthracycline Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT01671696
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The main hypothesis being tested is that magnetic resonance imaging and serologic biomarkers of apoptosis and extracellular matrix remodeling will precede echocardiographic indices of systolic and diastolic function among childhood cancer survivors treated with anthracyclines thus allowing evaluation of new therapies to prevent and manage heart failure in these patients.
Study Results: NO
Conditions: Cardiovascular Disease
Interventions: OTHER: Cardiac MRI
Primary Outcome Measures: To see if a CMRI is better at detecting occult asymptomatic cardiotoxicity, Changes in T1 mapping-derived relaxation time and left ventricular myocardial peak circumferential and longitudinal strain magnitude and segmental circumferential strain magnitude are present in asymptomatic post-chemotherapy pediatric patients who have normal standard CMRI parameters. Circumferential strain analysis and measurement of the T1 myocardial relaxation time by CMRI may accurately identify occult cardiovascular dysfunction in patients exposed to high dose anthracyclines., 2 year
Secondary Outcome Measures: To quantitate serological markers of diffuse myocardial fibrosis and apoptosis, Testing changes in extracellular matrix remodeling and increases in tissue apoptosis occur in asymptomatic post chemotherapy patients, 1 year
Other Outcome Measures: To conduct phenotype analysis of DNA/microRNA of patients exposed to anthracycline, Analyzing DNA/microRNA in patients who were treated with high and low dose anthracyclines that may cause cardiotoxicity, 1 year
Sponsor: Connecticut Children's Medical Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 80
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 10-096 CCMC
Start Date: 2011-11-15
Primary Completion Date: 2017-10-06
Completion Date: 2023-05-31
First Posted: 2012-08-23
Results First Posted:
Last Update Posted: 2023-02-06
Locations: Connecticut Children's Medical Center, Hartford,

Connecticut, 06106, United States
Study Documents:

NCT Number: NCT03882580
Study Title: Reporting, Evaluating, Preventing and Treating the Cardiotoxicity Induced by Anticancer Drugs During a Specific Cardio-oncology Consult and Follow up in Routine Care
Study URL: https://beta.clinicaltrials.gov/study/NCT03882580
Acronym: NEOCARDIO
Study Status: RECRUITING
Brief Summary: Several Drugs used in routine care in oncology induce rare but often severe or fatal cardiovascular or metabolic side effects. This study will investigate, evaluate, report and treat the cardiovascular side effects of anticancer drugs, through a specific cardiovascular routine checkup and follow-up taking place in several Cardio-oncology programs throughout France. The different including centers will be: Assistance Publique - Hôpitaux de Paris (APHP.6: Pitié-Salpétrière, Saint Antoine and Tenon's hospitals, Paris, France).
Study Results: NO
Conditions: Cardiovascular Complication|Cardiovascular Insufficiency|Cardiac Complication|Oncologic Complications|Cardiac Insufficiency|Metabolic Disorder|Vascular Disorder|Cardiac Disorder
Interventions: DRUG: Anti-Cancer Agents
Primary Outcome Measures: Number of patients having a benefit after this specific cardio-oncology check up and follow up, 5 years
Secondary Outcome Measures: Evaluating the overall survival of patients suffering from cardiovascular or metabolic side effect of oncology treatments, 5 years|All relevants staisticals associations between adverse events and anticancer drugs, 5 years|All relevant statistical associations between cardiovascular toxicities, and anticancer drugs, 5 years|All relevants statistical associations between cardiovascular side effects induced by oncology treatments , and other potentials kind of side effects induced by oncology treatments, 5 years|All relevant statistical associations between duration and type of treatement used to manage cardiovascular side effects induced by oncology treatments, and overall survival, 5 years|All relevants statistical associations between differential features of subgroups of patients, and the occurence of cardiovascular side effects induced by oncology treatments, 5 years|All relevant statistical associations between new therapies to treat or prevent the cardiovascular side effects induced by oncology treatments, and overall survival, 5 years|All relevant statistical associations between the pre therapeutic cardiovascular checkup and follow up for patients with cancer or history of cancer, and the occurence of cardiovascular toxicities of oncology treatments., 5 years|All relevant statistical associations between metabolic toxicities, and anticancer drugs, 5 years|All relevants statistical associations between metabolic side effects induced by oncology treatments , and other potentials kind of side effects induced by oncology treatments,

5 years|All relevant statistical associations between duration and type of treatement used to manage metabolic side effects induced by oncology treatments, and overall survival, 5 years|All relevants statistical associations between differential features of subgroups of patients, and the occurence of metabloic side effects induced by oncology treatments, 5 years|All relevant statistical associations between new therapies to treat or prevent the metabolic side effects induced by oncology treatments, and overall survival, 5 years|All relevant statistical associations between the pre therapeutic metabolic checkup and follow up for patients with cancer or history of cancer, and the occurence of metabolic toxicities of oncology treatments., 5 years
Other Outcome Measures:
Sponsor: Groupe Hospitalier Pitie-Salpetriere
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 5000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CIC1421-19-05
Start Date: 2019-03-01
Primary Completion Date: 2025-03-01
Completion Date: 2025-03-01
First Posted: 2019-03-20
Results First Posted:
Last Update Posted: 2023-04-24
Locations: AP-HP, Saint-Antoine Hospital, Department of cardiology, Paris, 75012, France|AP-HP, Pitié-Salpêtrière Hospital, Department of Pharmacology, CIC-1421, Pharmacovigilance Unit, INSERM, Paris, 75013, France|AP-HP, Tenon Hospital, Department of Cardiology, Paris, 75020, France
Study Documents:

NCT Number: NCT03448757
Study Title: Determination of Autonomic Responses to the Exposure of Low Energy Electromagnetic Fields With Frequency Modulation in Patients With Advanced Hepatocellular Carcinoma and Healthy Individuals.
Study URL: https://beta.clinicaltrials.gov/study/NCT03448757
Acronym:
Study Status: UNKNOWN
Brief Summary: Biofeedback is an autonomic response observed during the exposure period to CEMBE. After prospectively evaluating 20 healthy individuals or 40 patients with advanced breast cancer or hepatocarcinoma, it was possible to determine subtle hemodynamic changes consistent with the biofeedback effect associated with exposure to a cancer-specific set of modulated frequencies.

Once CEMBE is administered through an intra-oral administration device, the human body absorbs the energy applied at the level of 0.2-1 mW / kg, with a peak absorption in 10 g of tissue between 55 and 132 mW / kg. Initially, the discriminatory study analyzing 9 hemodynamic parameters recorded beat heart beat in 18 individuals demonstrated a hemodynamic pattern specific for hepatocarcinoma and breast cancer, with sensitivity of 94.1% and 95%, respectively, and specificity of 75% and 95%, respectively. These findings were validated in blind analysis in the remaining 56 patients, confirming the high rate of discriminatory success.

A specific pattern of response associated with exposure of a cancer-specific frequency group was also observed in patients diagnosed with neoplasia, since the control group of healthy individuals did not present these response patterns.

This specific signature of response to CEMBE-modulated exposure to cancer-specific frequencies was significantly altered only in patients with hepatocarcinoma after tumor withdrawal (Costa et al, 2015a).
Study Results: NO
Conditions: Hepatocellular Carcinoma
Interventions: OTHER: measuring hemodynamic parameters heart beat to heart beat during single-frequency exposure
Primary Outcome Measures: non-invasive hemodynamic parameter measurements during exposure AM RF EMF, Identification of hemodymanic alterations induced by the exposure to low levels of amplitude modulation radiofrequency electromagnetic fields (AM RF EMF) in healthy individuals and patients with advanced hepatocellular carcinoma using Artificial Intelligence program to analyze the recorded data set collected by a high-precision and non-invasive hemodynamic monitor., 90 min on day 1 and day 2
Secondary Outcome Measures: Hemodynamic alteration´s comparison among advanced cancer patients and healthy controls, Comparison of hemodynamic alteration during exposure to a group of hepatocellular-specific AM RF EMF recorded in healthy individuals and patients with advanced hepatocellular carcinoma using Artificial Intelligence algorithms to compare the recorded data set collected by a high-precision and non-invasive hemodynamic monitor., 120 min (single procedure)
Other Outcome Measures: Searching for cancer-specific frequency modulation, Identification of specifc hemodynamic alteration recorded during the exposure to a series of specific frequency modulations AM RF EMF recorded in healthy individuals and patients with advanced hepatocellular carcinoma using Artificial Intelligence program., 120 min (single procedure)
Sponsor: Hospital Sirio-Libanes
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: NA
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: HSL 2016-83
Start Date: 2018-02-15
Primary Completion Date: 2019-04-15
Completion Date: 2020-02-16
First Posted: 2018-02-28
Results First Posted:
Last Update Posted: 2018-08-06
Locations: Hospital Sírio-Libanês, São Paulo, Brazil
Study Documents:

NCT Number: NCT00577798
Study Title: Cardiac Magnetic Resonance Imaging in Patients With Newly Diagnosed Non-Hodgkin Lymphoma or Hodgkin Lymphoma Receiving Doxorubicin
Study URL: https://beta.clinicaltrials.gov/study/NCT00577798
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Diagnostic procedures, such as cardiac magnetic resonance imaging, may help doctors detect early changes in the heart caused by chemotherapy.

PURPOSE: This clinical trial is studying how well cardiac magnetic resonance imaging works in patients with newly diagnosed non-Hodgkin lymphoma or Hodgkin lymphoma receiving doxorubicin.
Study Results: NO
Conditions: Cardiac Toxicity|Chemotherapeutic Agent Toxicity|Lymphoma
Interventions: DRUG: doxorubicin hydrochloride|PROCEDURE: contrast-enhanced magnetic resonance imaging
Primary Outcome Measures: Change in myocardial function and structure, cMRI will be done prior to induction of doxorubicin based chemotherapy and at three months after completion of the doxorubicin based chemotherapy regimen.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Nebraska
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 13
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: DIAGNOSTIC

Other IDs: 409-07|P30CA036727|UNMC-40907
Start Date: 2007-11
Primary Completion Date: 2012-12
Completion Date: 2013-02
First Posted: 2007-12-20
Results First Posted:
Last Update Posted: 2018-12-10
Locations: UNMC Eppley Cancer Center at the University of Nebraska Medical Center, Omaha, Nebraska, 68198-6805, United States
Study Documents:

NCT Number: NCT00002657
Study Title: SWOG-9239 Reduction of Immunosuppression Plus Interferon Alfa and Combination Chemotherapy in Treating Patients With Malignant Tumors That Develop After Organ Transplant
Study URL: https://beta.clinicaltrials.gov/study/NCT00002657
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Reducing the amount of drugs used to prevent transplant rejection may help a person's body kill tumor cells. Giving biological therapy, such as interferon alfa, which may interfere with the growth of cancer cells, or combination chemotherapy, which uses different ways to stop tumor cells from dividing so they stop growing or die, may kill more tumor cells.

PURPOSE: Phase II trial to study the effectiveness of reducing immunosuppression, and giving interferon alfa and combination chemotherapy, in treating patients who have malignant tumors that develop after organ transplant.
Study Results: NO
Conditions: Lymphoma|Multiple Myeloma and Plasma Cell Neoplasm
Interventions: BIOLOGICAL: bleomycin sulfate|BIOLOGICAL: recombinant interferon alfa|DRUG: cyclophosphamide|DRUG: cytarabine|DRUG: doxorubicin hydrochloride|DRUG: etoposide|DRUG: methotrexate|DRUG: prednisone|DRUG: vincristine sulfate|PROCEDURE: conventional surgery|RADIATION: radiation therapy
Primary Outcome Measures: Response, every 3 months while on protocol treatment
Secondary Outcome Measures: overall survival, every 3 months while on treatment, then every 6 months thereafter
Other Outcome Measures:
Sponsor: SWOG Cancer Research Network
Collaborators: National Cancer Institute (NCI)|Eastern Cooperative Oncology Group
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 20
Funder Type: NETWORK
Study Type: INTERVENTIONAL

Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CDR0000064200|SWOG-9239|E-S9239|U10CA032102
Start Date: 1995-05
Primary Completion Date: 2003-11
Completion Date: 2011-07
First Posted: 2004-06-22
Results First Posted:
Last Update Posted: 2013-01-24
Locations: MBCCOP - University of South Alabama, Mobile, Alabama, 36688, United States|CCOP - Greater Phoenix, Phoenix, Arizona, 85006-2726, United States|Veterans Affairs Medical Center - Phoenix (Hayden), Phoenix, Arizona, 85012, United States|Veterans Affairs Medical Center - Tucson, Tucson, Arizona, 85723, United States|Arizona Cancer Center, Tucson, Arizona, 85724, United States|University of Arkansas for Medical Sciences, Little Rock, Arkansas, 72205, United States|Veterans Affairs Medical Center - Little Rock (McClellan), Little Rock, Arkansas, 72205, United States|Veterans Affairs Medical Center - Long Beach, Long Beach, California, 90822, United States|USC/ Norris Comprehensive Cancer Center, Los Angeles, California, 90033-0800, United States|Jonsson Comprehensive Cancer Center, UCLA, Los Angeles, California, 90095-1781, United States|Beckman Research Institute, City of Hope, Los Angeles, California, 91010, United States|Veterans Affairs Outpatient Clinic - Martinez, Martinez, California, 94553, United States|CCOP - Bay Area Tumor Institute, Oakland, California, 94609-3305, United States|University of California Davis Medical Center, Sacramento, California, 95817, United States|CCOP - Santa Rosa Memorial Hospital, Santa Rosa, California, 95403, United States|David Grant Medical Center, Travis Air Force Base, California, 94535, United States|Veterans Affairs Medical Center - Denver, Denver, Colorado, 80220, United States|University of Colorado Cancer Center, Denver, Colorado, 80262, United States|CCOP - Atlanta Regional, Atlanta, Georgia, 30342-1701, United States|Cancer Research Center of Hawaii, Honolulu, Hawaii, 96813, United States|CCOP - Central Illinois, Decatur, Illinois, 62526, United States|Veterans Affairs Medical Center - Hines (Hines Junior VA Hospital), Hines, Illinois, 60141, United States|Loyola University Medical Center, Maywood, Illinois, 60153, United States|University of Kansas Medical Center, Kansas City, Kansas, 66160-7357, United States|CCOP - Wichita, Wichita, Kansas, 67214-3882, United States|Veterans Affairs Medical Center - Wichita, Wichita, Kansas, 67218, United States|Veterans Affairs Medical Center - Lexington, Lexington, Kentucky, 40511-1093, United States|Albert B. Chandler Medical Center, University of Kentucky, Lexington, Kentucky, 40536-0084, United States|MBCCOP - LSU Medical Center, New Orleans, Louisiana, 70112, United States|Tulane University School of Medicine, New Orleans, Louisiana, 70112, United States|Veterans Affairs Medical Center - New Orleans, New Orleans, Louisiana, 70112, United States|Louisiana State University Health Sciences Center - Shreveport, Shreveport, Louisiana, 71130-3932, United States|Veterans Affairs Medical Center - Shreveport,

Shreveport, Louisiana, 71130, United States|Boston Medical Center, Boston, Massachusetts, 02118, United States|Veterans Affairs Medical Center - Boston (Jamaica Plain), Jamaica Plain, Massachusetts, 02130, United States|Veterans Affairs Medical Center - Ann Arbor, Ann Arbor, Michigan, 48105, United States|University of Michigan Comprehensive Cancer Center, Ann Arbor, Michigan, 48109-0752, United States|Veterans Affairs Medical Center - Detroit, Detroit, Michigan, 48201-1932, United States|Barbara Ann Karmanos Cancer Institute, Detroit, Michigan, 48201, United States|Henry Ford Hospital, Detroit, Michigan, 48202, United States|CCOP - Grand Rapids Clinical Oncology Program, Grand Rapids, Michigan, 49503, United States|Providence Hospital - Southfield, Southfield, Michigan, 48075-9975, United States|CCOP - Metro-Minnesota, Saint Louis Park, Minnesota, 55416, United States| Veterans Affairs Medical Center - Biloxi, Biloxi, Mississippi, 39531-2410, United States|University of Mississippi Medical Center, Jackson, Mississippi, 39216-4505, United States|Veterans Affairs Medical Center - Jackson, Jackson, Mississippi, 39216, United States| Keesler Medical Center - Keesler AFB, Keesler AFB, Mississippi, 39534-2576, United States|Veterans Affairs Medical Center - Kansas City, Kansas City, Missouri, 64128, United States|CCOP - Kansas City, Kansas City, Missouri, 64131, United States|St. Louis University Health Sciences Center, Saint Louis, Missouri, 63110-0250, United States|CCOP - St. Louis-Cape Girardeau, Saint Louis, Missouri, 63141, United States|CCOP - Cancer Research for the Ozarks, Springfield, Missouri, 65807, United States|CCOP - Montana Cancer Consortium, Billings, Montana, 59101, United States|Veterans Affairs Medical Center - Albuquerque, Albuquerque, New Mexico, 87108-5138, United States|MBCCOP - University of New Mexico HSC, Albuquerque, New Mexico, 87131, United States|Veterans Affairs Medical Center - Brooklyn, Brooklyn, New York, 11209, United States|Herbert Irving Comprehensive Cancer Center, New York, New York, 10032, United States|Barrett Cancer Center, The University Hospital, Cincinnati, Ohio, 45219, United States|Veterans Affairs Medical Center - Cincinnati, Cincinnati, Ohio, 45220-2288, United States|Cleveland Clinic Cancer Center, Cleveland, Ohio, 44195, United States|CCOP - Columbus, Columbus, Ohio, 43206, United States|Veterans Affairs Medical Center - Dayton, Dayton, Ohio, 45428, United States|CCOP - Dayton, Kettering, Ohio, 45429, United States|Oklahoma Medical Research Foundation, Oklahoma City, Oklahoma, 73104, United States|Veterans Affairs Medical Center - Oklahoma City, Oklahoma City, Oklahoma, 73104, United States|Oregon Cancer Center at Oregon Health Sciences University, Portland, Oregon, 97201-3098, United States|Veterans Affairs Medical Center - Portland, Portland, Oregon, 97207, United States|CCOP - Columbia River Program, Portland, Oregon, 97213, United States|CCOP - Greenville, Greenville, South Carolina, 29615, United States|CCOP - Upstate Carolina, Spartanburg, South Carolina, 29303, United States|Veterans Affairs Medical Center - Nashville, Nashville, Tennessee, 37212, United States|Vanderbilt Cancer Center, Nashville, Tennessee, 37232-6838, United States|Brooke Army Medical Center, Fort Sam Houston, Texas, 78234, United States| University of Texas Medical Branch, Galveston, Texas, 77555-1329,

United States|Texas Tech University Health Science Center, Lubbock, Texas, 79423, United States|University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78284-7811, United States|Veterans Affairs Medical Center - San Antonio (Murphy), San Antonio, Texas, 78284, United States|Veterans Affairs Medical Center - Temple, Temple, Texas, 76504, United States|CCOP - Scott and White Hospital, Temple, Texas, 76508, United States|Huntsman Cancer Institute, Salt Lake City, Utah, 84132, United States|Veterans Affairs Medical Center - Salt Lake City, Salt Lake City, Utah, 84148, United States|CCOP - Virginia Mason Research Center, Seattle, Washington, 98101, United States|Swedish Cancer Institute, Seattle, Washington, 98104, United States|Veterans Affairs Medical Center - Seattle, Seattle, Washington, 98108, United States|Puget Sound Oncology Consortium, Seattle, Washington, 98109, United States|CCOP - Northwest, Tacoma, Washington, 98405-0986, United States
Study Documents:

NCT Number: NCT01301040
Study Title: Early Cardiac Toxicity of Adjuvant CT in Elderly BC.
Study URL: https://beta.clinicaltrials.gov/study/NCT01301040
Acronym:
Study Status: TERMINATED
Brief Summary: The primary objective is to evaluate the difference in cardiac strain rate evolution in elderly early BC patients treated with (neo) adjuvant anthracycline-based chemotherapy compared with a non-anthracycline regimen (Taxotere-cyclophosphamide) CT.

This study also will compare the serum biomarkers profile during and after the (neo) adjuvant CT in both treatment arms, assess whether MRI allows detecting earlier than standard echocardiography the signs of cardiotoxicity, during and after adjuvant (neo) CT, assess whether brain PET-CT allows detecting regional functional impairment in patients receiving CT, evaluate cognitive function before and after (neo) adjuvant CT in both treatment arms, evaluate distress and functional autonomy before and after (neo) adjuvant CT in both treatment arms, evaluate psychological state and burden of primary caregivers before and after (neo) adjuvant CT in both treatment arms, evaluate primary caregivers abilities to detect patients' distress and functional autonomy before and after (neo) adjuvant CT in both treatment arms, evaluate the short and long-term toxicity profile of the regimens, estimate the 10-year risk of relapse and/or death using the Adjuvant!Online tool, and estimate the Framingham risk score for Hard Coronary Heart Disease (10-year risk).
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: epirubicin, cyclophosphamide, docetaxel
Primary Outcome Measures: The difference between cardiac strain rates measured at baseline and after 4 cycles of chemotherapy., The primary null hypothesis is that the means are equal versus the alternative hypothesis that the means are different. We plan to perform the

comparison using a two-sided Student's t-test with α=5%. The power of the study to detect the difference described below has been set at 90%.

One hundred twenty patients candidate to receive neoadjuvant or adjuvant CT for early BC will be randomized 1:1 to receive either epirubicin-cyclophosphamide (EC) or docetaxel (Taxotere) -cyclophosphamide (TC) for 4 cycles., Before chemotherapy, after chemotherapy, at 6 months, one , two and 3 years from randomization.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Jules Bordet Institute
Collaborators: Sanofi
Sex: FEMALE
Age: OLDER_ADULT
Phases: PHASE2
Enrollment: 2
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: IJB 11-01|2011-000562-35
Start Date: 2011-03
Primary Completion Date: 2013-03
Completion Date: 2016-03
First Posted: 2011-02-23
Results First Posted:
Last Update Posted: 2013-08-30
Locations: Institut Jules Bordet, Brussels, 1000, Belgium
Study Documents:

NCT Number: NCT04361240
Study Title: Cardiotoxicity in Breast Cancer Patients Treated With Proton or Photon Radiotherapy: A RadComp Ancillary Study
Study URL: https://beta.clinicaltrials.gov/study/NCT04361240
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: This is an ancillary study to the "Pragmatic Randomized Trial of Proton vs Photon Therapy for Patients with non-Metastatic Breast Cancer Receiving Comprehensive Nodal Radiation: A Radiotherapy Comparative Effectiveness (RadComp) Consortium Trial" (NCT02603341). The investigators will collect cardiovascular (CV) biomarkers and echocardiograms prior to, during, and for up to 1 year following radiation for a subset of patients enrolled on RadComp and to evaluate the impact of proton vs photon radiation therapy (RT) on CV function and structure.
Study Results: NO
Conditions: Breast Cancer|Cardiotoxicity
Interventions: RADIATION: Proton vs Photon Radiation
Primary Outcome Measures: Left ventricular ejection fraction (LVEF),

Change in echocardiography derived LVEF from baseline, 14 months|Right Ventricular (RV) Fractional Area Change (FAC), Change in echocardiography derived RV FAC from baseline, 14 months|Circulating N-terminal pro B-type natriuretic peptide (NTproBNP), Change in NTproBNP levels from baseline, 14 months|Circulating Placental Growth Factor (PIGF), Change in PIGF levels from baseline, 14 months|Circulating Growth Differentiation Factor-15 (GDF-15), Change in GDF-15 levels from baseline, 14 months
Secondary Outcome Measures: LV systolic strain, Change in 2D echocardiography derived LV global longitudinal strain and circumferential strain from baseline, 14 months|Echocardiography derived Ventricular Arterial Coupling Measurement, Change from baseline in ventricular arterial coupling as defined by end systolic elastance divided by effective arterial elastance, 14 months|Diastolic function (E/e'), Change in E/e' from baseline as measured by echocardiogram, 14 months|Circulating Troponin T(TnT), Change in high-sensitivity TnT levels from baseline, 14 months|Circulating high-sensitivity C-Reactive Protein (hsCRP), Change in hsCRP levels from baseline, 14 months
Other Outcome Measures: 3D LVEF, Change in 3d echocardiography derived LVEF from baseline, 14 months|3D LV systolic strain, Change in 3D echocardiography derived longitudinal and circumferential strain from baseline, 14 months|LV Twist and Torsion, Change in 3D echocardiography derived measures of LV twist and torsion from baseline, 14 months|Patient Reported Outcomes (PRO) Common Terms and Criteria for Adverse Events (CTCAE), Incidence and severity of PRO CTCAEs, 14 months|Incidence of major cardiovascular events (MCE), Collected, defined, and adjudicated by the RadComp study team, 10 years
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators: National Heart, Lung, and Blood Institute (NHLBI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 175
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 17119
Start Date: 2020-08-01
Primary Completion Date: 2025-04
Completion Date: 2025-04
First Posted: 2020-04-24
Results First Posted:
Last Update Posted: 2023-06-12
Locations: University of Alabama, Birmingham, Alabama, 35233, United States|Northwestern Medicine, Warrenville, Illinois, 60555, United States|Johns Hopkins, Baltimore, Maryland, 21287, United States|Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States|Abramson Cancer Center at University of Pennsylvania,

Philadelphia, Pennsylvania, 19104, United States|University of Washington, Seattle, Washington, 98195, United States
Study Documents:

NCT Number: NCT02086695
Study Title: Early Detection of Broken Hearts in Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02086695
Acronym: ASPER
Study Status: COMPLETED
Brief Summary: The early detection of BVZ or Sunitinib mediated cardiotoxicity using cardiac biomarkers and novel Transthoracic Echocardiogram (TTE) techniques may allow one to adjust treatment and/or administer prophylactic cardioprotective agents, prior to the development of irreversible cardiac dysfunction. We hypothesize that cardiac biomarkers, TVI/strain-derived indices will be able to accurately detect subtle cardiac injury at a time when conventional Left Ventricular Ejection Fraction (LVEF) remains normal in BVZ or Sunitinib mediated cardiotoxicity. Additionally, we hypothesize that Endothelial Function Test (EndoPAT) testing can detect early BVZ or Sunitinib mediated endothelial dysfunction.
Study Results: NO
Conditions: Cardiotoxicity
Interventions:
Primary Outcome Measures: Number of participants with changes in Tissue velocity imaging (TVI), myocardial deformation indices (Strain, strain rate, twist and torsion), and diastolic function indices (Mitral Valve Pulsed Wave Doppler, Tissue Doppler Imaging, Left Atrial volumes), Baseline to 2 years
Secondary Outcome Measures: Number of participants with changes in quantitative myocardial perfusion parameters including myocardial blood flow velocity and myocardial blood flow derived from contrast perfusion echocardiography, Baseline to 2 years
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators: The Asper Foundation|St. Boniface Hospital|Lantheus Medical Imaging
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 43
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 12-005362
Start Date: 2013-06
Primary Completion Date: 2015-09
Completion Date: 2015-09
First Posted: 2014-03-13
Results First Posted:
Last Update Posted: 2016-01-29

Locations: Mayo Clinic, Rochester, Minnesota, 55905, United States|St. Boniface General Hospital, Winnipeg, Manitoba, R2H 2A6, Canada
Study Documents:

NCT Number: NCT03971344
Study Title: Impact of Serious Pediatric Illness on Parent and Sibling Health
Study URL: https://beta.clinicaltrials.gov/study/NCT03971344
Acronym:
Study Status: COMPLETED
Brief Summary: To estimate the impact of having a child with serious illness (SI) on the health and healthcare of other members of the child's family.
Study Results: NO
Conditions: Family Members of: Newborns Extremely Premature|Family Members of: New Pediatric Oncology Patients|Family Members of: Critical Congenital Heart Defect Patients|Family Members of: Children Severe Neurological Impairment
Interventions:
Primary Outcome Measures: New mental health diagnoses among parents, Outcome will be assessed based on diagnoses in de-identified claims data, 3 years|New mental health diagnoses among siblings, Outcome will be assessed based on diagnoses in de-identified claims data, 3 years|New physical health diagnoses among parents, Outcome will be assessed based on diagnoses in de-identified claims data, 3 years|New physical health diagnoses among siblings, Outcome will be assessed based on diagnoses in de-identified claims data, 3 years|New mental health prescriptions among parents, Outcome will be assessed based on prescription data in de-identified claims data, 3 years|New mental health prescriptions among siblings, Outcome will be assessed based on prescription data in de-identified claims data, 3 years|New physical health prescriptions among parents, Outcome will be assessed based on prescription data in de-identified claims data, 3 years|New physical health prescriptions among siblings, Outcome will be assessed based on prescription data in de-identified claims data, 3 years
Secondary Outcome Measures: Emergency department usage among parents, Outcome will be assessed based on encounter data in de-identified claims data, 3 years|Emergency department usage among siblings, Outcome will be assessed based on encounter data in de-identified claims data, 3 years|Ambulatory care usage among parents, Outcome will be assessed based on encounter data in de-identified claims data, 3 years|Ambulatory care usage among siblings, Outcome will be assessed based on encounter data in de-identified claims data, 3 years|Hospitalizations among parents, Outcome will be assessed based on encounter data in de-identified claims data, 3 years|Hospitalizations among siblings, Outcome will be assessed based on encounter data in de-identified claims data, 3 years|Adherence to chronic disease management standards among parents, Outcome will be assessed based on data in de-identified claims data, 3 years|Receipt of well-child visit and childhood immunizations among siblings, Outcome will be assessed

based on data in de-identified claims data, 3 years
Other Outcome Measures:
Sponsor: Children's Hospital of Philadelphia
Collaborators: Cigna Foundation
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 161000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: FP00024612
Start Date: 2020-01-30
Primary Completion Date: 2020-07-31
Completion Date: 2020-07-31
First Posted: 2019-06-03
Results First Posted:
Last Update Posted: 2020-08-31
Locations: Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT04820569
Study Title: Long-term Heart-specific Mortality in the Presence of Competing Risks Among Patients With Non-metastatic Gastric Adenocarcinoma Undergoing Resection and Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04820569
Acronym: GaCCoR-01
Study Status: COMPLETED
Brief Summary: In this population-based cohort study, data on patients diagnosed with nmGaC in 2004 through 2016, managed with resection and chemotherapy, followed up until the end of 2016, and surviving ≥1 month were retrieved from the US Surveillance, Epidemiology, and End Results-18 Program. Cumulative mortality functions were calculated. Prognostic factors for heart-specific mortality were evaluated using both multivariable-adjusted Fine-Gray subdistribution and cause-specific hazard functions.
Study Results: NO
Conditions: Long-term Heart-specific Mortality in the Presence of Competing Risks Among Patients With Gastric Adenocarcinoma Undergoing Resection and Chemotherapy
Interventions: PROCEDURE: Resection and chemotherapy
Primary Outcome Measures: Cumulative mortality, Cumulative incidence functions (CIFs), which, unlike the standard Kaplan-Meier method, allow for estimation of the incidence of the occurrence of an event while taking competing risks from other causes of death into account, were computed and plotted for cause-specific mortalities., Jan 12, 2020-Mar 5, 2021|Prognostic factors for disease-specific mortalities, Evaluated using both multivariable-adjusted Fine-Gray subdistribution and cause-specific hazard functions., Jan 12, 2020-Mar 5, 2021

Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: The First Affiliated Hospital of Anhui Medical University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 21257
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: GaCCoR-01
Start Date: 2004-01-01
Primary Completion Date: 2016-12-31
Completion Date: 2016-12-31
First Posted: 2021-03-29
Results First Posted:
Last Update Posted: 2021-03-29
Locations:
Study Documents:

NCT Number: NCT05777369
Study Title: R-CMOP in Patients With Primary Diffuse Large B-cell Lymphoma
Study URL: https://beta.clinicaltrials.gov/study/NCT05777369
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: To evaluate the efficacy and safety of R-CMOP regimen based on mitoxantrone hydrochloride liposome injection in the treatment of newly diagnosed diffuse large B-cell lymphoma (DLBCL) based on cardiac function screening
Study Results: NO
Conditions: Diffuse Large B-cell Lymphoma
Interventions: DRUG: Rituximab|DRUG: Mitoxantrone hydrochloride liposome|DRUG: Cyclophosphamide|DRUG: Vincristine/Vindesine|DRUG: Prednisone
Primary Outcome Measures: Objective Response Rate(ORR), Objective response rate (ORR) after 6 cycles of R-CMOP chemotherapy, up to 6 cycles of chemotherapy (each cycle is 21 days)
Secondary Outcome Measures: Complete remission rate(CRR), Complete remission rate(CRR) after 6 cycles of R-CMOP chemotherapy, up to 6 cycles of chemotherapy (each cycle is 21 days)|Duration of remission(DOR), Time from reaching CR or PR for the first time to disease progression, up to 6 cycles of chemotherapy (each cycle is 21 days)|Progression-Free-Survival rate, from date of inclusion to date of progression, relapse, or death from any cause, 1 year|Overall survival rate, from the date of inclusion to date of death, irrespective of cause, 1 year|Adverse events (AE), The safety of the drug was evaluated by NCI-CTC AE 5.0 standard, From the first day of medication to 28 days after the last dose

Other Outcome Measures:
Sponsor: The First Affiliated Hospital with Nanjing Medical University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 30
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CSPC-DED-DLBCL-K08
Start Date: 2023-03
Primary Completion Date: 2023-08
Completion Date: 2024-08
First Posted: 2023-03-21
Results First Posted:
Last Update Posted: 2023-03-21
Locations:
Study Documents:

NCT Number: NCT04291235
Study Title: The NEUROlogically-impaired Extubation Timing Trial (NEURO-ETT)
Study URL: https://beta.clinicaltrials.gov/study/NCT04291235
Acronym:
Study Status: UNKNOWN
Brief Summary: This trial in brain-injured patients will test which of the following will lead to better patient outcomes: (1) an airway management pathway consisting of daily assessments and removal of the breathing tube as soon as patients can breathe on their own and appear able to protect their airway; versus (2) the usual treatment patients would have received if they were not enrolled in this trial.
Study Results: NO
Conditions: Acute Brain Injury
Interventions: PROCEDURE: Airway Management Pathway|PROCEDURE: Usual Care
Primary Outcome Measures: Total Duration of Mechanical Ventilation, Total duration of mechanical ventilation (to 60 days) accounting for the competing risk of death, Up to 60 Days
Secondary Outcome Measures: Mortality at ICU discharge and Hospital Discharge, Mortality at ICU Discharge, Hospital Discharge, 3 months, and 6 months, ICU Discharge, Hospital Discharge, 3 months, and 6 months|Ventilator-Free Days at Day 60, Days alive and not receiving mechanical ventilation, Up to 60 days|ICU Free Days At Day 60, ICU free days (days alive and not spent in an ICU), Up to 60 Days|Airway or Tracheostomy complications, Presence versus absence of airway complication, Up to 30 days|Nutrition Intake, Time to normal oral nutrition intake, Up to 6 Months|Antibiotics Days, Injection or infusion of antibiotics given intravenously, Up to 30 Days|

Tracheostomy Rates, Presence versus absence of tracheostomy insertion, Up to 6 Months|ICU Readmission Rates, ICU readmission rates to hospital discharge, Hospital discharge, up to 90 days|Discharge Destination, Discharge destination for the patient post hospitalization, Hospital discharge, up to 90 days|Extended Glasgow Outcome Score, Minimum score 1 (worst) to maximum score 8 (best) at 3 months and 6 months, 3 months and 6 months|EuroQol-5D, Minimum score 1 (worst) to maximum score 100 (best) at 3 months and 6 months, 3 months and 6 months|Delirium Free Days, Days alive and free of delirium while in ICU up to day 30, Up to 30 Days
Other Outcome Measures:
Sponsor: Sunnybrook Health Sciences Centre
Collaborators: Canadian Institutes of Health Research (CIHR)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 332
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: NEURO-ETT
Start Date: 2020-04-01
Primary Completion Date: 2023-01-01
Completion Date: 2023-01-01
First Posted: 2020-03-02
Results First Posted:
Last Update Posted: 2020-03-02
Locations: University of Alberta Hospital, Edmonton, Alberta, T6G 2B7, Canada|Royal Columbian Hospital, New Westminster, British Columbia, V3L 3W7, Canada|Vancouver General Hospital, Vancouver, British Columbia, V5Z 1M9, Canada|Nova Scotia Health Authority, Halifax, Nova Scotia, B3H 3A7, Canada|Hamilton General Hospital, Hamilton, Ontario, L8N 3Z5, Canada|Kingston General Hospital, Kingston, Ontario, K7L 2V7, Canada|London Health Sciences Centre, London, Ontario, N6A 5A5, Canada|Ottawa Hospital, Ottawa, Ontario, K1H 8L6, Canada|Sunnybrook Health Sciences Centre, Toronto, Ontario, M4N 3M5, Canada|St. Michael's Hospital, Toronto, Ontario, M5B 1W8, Canada|Toronto Western Hospital, Toronto, Ontario, M5G 2N2, Canada|Hôpital du Sacré-Coeur de Montréal, Montreal, Quebec, H4J 1C5, Canada|Centre hospitalier de l'Université de Montréal, Montréal, Quebec, H2X 2H8, Canada|L'Hôpital de l'Enfant-Jésus, Quebec City, Quebec, G1J 1Z4, Canada
Study Documents:

NCT Number: NCT02004834
Study Title: Levobupivacaine and Lidocaine for Paravertebral Block Causes Greater Hemodynamic Oscillations Than Levobupivacaine
Study URL: https://beta.clinicaltrials.gov/study/NCT02004834
Acronym:
Study Status: ACTIVE_NOT_RECRUITING

Brief Summary: The purpose and the goal of this paper is to show whether the application of a combination of two local anesthetics, as opposed to the application of one local anesthetic at paravertebral block changes the hemodynamic variable. It is therefore a prospective randomized double- blind study, where we do a clinical trial in patients ASA(American Society of Anesthesiologists) 1 and 2 statuses between 18 and 80 years of age, using the ultrasound in plane technology.Upon arrival of patients in the unit for preparation procedures for anesthesia we set the ECG(electrocardiograph), noninvasive blood pressure, oxygen saturation, and arterial cannula in the radial artery After sterile washing of the dorsal surface, paravertebral space was identified with ultrasound using 8 Hz(hertz) linear transducer probe then needle position was confirmed with neurostimulation at the level of 2.0 - 5.0 mA(milliampere). When muscle contraction persisted at 0.4mA(milliampere), the anesthetic was applied in levels of Th 2, Th3, and Th 4 (7,0 milliliters per level). We applied the 0.5 % levobupivacaine and 2 % lidocaine, 7,0 milliliters of mixture per level in one group, while only 0.5 % levobupivacaine also 7,0 milliliters. by level in the second one. After that, the invasive hemodynamic monitoring was placed on patients and the induction with 1 % propofol 2-2.5 mg/kg.and Vecuronium 0,08 mg/kg. was performed with the application of supraglottic airway gel of appropriate size. The maintenance of anesthesia and sedation will be conducted with Propofol 1 % continuously (25-150 mcg / kg / min.)The measurements will be taken every 5 minutes during the first hour of the application of paravertebral block, then every 15 minutes during the second hour and if the operation takes more than two hours, the measurements are performed every 30 minutes. Postoperatively, invasive hemodynamic monitoring will be removed in post-anesthesia recovery room together with the arterial cannula and the patient will be sent to the hospital ward with non-invasive hemodynamic monitoring (blood pressure, pulse, saturation) until the termination of the blocks.Statistical methods, By comparing two target groups, we analysed the strength of the test with following assumptions: X2 difference test, the expected difference in variances in stroke volume between groups of 60%, α significance level of 0.05, and the minimum statistical test strength of 85%. The required total sample should include at least 80 patients, that is, 40 per group.Data will be presented in tables and graphs. Descriptive statistics of examined variables with appropriate measures of central tendency will be made. Smirnov -Kolmogorov test will assess the normality of data distribution. According to the received results, the appropriate parametric and / or nonparametric tests will be used. Comparisons of quantitative values between the two groups will be analyzed using the independent t-test or Mann-Whitney U test. Dependent values within each group will be analyzed using analysis of variance for repeated measures or Friedman test. Differences in categorical values will be analyzed by X2 test. The appropriate regression model will be made in order to predict the variability of stroke volume in which the dependent variable will be a variation of the stroke volume, while

relevant clinical values will be taken as predictor variables. All P values smaller than 0.05 will be considered significant.

This research is to present the main results - the existence of the significant change in Stroke Volume Variation (SVV) between groups using invasive hemodynamic monitoring, the changes of Stroke Volume Variation(SVV) depending on the time from the application within groups, differences in volume compensation of crystalloids and colloids and the need for the application of vasoactive drugs. Furthermore, as a secondary results we will present the time to maximal block development, the duration of post operative analgesia, patient satisfaction and time needed for the full recovery from the block.
Study Results: NO
Conditions: Breast Tumors|Hypotension|Bradycardia
Interventions: DRUG: levobupivacaine
Primary Outcome Measures: Stroke Volume Variation(SVV)within and between groups of patients, Determine which solution of local anesthetic with paravertebral block has a the most favorable effect with regard to the analgesic and hemodynamic effects.

Stroke Volume Variation(SVV)will be expressed in percentage change., 12 hours perioperative
Secondary Outcome Measures: postoperative analgesic consumption, Achieve satisfactory postoperative analgesia and thereby faster patient mobilization, 12 hours
Other Outcome Measures:
Sponsor: University Hospital Dubrava
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 80
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: TREATMENT
Other IDs: 260320131980
Start Date: 2013-08
Primary Completion Date: 2023-07
Completion Date: 2023-10
First Posted: 2013-12-09
Results First Posted:
Last Update Posted: 2022-05-18
Locations: University Hospital Dubrava, Zagreb, 10000, Croatia
Study Documents:

NCT Number: NCT00590434
Study Title: Yield and Safety of Colonoscopy in Patients Older Than 80 Years

Study URL: https://beta.clinicaltrials.gov/study/NCT00590434
Acronym:
Study Status: COMPLETED
Brief Summary: The aim of the study is to study the risk of colorectal cancer and polyps in people older than 80 years compared to the younger age group. The researchers hypothesized that colonoscopy in older people is likely to have more complications without detection of a significant number of large polyps and cancer.
Study Results: NO
Conditions: Colorectal Neoplasms
Interventions:
Primary Outcome Measures: Proportion of elderly patients (>80 yrs) with colorectal neoplasia, 2 years|proportion of patients with complications including perforation, bleeding, MI or CVA within 24 hours of colonoscopy in >80 vs. <80 agr group, 2 years
Secondary Outcome Measures: Five year disease free survival and five year mortality rates after the diagnosis of colon cancer in older (>80 yrs) vs. younger group (<80 yrs), 2 years
Other Outcome Measures:
Sponsor: Midwest Biomedical Research Foundation
Collaborators: US Department of Veterans Affairs
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 169
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: AB0002
Start Date: 2006-08
Primary Completion Date: 2009-12
Completion Date: 2009-12
First Posted: 2008-01-10
Results First Posted:
Last Update Posted: 2012-10-26
Locations: Kansascity VA Medical center, Kansas city, Missouri, 64128, United States
Study Documents:

NCT Number: NCT02130934
Study Title: Cardiac 3D MRI in Pediatric Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02130934
Acronym:
Study Status: WITHDRAWN
Brief Summary: This is a non-randomized prospective pilot study in a single academic center with historic controls. This study will compare Cardiac Magnetic Resonance Images (MRI) of patients who have undergone childhood cancer treatment that has cardio-toxic effects to historic controls. The ultimate goal of this study is to develop a safe and effective method for early diagnosis of heart problems in children who

are receiving chemotherapy treatments that may be toxic to the heart.
Study Results: NO
Conditions: Childhood Cancer
Interventions: PROCEDURE: Cardiac 3D MRI
Primary Outcome Measures: Ventricular Function Measurement, Quantify ventricular functional measurements including strain patterns and measurements using offline processing software that Dr. Fornwalt lab has., Up to 2 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Majd Makhoul
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 0
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 14-0315
Start Date: 2014-05
Primary Completion Date: 2016-03
Completion Date: 2016-03
First Posted: 2014-05-06
Results First Posted:
Last Update Posted: 2016-11-15
Locations: UK Medical Center, Lexington, Kentucky, 40536, United States|University of Kentucky Medical Center, Lexington, Kentucky, 40536, United States
Study Documents:

NCT Number: NCT05819528
Study Title: Primary Cardiac Lymphoma: Italian Multicenter Experience
Study URL: https://beta.clinicaltrials.gov/study/NCT05819528
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: The rationale of this study is to provide an overview on PCL (Primary Cardiac Lymphoma) in Italy, trying to shed light on unknown aspects of the disease and on unanswered questions about its management that could be helpful in clinical practice.
Study Results: NO
Conditions: Primary Cardiac Lymphoma
Interventions:
Primary Outcome Measures: Overall survival (OS), Overall survival, the percentage of patients alive of the cohort (patients with cardiac lymphoma diagnosed from 01/01/2000 to 31/12/2020)., The endpoint will be evaluated within 2 months from the end of data collection. The end of data collection is scheduled within the Q4 (fourth quarter) of 2023.
Secondary Outcome Measures: Complete remission (CR), The Complete

Remission is defined as the lack of detectable evidence of tumor in the cohort of patients (patients with cardiac lymphoma diagnosed from 01/01/2000 to 31/12/2020)., The endpoint will be evaluated within 2 months from the end of data collection. The end of data collection is scheduled within the Q4 (fourth quarter) of 2023.|Overall Response Rate (ORR), The Overall Response Rate is defined as the proportion of patients who have a partial or complete response to therapy (patients with cardiac lymphoma diagnosed from 01/01/2000 to 31/12/2020)., The endpoint will be evaluated within 2 months from the end of data collection. The end of data collection is scheduled within the Q4 (fourth quarter) of 2023.|Progression-Fee Survival (PFS), The Progression-Free Survival is the length of time during and after the treatment that patients live with the disease, but it does not get worse (patients with cardiac lymphoma diagnosed from 01/01/2000 to 31/12/2020)., The endpoint will be evaluated within 2 months from the end of data collection. The end of data collection is scheduled within the Q4 (fourth quarter) of 2023.|Frequencies of the type of chemo(immuno)therapy and of the number of cycles received as first and second line., The numbers of treatment types and numbers of cycles of therapy received by the cohort of patients (patients with cardiac lymphoma diagnosed from 01/01/2000 to 31/12/2020)., The endpoint will be evaluated within 2 months from the end of data collection. The end of data collection is scheduled within the Q4 (fourth quarter) of 2023.|Frequencies of the type of Central Nervous System (CNS) prophylaxis, The numbers of treatment prophylaxis types for Central Nervous System administered to the cohort of patients (patients with cardiac lymphoma diagnosed from 01/01/2000 to 31/12/2020)., The endpoint will be evaluated within 2 months from the end of data collection. The end of data collection is scheduled within the Q4 (fourth quarter) of 2023.|Cumulative incidence rate of Central Nervous System (CNS) relapse detected during treatment or follow-up., The proportion of patients with disease relapse on Central Nervous System (CNS), The endpoint will be evaluated within 2 months from the end of data collection. The end of data collection is scheduled within the Q4 (fourth quarter) of 2023.|Characteristics of patients, Analysis of the following characteristics: Age, gender, disease localization (atria, ventricles, cardiac arteries and veins, pericardium), HIV positivity, type of symptoms at diagnosis., The endpoint will be evaluated within 2 months from the end of data collection. The end of data collection is scheduled within the Q4 (fourth quarter) of 2023.
Other Outcome Measures:
Sponsor: Fondazione Italiana Linfomi - ETS
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 43
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p

Other IDs: FIL_Lympho-Heart
Start Date: 2023-05-01
Primary Completion Date: 2023-12-31
Completion Date: 2024-02-29
First Posted: 2023-04-19
Results First Posted:
Last Update Posted: 2023-04-21
Locations: Presidio ospedaliero "A. TORTORA" - U.O. Onco-ematologia, Pagani, Salerno, 84016, Italy|AOU di Sassari - Ematologia, Sassari, SS, 07100, Italy|Azienda Sanitaria Universitaria Giuliano Isontina (ASUGI) - SC Ematologia, Trieste, TS, 34121, Italy|Ospedale Dell'angelo - U.O. Ematologia, Mestre, Venezia, 30174, Italy|Azienda Ospedaliera Papa Giovanni XXIII - Ematologia, Bergamo, 24127, Italy|ASST Spedali Civili di Brescia - Ematologia, Brescia, 25123, Italy|Azienda Ospedaliero-Universitaria di Ferrara - Arcispedale Sant'Anna - Ematologia e fisiopatologia della coagulazione, Ferrara, 44124, Italy|Istituto Scientifico San Raffaele - Unita Linfomi - Dipartimento Oncoematologia, Milano, 20132, Italy|Fondazione IRCCS Istituto Nazionale dei Tumori di Milano - Ematologia, Milano, 20133, Italy|ASST Grande Ospedale Metropolitano Niguarda - SC Ematologia, Milano, 20162, Italy|Ospedale S. Maria della Misericordia - Ematologia, Perugia, 06129, Italy|P.O. Spirito Santo di Pescara - UOS Dipartimentale - Centro di diagnosi e Terapia dei linfomi, Pescara, 65124, Italy|AOU Pisana - U.O. Ematologia, Pisa, 56126, Italy|Roma - Universita Cattolica S. Cuore - Ematologia, Roma, 00168, Italy|AO Sant'Andrea - Ematologia, Roma, 00183, Italy|A.O. S. Maria di Terni - S.C. Oncoematologia, Terni, 05100, Italy|A.O.U. Città della Salute e della Scienza di Torino - Ematologia Universitaria, Torino, 10126, Italy|Ospedale Ca Foncello - S.C di Ematologia, Treviso, 31100, Italy|AOU Integrata di Verona - U.O. Ematologia, Verona, 37134, Italy
Study Documents:

NCT Number: NCT02654340
Study Title: Biomarkers for Tuberous Sclerosis Complex (BioTuScCom)
Study URL: https://beta.clinicaltrials.gov/study/NCT02654340
Acronym: TuScCom
Study Status: TERMINATED
Brief Summary: International, multicenter, observational, longitudinal study to identify biomarker/s for Tuberous Sclerosis Complex and to explore the clinical robustness, specificity, and long´-term variability of these biomarker/s
Study Results: NO
Conditions: Hypomelanotic Macules|Facial Angiofibroma|Shagreen Patches|Ungual Fibromas|Cortical Dysplasia|Cardiac Rhabdomyoma|Lymphangioleiomyomatosis|Renal Angiomyolipoma|Subependymal Giant Cell Astrocytoma
Interventions:
Primary Outcome Measures: Identification of TSC biomarker/s, All samples will be analyzed for the identification of biomarker/s via Liquid Chromatography Multiple Reaction-monitoring Mass Spectrometry

(LC/MRM-MS) and compared to merged control, in order to establish the disease-specific biomarker/s. The LC/MRM-MS is performed on an ABSciex 6500 triple quadrupole mass spectrometer, coupled with a Waters Acquity UPLC., 36 months
Secondary Outcome Measures: Exploring the clinical robustness, specificity, and longterm variability of TSC biomarker/s, Samples will be analyzed for the candidate biomarker/s via Liquid Chromatography Multiple Reaction-monitoring Mass Spectrometry (LC/MRM-MS) and compared to merged control, in order to establish the disease-specific biomarker/s. The LC/MRM-MS is performed on an ABSciex 6500 triple quadrupole mass spectrometer, coupled with a Waters Acquity UPLC., 36 months
Other Outcome Measures:
Sponsor: CENTOGENE GmbH Rostock
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 20
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: TSC 08-2018
Start Date: 2018-08-01
Primary Completion Date: 2022-12-30
Completion Date: 2022-12-30
First Posted: 2016-01-13
Results First Posted:
Last Update Posted: 2023-02-10
Locations: University Hospital Center Mother Teresa, Tirana, 10001, Albania|Department of Pediatrics, Alexandria University Children's Hospital, Alexandria, 21131, Egypt|Departmnet of Molecular and Medical Genetics, Tbilisi State Medical University, Tbilisi, 0177, Georgia|Department of Pediatric Genetics, Amrita Institute of Medical Sciences & Research Centre, Cochin, Kerala, 682041, India|Rare diseases coordinating centre, Vilnius University Hospital Santaros klinikos, Vilnius, Lithuania|Departmnet of Pediatric Gastroenterology and Hepatology, The Children's Hospital and Institute of Child Health, Lahore, 54600, Pakistan|Emergency Hospital for Children "Louis Turcanu", Timişoara, 300011, Romania|Lady Ridgeway Hospital for Children, Colombo, 00800, Sri Lanka
Study Documents:

NCT Number: NCT05900544
Study Title: Maximizing Benefit of Lung Cancer Screening Incidental Findings of Cardiovascular, Respiratory and Breast Measures
Study URL: https://beta.clinicaltrials.gov/study/NCT05900544
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: The investigators will implement a patient-centered

outcomes tool for participants in lung cancer screening programs that receive clinically important incidental findings relevant to heart, breast and lung health. The study objective is to evaluate participant response and clinical follow-up following implementation of a patient-centered incidental findings communication tool.
Study Results: NO
Conditions: Coronary Disease|Emphysema or COPD|Breast Density
Interventions: OTHER: System implementation of patient-centered incidental findings report
Primary Outcome Measures: Precaution Adoption Process Model (PAPM) health behavior stage, The PAPM is a theoretical, stages of change model that, in conjunction with the Health Belief model, has been used to guide the study of health behaviors, including to promote screening for health conditions. The PAPM outlines seven stages along a continuum toward health behavior change: (1) unaware of the health behavior, (2) aware but unengaged with the health behavior, (3) engaged and thinking about acting (deciding), (4) decided not to act, (5) decided to act (but not yet acting), (6) acting, and (7) maintenance of the health behavior. Using a questionnaire, we will capture the participants' stage of change before and after implementation of the incidental findings communication tool. The desired directionality of change is a higher stage with 7 being the maximum score and 1 being the minimum score., 3 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Montana
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 300
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: 25-0592-P0001
Start Date: 2024-10
Primary Completion Date: 2027-10
Completion Date: 2029-03
First Posted: 2023-06-12
Results First Posted:
Last Update Posted: 2023-06-12
Locations:
Study Documents:

NCT Number: NCT04094974
Study Title: Heartrate Variability and Intraoperative Brain Conditions in Supratentorial Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT04094974
Acronym:

Study Status: COMPLETED
Brief Summary: This study aims to determine the relationship between heart rate variability and intraoperative brain relaxation conditions in patients with brain tumors.
Study Results: NO
Conditions: Supratentorial Brain Tumors
Interventions: DEVICE: ANSiscope
Primary Outcome Measures: Brain relaxation, 1. Tight Brain-the brain surface is jutting out or expanding beyond the craniotomy margins, brain pulsations are not clearly defined.
2. Brain surface at level of craniotomy margins, Brain pulsations faintly observed
3. Brain surface just below the surface of craniotomy margin. Brain pulsations well seen.
4. Brain surface well below the surface of craniotomy margin, well retracted in to the cranial cavity with good brain pulsations.Brain relaxation score will me measured only once. There is no follow up, 2hours
Secondary Outcome Measures: Hemodynamic Measurement-Heartrate, The change in hemodynamic variable heart rate in beats per minute will be measured through the study period, 2hours|Hemodynamic Measurement-Bloodpressure, The change in hemodynamic variable blood pressure in mmHg will be measured through the study period, 2hours
Other Outcome Measures:
Sponsor: DyAnsys, Inc.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 58
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CS009
Start Date: 2019-10-12
Primary Completion Date: 2020-10-03
Completion Date: 2020-10-03
First Posted: 2019-09-19
Results First Posted:
Last Update Posted: 2021-01-25
Locations: National Institute of Mental Health and Neurosciences, Bengaluru, Karnataka, 560029, India
Study Documents:

NCT Number: NCT04395495
Study Title: RASopathy Biorepository
Study URL: https://beta.clinicaltrials.gov/study/NCT04395495
Acronym:
Study Status: RECRUITING
Brief Summary: The RASopathies are a group of developmental disorders

caused by genetic changes in the genes that compose the Ras/mitogen activated protein kinase (MAPK) pathway. New RASopathies are being diagnosed frequently. This pathway is essential in the regulation of the cell cycle and the determination of cell function. Thus, appropriate function of this pathway is critical to normal development. Each syndrome in this group of disorders has unique phenotypic features, but there are many overlapping features including facial features, heart defects, cutaneous abnormalities, cognitive delays, and a predisposition to malignancies. This research study proposes to collect and store human bio-specimens from patients with suspected or diagnosed RASopathies. Once obtained, blood and/or tissue samples will be processed for: metabolic function studies, biomarkers, genetic studies, and/or the establishment of immortalized cell lines. In addition, data from the medical record (including neuropsychological evaluations) and surveys will be stored to create a longitudinal database for research conducted at CCHMC or at other research institutions.
Study Results: NO
Conditions: RAS Mutation|Neurofibromatosis 1|Noonan Syndrome|Noonan Syndrome With Multiple Lentigines|Noonan Neurofibromatosis Syndrome|Cardiofaciocutaneous Syndrome|Costello Syndrome|Legius Syndrome|Smith-Kingsmore Syndrome|MTOR Gene Mutation|GATOR-1 Gene Mutation|SYNGAP1-Related Intellectual Disability|DLG4|MAPK1 Gene Mutation
Interventions:
Primary Outcome Measures: Collection of biospecimen, Collect specimens derived from blood, buccal cells, sputum, urine, bone marrow, tumor tissue and residual specimens, including but not limited to pleural fluid, ascetic fluid, chyle, skin, lung, lymphatic or renal tissue and/or bronchoalveolar lavage fluid, tissue specimens, and/or cells that are left over from clinical procedures from enrolled patients for research purposes only., 50 years|Collection of medical history, Collect demographic information, medical history, and clinical test results to create a longitudinal research database of participants with suspected or diagnosed RASopathies. Participants will also complete surveys to be included in the research database (see "Research Database" section for details)., 50 years
Secondary Outcome Measures: Release of Specimens and Clinical Data to Other Investigators for use in RASopathy Research, Release of fresh or frozen specimens and clinical data to both CCHMC and external investigators. Applications for use of bio-specimen and/or data must be approved by the Repository Use Committee through the completion of a specimen request form. Among other data, the specimen request form will require information concerning: Principal Investigator, funding sources, a research synopsis, Institutional Review Board (IRB) approval of the research project, and details about the required samples. At the time a de-identified sample is requested, the requesting investigator may also request de-identified clinical data if needed., 50 years
Other Outcome Measures:
Sponsor: Children's Hospital Medical Center, Cincinnati

Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 1000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2016-7017
Start Date: 2017-06-27
Primary Completion Date: 2065-12
Completion Date: 2065-12
First Posted: 2020-05-20
Results First Posted:
Last Update Posted: 2023-07-12
Locations: Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, 45229, United States
Study Documents: Study Protocol|Informed Consent Form

NCT Number: NCT04331535
Study Title: The Genomic Medicine at VA Study
Study URL: https://beta.clinicaltrials.gov/study/NCT04331535
Acronym: GenoVA
Study Status: RECRUITING
Brief Summary: This trial will determine the clinical effectiveness of polygenic risk score testing among patients at high genetic risk for at least one of six diseases (coronary artery disease, atrial fibrillation, type 2 diabetes mellitus, colorectal cancer, breast cancer, or prostate cancer), measured by time-to-diagnosis of prevalent or incident disease over 24 months.
Study Results: NO
Conditions: Coronary Artery Disease|Atrial Fibrillation|Type 2 Diabetes|Colorectal Cancer|Breast Cancer|Prostate Cancer
Interventions: DIAGNOSTIC_TEST: Polygenic risk score (PRS)
Primary Outcome Measures: Time-to-new diagnosis of common complex disease, The primary outcome of the study is time-to-diagnosis both of undiagnosed prevalent cases of the 6 target conditions and incident cases during the study period. This composite outcome will only include clinically significant diagnoses, as adjudicated by expert clinical chart review., 24 months after enrollment
Secondary Outcome Measures: Diagnostic testing, Any evidence that the patient-participant underwent additional diagnostic testing for the six target diseases since enrollment: coronary artery disease (stress testing, cardiac CT for coronary artery calcium (CAC), coronary angiography), atrial fibrillation (ECG, heart rhythm monitoring), type 2 diabetes (hemoglobin A1c, blood glucose), colorectal cancer (colonoscopy, sigmoidoscopy, fecal blood testing, CT colonography), breast cancer (mammography, breast MRI, breast ultrasound, breast biopsy), and prostate cancer (PSA testing, prostate biopsy)., 24 months after enrollment|Patient activation, Self-reported

understanding, competence, and willingness to participate health care decisions and processes assessed on the baseline and end-of-study surveys, using the 13-item short form of the Patient Activation Measure (Hibbard, Health Services Research 2005)., Baseline and 24 months after enrollment|Healthcare costs, A combination of administrative data and microcosting approaches will be used to estimate the costs of the intervention and the subsequent patient-level healthcare costs over the 24 months after enrollment. Estimates of the infrastructure and personnel needed to deliver the intervention will be derived empirically from the study. Healthcare costs will be abstracted from billing and administrative data., 24 months after enrollment|Medication adherence, Self-report of taking medications as prescribed assessed on the baseline and end-of-study surveys, using the 3-item Voils Medication Adherence Survey (Voils, Medical Care, 2012)., Baseline and 24 months after enrollment
Other Outcome Measures: Provider knowledge and beliefs about PRS, Semi-structured interviews will collect qualitative data on participating providers' understanding of and perceived utility of the PRS risk information., 24 months after enrollment|Blood pressure, The most recent systolic and diastolic blood pressure values recorded in the medical record prior to or on the date of enrollment and prior to or on the date 24 months after enrollment., Baseline and 24 months after enrollment|Body-mass index (BMI), The most recent BMI values recorded in the medical record prior to or on the date of enrollment and prior to or on the date 24 months after enrollment., Baseline and 24 months after enrollment|Aspirin use, Self-reported use of prescription or over-the-counter aspirin will be assessed on the baseline and end-of-study surveys., Baseline and 24 months after enrollment|Physical activity, Self-reported physical will be assessed on the baseline and end-of-study surveys using the Rapid Assessment of Physical Activity., Baseline and 24 months after enrollment.|Alcohol intake, Self-reported alcohol will be assessed on the baseline and end-of-study surveys using measures from the Behavioral Risk Factor Surveillance System, recorded as an ordinal 5-item Likert response (from "Never" to "Very often")., Baseline and 24 months after enrollment|Processed meat consumption, Self-reported processed meat intake assessed on the baseline and end-of-study surveys using a food frequency question from National Cancer Institute Eating Habits Questionnaire, recorded as an ordinal 5-item Likert response (from "Never" to "Very often")., Baseline and 24 months after enrollment|Low-density lipoprotein cholesterol (LDL-C), The most recent LDL-C values recorded in the medical record prior to or on the date of enrollment and prior to or on the date 24 months after enrollment., Baseline and 24 months after enrollment|Smoking status, Self-reported smoking status will be assessed on the baseline and end-of-study surveys using measures from the Behavioral Risk Factor Surveillance System., Baseline and 24 months after enrollment|Risk-reducing medication prescriptions, Relevant prescription medication changes during 24-month observation period, including antihypertensives, cholesterol-lowering medications, anticoagulants, antiplatelet

medications, 5-alpha reductase inhibitors, selective estrogen receptor modulators, aromatase inhibitors, as abstracted from medical record review., 24 months after enrollment|Health status and quality of life, As determined by data collected from the baseline survey (VR-12), Baseline and 24 months after enrollment
Sponsor: Boston VA Research Institute, Inc.
Collaborators: VA Boston Healthcare System
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1076
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SCREENING
Other IDs: 0594
Start Date: 2020-07-17
Primary Completion Date: 2025-09-30
Completion Date: 2025-09-30
First Posted: 2020-04-02
Results First Posted:
Last Update Posted: 2022-10-03
Locations: VA Boston Healthcare System, Boston, Massachusetts, 02130-4817, United States
Study Documents: Informed Consent Form

NCT Number: NCT04260269
Study Title: Feasibility of Switching Fluoropyrimidine Due to Cardiotoxicity Study
Study URL: https://beta.clinicaltrials.gov/study/NCT04260269
Acronym: CardioSwitch
Study Status: ENROLLING_BY_INVITATION
Brief Summary: The purpose of the present study is to evaluate cardiotoxicity during re-challenge of a different modality of fluoropyrimidine (primary end-point S-1 and secondary any other fluoropyrimidine) after having perceived cardiotoxicity with a fluoropyrimidine based regimen previously. The patient population is being treated for solid tumors.
Study Results: NO
Conditions: Solid Tumor
Interventions: DRUG: Fluoropyrimidine
Primary Outcome Measures: Recurrence of fluoropyrimidine related cardiac toxicity after switch to S-1 based treatment, Cardiac tolerability according to NCI-CTCAE following cardiotoxicity initiated switch of fluoropyrimidine to S-1, After switch to and during one line of S-1 based chemotherapy (average 6 months)
Secondary Outcome Measures: Recurrence of fluoropyrimidine related cardiac toxicity after switch to any fluoropyrimidine, Cardiac tolerability according to NCI-CTCAE following cardiotoxicity initiated switch of fluoropyrimidine to another fluoropyrimidine chemotherapy,

After switch to and during one line of another fluoropyrimidine regimen (average 6 months)|Cardiac symptoms during fluoropyrimidine chemotherapy, Frequency and severity according to NCI-CTCAE of cardiac symptoms during different fluoropyrimidines and the correlation with other added cytotoxics or biologics, During one line of fluoropyrimidine based chemotherapy (average 6 months)|Diagnostic work-up, Diagnostic work-up for cardiotoxicity in real world data, During one line of fluoropyrimidine based chemotherapy (average 6 months)|Time-lines for cardiotoxicity, Time-lines for appearance of cardiotoxicity during fluoropyrimidine-based chemotherapy, During one line of fluoropyrimidine based chemotherapy (average 6 months)|Dose-intensity, Dose-intensity of the therapy at the cycle causing cardiotoxicity, During one cycle (average 3 weeks) of fluoropyrimidine-based chemotherapy causing cardiac toxicity| Alteration in cardiac functional parameters during fluoropyrimidine treatment induced cardiotoxicity, The alterations of (if evaluated), graded as normal, non-significant abnormalities or significant abnormalities.:

* ECG abnormalities
* Ejection fraction in %
* Coronary artery status on angiogram
* Cardiac arrhythmias in ECG, Holter or cardiac monitor registration
* Plasma troponin concentration and other cardiac enzymes and other laboratory tests as within reference range ro abnormal
* Serum alpha-fluoro-beta-alanine (FBAL) concentration, During one cycle (average 3 weeks) of fluoropyrimidine-based chemotherapy causing cardiac toxicity

Other Outcome Measures:
Sponsor: Helsinki University Central Hospital
Collaborators: Tampere University Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 200
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: R18045
Start Date: 2018-06-01
Primary Completion Date: 2020-12
Completion Date: 2025-12
First Posted: 2020-02-07
Results First Posted:
Last Update Posted: 2020-02-07
Locations: Odense University Hospital, Odense, Denmark|Department of Oncology, Tampere, Pirkanmaa, 33520, Finland|Helsinki University Central Hospital, Helsinki, Uusimaa, 00290, Finland|Oulu university hospital, Oulu, Finland|Turku university hospital, Turku, Finland| Landspitali, Reykjavík, Iceland|St. Vincents University Hospital,

Dublin, Ireland|Academic Medical Center, Amsterdam, Netherlands|Haukeland University Hospital, Bergen, Norway|Skone university hospital, Lund, Sweden|Karolinska University Hospital, Stockholm, Sweden|Sundsvall hospital, Sundsvall, Sweden|Uppsala academic hospital, Uppsala, Sweden
Study Documents:

NCT Number: NCT04325269
Study Title: Continuous Ambulatory ECG Monitoring for Detection of Postoperative Atrial Fibrillation Following Thoracic Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT04325269
Acronym:
Study Status: UNKNOWN
Brief Summary: Atrial fibrillation (AF) is a common and serious complication after lung resection. The incidence is likely underestimated, and risk may persist after leaving hospital. Recent development of simple wearable patch ECG devices may provide sensitive detection of AF in the extended postoperative period. Specific biomarkers may allow us to predict which patients are at risk of developing postoperative AF.
Study Results: NO
Conditions: Lung Cancer|Atrial Fibrillation
Interventions:
Primary Outcome Measures: Absolute incidence of postoperative atrial fibrillation, Detected by device, 14 days postop
Secondary Outcome Measures: Rate of accrual relative to the number of eligible patients per month, Determined by proportion of patients enrolled, 6-month recruitment period|90-day mortality, Determined by telephone follow-up and check of medical records, 90 days following surgery|Incidence of stroke, Clinical diagnosis based on treatment, 90 days following surgery|Atrial fibrillation burden, Number of atrial fibrillation events per patient developing POAF, 14 days postop|Atrial fibrillation burden, Duration of atrial fibrillation events per patient developing POAF, 14 days postop|Incidence of preoperative subclinical atrial fibrillation, Number of patients with subclinical AF prior to surgery, 14 days within 6 weeks prior to surgery|Adherence to study protocol: Number of patients completing full 14-day use of CardioSTAT device, Number of patients completing full 14-day use of CardioSTAT device, 14 days preop, 14 days postop|Adherence to study protocol: Number of days CardioSTAT device worn per patient, Number of days CardioSTAT device worn per patient, 14 days postop|Adherence to study protocol: Number of patients completing symptom journal, Number of patients completing symptom journal, 14 days postop
Other Outcome Measures:
Sponsor: University of Manitoba
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100

Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: HS23428
Start Date: 2020-04-01
Primary Completion Date: 2021-02-01
Completion Date: 2021-06-01
First Posted: 2020-03-27
Results First Posted:
Last Update Posted: 2020-04-03
Locations: Health Sciences Centre, Winnipeg, Manitoba, R3A1R9, Canada
Study Documents:

NCT Number: NCT00000611
Study Title: Women's Health Initiative (WHI)
Study URL: https://beta.clinicaltrials.gov/study/NCT00000611
Acronym:
Study Status: COMPLETED
Brief Summary: To address cardiovascular disease, cancer, and osteoporosis, the most common causes of death, disability, and impaired quality of life in postmenopausal women. The three major components of the WHI are: a randomized controlled clinical trial of hormone replacement therapy (HRT), dietary modification (DM), and calcium/vitamin D supplementation (CaD); an observational study (OS); and a community prevention study (CPS). On October 1, 1997, administration of the WHI was transferred to the NHLBI where it is conducted as a consortium effort led by the NHLBI in cooperation with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Cancer Institute (NCI), and the National Institute on Aging (NIA).
Study Results: NO
Conditions: Bone Diseases|Breast Neoplasms|Cardiovascular Diseases|Colonic Neoplasms|Coronary Disease|Heart Diseases|Myocardial Ischemia|Osteoporosis|Postmenopause
Interventions: DRUG: hormone replacement therapy|DRUG: estrogens|DRUG: progestins|DRUG: estrogen replacement therapy|BEHAVIORAL: diet, fat-restricted|DRUG: calcium|DRUG: vitamin D|BEHAVIORAL: dietary supplements
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
Collaborators: National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)|National Cancer Institute (NCI)|National Institute on Aging (NIA)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment:
Funder Type: NIH

Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: |Masking: |
Primary Purpose: PREVENTION
Other IDs: 114
Start Date:
Primary Completion Date: 2005-03
Completion Date:
First Posted: 1999-10-28
Results First Posted:
Last Update Posted: 2016-04-15
Locations:
Study Documents:

NCT Number: NCT05223413
Study Title: REmote iSchemic condItioning in Lymphoma PatIents REceiving ANthraCyclinEs
Study URL: https://beta.clinicaltrials.gov/study/NCT05223413
Acronym: RESILIENCE
Study Status: RECRUITING
Brief Summary: Multinational, prospective, proof of concept phase II, double-blinded, sham-controlled, randomized clinical trial (RCT) to evaluate the efficacy and safety of Remote Ischaemic PreConditioning (RIPC) in Non-Hodgkin lymphoma (NHL) patients receiving anthracyclines.
Study Results: NO
Conditions: Anthracycline-induced Cardiac Toxicity|Non-Hodgkin Lymphoma
Interventions: DEVICE: RIPC|DEVICE: Simulated RIPC (Sham)
Primary Outcome Measures: Primary efficacy endpoint: (RIC vs Sham) Absolute change in LVEF, change in LVEF between baseline and any follow-up CMRs, whichever shows worse LVEF

UNITS: LVEF is expressed as % LVEF= (LV end-diastolic volume - LV end-systolic volume) / LV end-systolic volume), %, 9 weeks after the last chemotherapy cycle (anticipated to be between 150 and 200 days from enrollment)
Secondary Outcome Measures: Rate of anthracycline-induced cardiotoxicity events, Cardiotoxicity event is defined as one of the following:

* Drop in LVEF between study CMRs of ≥10 absolute points regardless the absolute value of follow- up ejection fraction (EF).
* Drop in LVEF between study CMRs of ≥5 to \<10 absolute points with a follow-up EF value \<50%

UNITS: absolute number of patients in each arm qualifying for cardiotoxicity event (i.e. each patient will be qualified at the end of the study as YES/NO)., 9 weeks after the last chemotherapy cycle (anticipated to be between 150 and 200 days from enrollment)|Rate of tumor regression., Response to chemotherapy

UNITS: absolute number of patients in each arm qualifying as responder or no responder (i.e. each patient will be qualified at the end of the study as YES/NO)., 9 weeks after the last chemotherapy cycle (anticipated to be between 150 and 200 days from enrollment)|Change in Quality of Life-Haematological Malignancy Patient-Reported Outcome Measure questionnaire, Haematological Malignancy Patient-Reported Outcome Measure (HM-PRO) questionnaire

UNITS: absolute points in the questionnaire. minimum value 0 maximum value 84

the higher the total score, the better (greater the effect on a patient's QoL), 9 weeks after the last chemotherapy cycle (anticipated to be between 150 and 200 days from enrollment)|Change in Quality of Life-Euro Quality of Life-5 dimensions questionnaire, Euro Quality of Life-5 dimensions (EuroQoL-5D) questionnaire:

UNITS: absolute points in the questionnaire. minimum value 0 maximum value 100

the higher the total score, the better (greater the effect on a patient's QoL), 9 weeks after the last chemotherapy cycle (anticipated to be between 150 and 200 days from enrollment)|Change in Quality of Life-Kansas City Cardiomyopathy Questionnaire, Kansas City Cardiomyopathy Questionnaire (KCCQ-12)

UNITS: absolute points in the questionnaire. minimum value 0 maximum value 65

the higher the total score, the better (greater the effect on a patient's QoL), 9 weeks after the last chemotherapy cycle (anticipated to be between 150 and 200 days from enrollment)|Rate of Heart Failure Hospitalization, Rate of Heart Failure Hospitalization

UNITS: Absolute number of patients in each arm experiencing a heart failure hospitalization, 6-42 months
Other Outcome Measures:
Sponsor: Fundación Centro Nacional de Investigaciones Cardiovasculares Carlos III
Collaborators: European Commission
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 608
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION

Other IDs: RESILIENCE-H2020
Start Date: 2022-01-18
Primary Completion Date: 2025-08
Completion Date: 2026-05
First Posted: 2022-02-04
Results First Posted:
Last Update Posted: 2022-10-06
Locations: Aarhus University, Aarhus, Denmark|Henri Becquerel, Rouen, France|University Hospital Duesseldorf UDUS, Duesseldorf, Germany|Amsterdam UMC, Amsterdam, Netherlands|Hospital da Luz Learning Health (GLSMED), Lisboa, Portugal|IPO Lisboa, Lisboa, Portugal|Instituto Catalán de Oncología, Barcelona, Spain|Hospital Universitario Virgen de las Nieves, Granada, Spain|Centro Nacional de Investigaciones Cardiovasculares (CNIC), Madrid, Spain|Fundacion Jimenez Diaz, Madrid, Spain|Hospital General Universitario Gregorio Marañon, Madrid, Spain|Hospital Puerta de Hierro, Madrid, Spain|Hospital Universitario 12 de Octubre, Madrid, Spain|Hospital Universitario Clínico San Carlos, Madrid, Spain|Hospital Universitario la Paz, Madrid, Spain|Hospital Universitario Ramon y Cajal, Madrid, Spain|Hospital Universitario de Salamanca, Salamanca, Spain|Hospital Universitario Virgen del Rocío, Sevilla, Spain|Hospital Clinico Universitario de Valladolid, Valladolid, Spain
Study Documents:

NCT Number: NCT00532064
Study Title: Cardiac Biomarkers in Early Detection of Cardiotoxicity in Patients Receiving Sunitinib or Sorafenib Chemotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT00532064
Acronym:
Study Status: TERMINATED
Brief Summary: This trial studies how well cardiac biomarkers work in the early detection of cardiotoxicity in patients receiving sunitinib malate or sorafenib chemotherapy. Some chemotherapies are known to cause damage to heart muscle cells, resulting in heart failure. Often, the damage is not detected until heart failure has already occurred. Testing for cardiac biomarkers, such as troponin I and/or T and B-type natriuretic peptide (BNP), may be useful in detecting heart damage earlier than other tests currently performed (such as echocardiogram and electrocardiogram).
Study Results: NO
Conditions: Malignant Neoplasm
Interventions: PROCEDURE: Biospecimen Collection|OTHER: Questionnaire Administration
Primary Outcome Measures: Sensitivity of each biomarker for detecting cardiotoxicity, Will estimate with exact 95% confidence intervals., Up to 6 months|Specificity of each biomarker for detecting cardiotoxicity, Will estimate with exact 95% confidence intervals., Up to 6 months
Secondary Outcome Measures: Incidence of cardiotoxicity, Will use the methods of Gooley, et al (1999) to estimate the cumulative incidence

of cardiotoxicity while considering deaths from other causes as a competing risk. Will estimate the cumulative incidence of cardiotoxicity while stratifying by common risk factors (one at a time). Will use mixed linear models to model the biomarker levels over time, accounting for the correlation between biomarker levels within patient. Will use logistic regression to model the log odds of cardiotoxicity as a function of common risk factors for cardiotoxicity. Will also include the duration of chemotherapy use and the MD Anderson Symptom Inventory - Heart Failure (MDASI-HF) score as a potential prognostic factor for cardiotoxicity., Up to 6 months|MD Anderson Symptom Inventory - Heart Failure (MDASI-HF) score, Will summarize the MD Anderson Symptom Inventory - Heart Failure (MDASI-HF) score over time with descriptive statistics and boxplots., Up to 6 months
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 55
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2006-0921|NCI-2018-02471|2006-0921|P30CA016672
Start Date: 2007-09-12
Primary Completion Date: 2018-05-02
Completion Date: 2018-05-02
First Posted: 2007-09-19
Results First Posted:
Last Update Posted: 2020-01-22
Locations: M D Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT04928261
Study Title: Evaluating 6-months of HER2-targeted Therapy in Patients With HER2 Positive Early-stage Breast Cancer That Achieve a Pathological Complete Response to Neoadjuvant Systemic Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04928261
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The activity of trastuzumab in early-stage, HER2-positive breast cancer, has been demonstrated in many studies, with meta-analyses showing that in combination with a variety of chemotherapy backbones, trastuzumab reduces the risk of recurrence by nearly half, and death by a third. However, treatment with trastuzumab can result in cardiotoxicity, including heart failure, as well as the significant cost of treatment and the requirement for patients to attend the chemotherapy unit for treatment every 3 weeks for one year.

Therefore there has been increasing interest in identifying which patients can safely have less treatment. The investigators therefore propose a real-world, single arm, multicentre trial evaluating 6 months of HER2 targeted therapy, for patients with early-stage, HER2 positive breast cancer, who achieve a pathological complete response (pCR) with upfront systemic chemotherapy and HER2 targeted therapy.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Trastuzumab
Primary Outcome Measures: Multiple site activation, Evaluating the feasibility of multiple Canadian site activation within the first year of study accrual. Achieved by the activation of at least 4 Canadian sites within 1 year of the first patient being accrued into the study., 1 year after first participant is accrued|Medical oncologist active participation, Evaluating the number of medical oncologists at each study site who actively participate in the trial. Active participation includes approaching eligible patients for the study, as well as following up with the patients who are taking part in the study., Through to end of accrual - average 2 years|Enrolment of at least 50 participants across all sites within 9 months of the fourth site accruing its first participant, Enrolment of at least 50 participants across all sites within 9 months of the fourth site accruing its first participant., 9 months after fourth site accrues first participant
Secondary Outcome Measures: Cardiac events, Cardiac events defined as death from a cardiac or heart failure of New York Heart Association (NYHA) class III or IV, or with a decrease in the left ventricular ejection fraction of at least 10 percentage points from baseline to a value of less than 50%. Cardiac monitoring will be assessed as per physician standards, 3 years after study enrolment|Rate of HER2-positive treatment discontinuation, De-escalated HER2-positive treatment discontinuation and the reasons why treatment was discontinued, 6 months after study enrolment|Health-related quality of life, Health-related quality of life measure using the EuroQol-5 Dimension-5 Level (EQ-5D-5L) questionnaire., Baseline, 3, 6, 12 and 36 months after study enrolment|Incremental cost-effectiveness ratios, The difference in cost between 6 months of HER2-positive therapy versus the standard 12 months of HER2-positive therapy., 3 years from study enrolment|Disease free survival, Disease Free Survival (DFS), defined as the percentage of people in the trial who are alive and disease-free (no local invasive breast cancer recurrence, new local invasive breast cancer) at 3 years, 3 years from study enrolment|Overall survival, Overall Survival (OS), defined as the number of people alive, with or without signs of cancer at 3 years, 3 years from study enrolment
Other Outcome Measures:
Sponsor: Ottawa Hospital Research Institute
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: PHASE4
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: REaCT-HER TIME
Start Date: 2021-12-13
Primary Completion Date: 2023-09
Completion Date: 2023-09
First Posted: 2021-06-16
Results First Posted:
Last Update Posted: 2023-03-02
Locations: The Ottawa Hospital Cancer Centre, Ottawa, Ontario, K1H8M2, Canada
Study Documents:

NCT Number: NCT04652973
Study Title: Evaluation of Atherosclerotic Plaques in Abdominal CT Studies
Study URL: https://beta.clinicaltrials.gov/study/NCT04652973
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Background:

Fat and calcium can build up as plaque in artery walls. The Agatston score measures plaque using computed tomography (CT) that does not use an injected contrast agent. Plaque in the arteries of the pelvis and abdomen is linked to cardiovascular disease (CVD) risk factors. It also may affect cancer. But abdominal CTs use a contrast agent (CECT). Therefore, the Agatston score cannot be used. Researchers want to find a way to measure plaque in CECTs. This will help them use abdominal CTs to measure plaque without extra radiation.

Objective:

To measure atherosclerotic plaques on CECT in a group of males.

Eligibility:

Men ages 30-90 with prostate cancer (proven with biopsies) who have abdomen CT studies in the PACS (picture archiving system) in the Clinical Center. Also, men or women of all ages who have multiphase abdomen and pelvic CT studies that are in the PACS.

Design:

This study will use data gathered since 1/1/2013. Data will also be taken from protocol 03-CC-0128 and clinical trials 15-C-0124, 16-C-0048, 14-C-0112, and 04-C-0274. Participants from these studies have

allowed their samples to be used in the future.

Participants will be found via keyword searches on NIH databases. Their CT and MRI scans will be used. Data such as age, race, disease, and treatment will be used. Results of other tests may be used.

The plaque in participants abdomen and iliac arteries will be measured. It will be compared with biomarkers related to CVD and prostate cancer, such as weight, age, and race.

This study will take place at one site. Data will be stored on secure computers. Printouts will be kept in locked rooms.
Study Results: NO
Conditions: Prostatic Neoplasms
Interventions:
Primary Outcome Measures: 1/Measure atherosclerotic plaques, Measure atherosclerotic plaques on contrast-enhanced computed tomography (CECT), End of study
Secondary Outcome Measures: 2/Plaque measurement and clinical biomarkers correlation, Find correlation between plaque measurement and clinical biomarkers of prostate cancer patients., End of study
Other Outcome Measures:
Sponsor: National Institutes of Health Clinical Center (CC)
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 1000
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 10000123|000123-CC
Start Date: 2020-11-19
Primary Completion Date: 2030-08-30
Completion Date: 2030-08-30
First Posted: 2020-12-04
Results First Posted:
Last Update Posted: 2023-01-27
Locations: National Institutes of Health Clinical Center, Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT05833360
Study Title: Prospective Study of oncRNA Stratification of Cancer by Size and Stage
Study URL: https://beta.clinicaltrials.gov/study/NCT05833360
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: Cancer strikes about one in three women and one in two men in the U.S. and more than 600,000 die from it each year. The best

chance to reduce these numbers and save lives is through early detection and intervention.

The investigators are developing a blood test to detect cancer from a simple blood draw also referred to as a liquid biopsy. This test is based on orphan non-coding RNAs (oncRNAs) that are abundant in the blood of patients with cancer and largely absent in people without cancer. Using artificial intelligence (AI) and machine learning (ML) investigators are able to interpret the thousands of oncRNAs found in the blood of patients with cancer by identifying unique, cancer-specific patterns. oncRNA patterns can be used to detect several types of cancer and detect cancer at the earliest stages.

This is a prospective, observational study to collect blood samples and medical information from participants with and without cancer to represent the population in the USA. The investigators have designed the study to include participants without cancer, participants with conditions that are a predisposition for cancer, participants with pre-malignant lesions, and participants with cancer. Patients with a wide variety of cancers are going to be included i.e. bladder, breast, colorectal, esophageal, gastric, kidney, liver, lung, ovarian, pancreatic, prostate, and uterine cancer.

Each participant will be asked to donate a small blood sample and to share their medical information. The participant's medical information will be updated during the course of the study. The blood will be tested for oncRNA. The objective is to create a blood repository and associated medical database to develop a blood test for cancer, for different cancer types. The study is designed to be inclusive and represent the population in America.

If this study is successful, the results will enable a world where cancer can be detected early with a simple blood test and diagnosed accurately, with better chances of cure. The investigators believe this study has the potential to transform cancer detection in America.
Study Results: NO
Conditions: Kidney Cancer|Liver Cancer|Lung Cancer|Ovarian Cancer|Pancreatic Cancer|Prostate Cancer|Uterine Cancer|Bladder Cancer|Breast Cancer|Colorectal Cancer|Esophageal Cancer|Gastric Cancer|Arthritis|Benign Prostatic Hypertrophy|Chronic Kidney Diseases|COPD|Chronic Prostatitis|Depression|Diabetes|Heart Failure|Hypercholesterolemia|Hypertension|Ischemic Heart Disease|Inflammatory Bowel Diseases|Chronic Pancreatitis|Cirrhosis|Hepatitis|Non-Alcoholic Fatty Liver Disease|Helicobacter Pylori Infection|Advanced Adenocarcinoma|Intraductal Papillary Mucinous Neoplasm|Gastric Polyp|DCIS
Interventions: DEVICE: Exai oncRNA blood test
Primary Outcome Measures: Optimize non-invasive cancer biomarker tests based on its small noncoding (snc)RNA technology, Analyze small noncoding (snc)RNA profiles differentially expressed in specimens obtained from case and control subjects to identify candidate sncRNA

biomarkers for use in deriving and optimizing oncRNA diagnostic models for multiple cancer applications, including screening, early diagnosis, minimal residual disease and monitoring for tumor recurrence, Seven years|Optimize oncRNA test clinical performance, Assess small noncoding (snc)RNA profiles potentially associated with demographic parameters, medication use, comorbid conditions, and/or cancer-predisposing conditions which might overlap with candidate cancer biomarkers to optimize oncRNA model clinical specificity performance, i.e., minimize false positives., Seven years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Exai Bio Inc.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 2400
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CP-23001
Start Date: 2023-07-30
Primary Completion Date: 2030-07-30
Completion Date: 2030-07-30
First Posted: 2023-04-27
Results First Posted:
Last Update Posted: 2023-06-18
Locations:
Study Documents:

NCT Number: NCT02136277
Study Title: Vascular Changes During Colorectal Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT02136277
Acronym: MaMiFlo
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to investigate whether increases in the blood flow from the heart (the cardiac output), induced by the administration of intravenous fluids, lead to an increase in the blood flow to the vital organs, in patients undergoing bowel surgery.

This study will involve 2 phases. Firstly, potential volunteers will be invited to meet the research fellow (medical doctor) undertaking this study, who will check their suitability to participate in the study and who will obtain informed consent.

The second phase is the study itself which will take place whilst volunteers are having their bowel operation. They will attend theatre in the normal way, but once they have been anaesthetised (put to sleep), a special monitor called an oesophageal doppler probe will be

placed into their oesophagus (food pipe) via the nose. This monitor is frequently used in bowel surgery to help assess how much intravenous fluid to administer to a patient by measuring the cardiac output (the amount of blood pumped out of the heart each minute). Using the cannula (drip) already inserted in the arm to allow administration of the anaesthetic, a special fluid, called an ultrasound contrast agent, will be injected into the drip, to allow a contrast enhanced ultrasound scan of the abdominal organs to be performed, to measure the blood flow to these organs. A small sample of blood will be taken from the earlobe to allow us to measure a chemical in the blood called lactate.

After this, intravenous fluid will be administered in order to increase the amount of blood pumped out of the heart. Once the oesophageal doppler monitor suggests that an adequate amount of fluid has been given, a second ultrasound scan will be performed to measure whether blood flow to the abdominal organs has also increased. A further blood sample will be taken from your earlobe to measure any change in lactate level.

At the completion of the operation, a third ultrasound scan will be performed and another sample of blood taken from the earlobe, to help assess blood flow to the organs.
Study Results: NO
Conditions: Patients Undergoing Open Resection of Colorectal Tumours
Interventions: DRUG: Hartmann's solution
Primary Outcome Measures: Changes in microvascular blood flow during colorectal surgery, Immediately following optimisation of cardiac output
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Nottingham
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 32
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 13115
Start Date: 2015-01
Primary Completion Date: 2016-01
Completion Date: 2016-06
First Posted: 2014-05-12
Results First Posted:
Last Update Posted: 2015-01-27
Locations: Royal Derby Hospital, Derby, Derbyshire, DE22 3NE, United Kingdom
Study Documents:

NCT Number: NCT04746729
Study Title: Health Effects of CArdiac FluoRoscopy and MOderN RadIotherapy in PediatriCs - Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04746729
Acronym: HARMONIC-RT
Study Status: RECRUITING
Brief Summary: The goal of the HARMONIC-RT study is to evaluate late health and social outcomes of modern external beam radiotherapy techniques in paediatric patients, based on the setting-up of a European, long-term registry complemented by a biobank.
Study Results: NO
Conditions: Neoplasms
Interventions: OTHER: No intervention
Primary Outcome Measures: Endocrinopathies, Late health outcomes, up to 20 years after RT|Cardiovascular diseases, Late health outcomes

* Neurovascular diseases
* Second and subsequent primary neaoplasms, up to 20 years after RT|Neurovascular diseases, Late health outcomes, up to 20 years after RT|Second and subsequent primary neaoplasms, Late health outcomes, up to 20 years after RT|Health-related quality of life (physical, emotional, social, and school functioning) assessed by the PedsQL™ core scale (validated questionnaire), Late social outcomes, up to 10 years after radiation therapy or attained age 25 years, whichever occurs first|Academic achievement, Late social outcomes, up to 10 years after radiation therapy or attained age 25 years, whichever occurs first
Secondary Outcome Measures: Dysfunctions in endocrine hormone levels, measured as:

1. insulin-like growth factor-1,
2. anterior pituitary hormones (GH, ACTH, TSH, LH, FSH),
3. thyroid hormones (fT3, fT4),
4. sexual hormones, up to 10 years after radiation therapy|Changes in blood markers of cardiovascular diseases, measured as blood markers (incl. troponin, BNP, CPK), up to 10 years after radiation therapy|Changes in imaging markers of cardiovascular diseases, measured as cardiac echography parameters (incl. ejection fraction, diastolic function), up to 10 years after radiation therapy|Changes in imaging markers of neurovascular damages, measured as scoring of large and small vessel damages, up to 5 years after radiation therapy|Changes in blood/saliva markers of protein activation relating to vascular damages, measured as signal quality of protein activity, up to 1 year after radiation therapy|Changes in blood/saliva markers of oxidative stress response, measured as markers of oxidative stress (incl. 8-oxo-dG, SOD2, DNA repair enzymes), up to 1 year after radiation therapy|Changes in blood/saliva markers of inflammatory response, Inflammatory markers (incl. PTX3, CRP, NF-kB, IL-1 and IL10), up to 1 year after radiation therapy|Changes in blood/saliva markers of carcinogenesis, Markers of carcinogenesis (incl. leukocyte telomere length,

mitochondrial DNA copy number, circulating microRNA), up to 1 year after radiation therapy|Multidimensional fatigue (general, sleep/rest, and cognitive fatigue), PedsQL™ multidimensional fatigue scale (validated questionnaire), up to 10 years after radiation therapy or attained age 25 years, whichever occurs first|Clinical events other than those mentioned as primary outcomes, Late morbidity, up to 20 years after radiation therapy|All-cause and cause-specific mortality, Late mortality, up to 20 years after radiation therapy
Other Outcome Measures:
Sponsor: Institut National de la Santé Et de la Recherche Médicale, France
Collaborators: Barcelona Institute for Global Health|The West German Proton Therapy Centre, Essen|Gustave Roussy, Cancer Campus, Grand Paris|Centre Francois Baclesse|KU Leuven|University of Aarhus|Princess Maxima Center for Pediatric Oncology|University Medical Center Groningen|Stockholm University|National Research Council, Institute of Clinical Physiology, Italy|University of Zurich|Commissariat A L'energie Atomique|Luxembourg Institute of Science and Technology| University Hospital, Essen|Aarhus University Hospital
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 2670
Funder Type: OTHER_GOV
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: C20-01|2020-A01037-32/1
Start Date: 2022-03-01
Primary Completion Date: 2040-09-30
Completion Date: 2040-09-30
First Posted: 2021-02-10
Results First Posted:
Last Update Posted: 2021-03-16
Locations: KU Leuven, Leuven, Belgium|Aarhus University hospital, Aarhus, Denmark|Centre Régional François Baclesse, Caen, France| Gustave Roussy, Villejuif, France|University Hospital Essen, The West German Proton Therapy Centre Essen, Essen, Germany
Study Documents:

NCT Number: NCT03781661
Study Title: Providing Patient Information and CT Examination Results
Study URL: https://beta.clinicaltrials.gov/study/NCT03781661
Acronym: INFOCT
Study Status: COMPLETED
Brief Summary: Chest pain is a common cause of visits in the Emergency Room and General Practice, and is most commonly connected as a symptom of coronary disease, as for instance angina pectoris and acute myocardial infarct. Approximately 75-80% of these patients are not diagnosed with coronary disease or other cardiac findings. However, many of these patients still report chest pain and worries about

cardiac disease.

This study is based on patients that are referred to a CT-examination of the coronary arteries on the background of chest pain, where the CT-examination shows normal coronary arteries.

The study aims to evaluate whether providing an intervention to this group of patients has an effect on patient satisfaction, patient's worry of cardiac disease and incidence of chest pain.

The intervention group will be compared with a similar group going through the same CT-examination, but is receiving the examination result from their regular general practitioner (RGP), which is considered standard care.

The hypothesis is that patients with chest pain with no coronary findings receiving extended information before getting the normal examination results experience a better patient satisfaction than those receiving the examination result from their RGP.
Study Results: NO
Conditions: Chest Pain|Nonmalignant Condition
Interventions: OTHER: Extended information
Primary Outcome Measures: Patient satisfaction: Seattle Angina Questionnaire, Our primary outcome is to examine whether patients with chest pain with normal coronary arteries experience greater satisfaction with their treatment if they receive extended information and the examination results immediately after the CT examination than those who receive the examination result from their RGP.

This is measured with 2 single items in Seattle Angina Questionnaire regarding satisfaction with treatment. Values range from 1-5, 1 is the lowest level of satisfaction, and 5 is the highest level of satisfaction. Greater satisfaction with treatment will be defined by a higher score at follow-up after 1 month.

In addition, there is a separate question of patients' trust in the CT examination measured with a VAS-scale , ranging from 1-10, 1 represents lowest possible degree of trust, and 10 represents highest possible degree of trust. Greater trust in the CT-examination is defined by higher scores at follow-up after 1 month., 1 month
Secondary Outcome Measures: Worry of having heart disease, To examine if patients report less worry of having a heart attack or sudden death after having a CT examination of the heart's arteries, when receiving extended information and the normal examination result immediately after the CT examination.

This is measured with a single item in Seattle Angina Questionnaire regarding worry of having heart attack or die suddenly. Values range from 1-5, 1 represents "worry all the time" and 5 represents "never worry". Less worry of having a heart attack or die suddenly will be

defined by higher scores at follow-up after 1, 6 and 12 months., 1 month, 6 months, 12 months|Incidence of chest pain, To examine if patients with chest pain with normal coronary arteries report less chest pain and/or less use of health care services if they receive extended information and the examination results immediately after the CT examination compared to those who receive the examination result from their RGP.

This is measured with 2 single items in Seattle Angina Questionnaire. One item regards limitations in everyday activities because of chest pain. Values range from 1-5, 1 represents lowest level, and 5 represents highest level of function. The second item is about incidence of chest pain the last week. Values range from 1-5, 1 represents high incidence of chest pain and 5 represents no chest pain. Less chest pain is associated with higher scores at all times of follow up, compared to baseline.

In addition, clinical data regarding participants use of primary and secondary health care the last 4 weeks is collected at all times of follow-up and is compared to baseline data., 1 month, 6 months, 12 months|Patient satisfaction: Seattle Angina Questionnaire, To examine whether patients with chest pain with normal coronary arteries experience greater satisfaction with their treatment if they receive extended information and the examination results immediately after the CT examination than those who receive the examination result from their RGP.

This is measured with 2 single items in Seattle Angina Questionnaire regarding satisfaction with treatment. Values range from 1-5, 1 is the lowest level of satisfaction, and 5 is the highest level of satisfaction. Greater satisfaction with treatment will be defined by a higher score at follow-up after 6 and 12 months., 6 months, 12 months
Other Outcome Measures:
Sponsor: Haukeland University Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 92
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 2016/1380
Start Date: 2018-06-11
Primary Completion Date: 2019-03-04
Completion Date: 2020-03-04
First Posted: 2018-12-20
Results First Posted:
Last Update Posted: 2020-10-14

Locations: Haukeland University Hospital, Bergen, 5021, Norway
Study Documents:

NCT Number: NCT01658553
Study Title: A Study to Look at the Electrical Activity of the Heart in Subjects With Solid Tumor Cancers, Before and After Receiving the Study Treatment, GSK1120212
Study URL: https://beta.clinicaltrials.gov/study/NCT01658553
Acronym:
Study Status: COMPLETED
Brief Summary: A multicenter, non-randomized, placebo-controlled, single dosing schedule, subject-blinded study to evaluate the effect of GSK1120212 on the electrical activity of the heart as compared to placebo in subjects with solid tumor cancers. All subjects will undergo Screening assessments within 21 days prior to the start of the study treatment to determine their eligibility for enrollment in the study. Eligible subjects will receive study treatment administered over a period of 15 days followed by a post-treatment follow-up visit. Study treatment (GSK1120212-matched placebo) will be blinded to subjects. Subjects will receive GSK1120212-matched placebo on one day during the first 14 days of dosing. On all other days the subject will receive a once-daily 2 mg dose of GSK1120212 except for Day 15 when the subject will receive 3mg dose of GSK1120212 12-lead ECG recordings will be obtained from continuous ECG recordings obtained via a 12-lead Holter monitor on Study Days 1 and 15 while subjects are in the clinical research unit. The effect of GSK1120212 on the electrical activity of the heart will be determined by time-matched ECGs obtained at the same time points relative to dosing on these days. Ambulatory blood pressure readings will be obtained from continuous 24-hour recordings via an ambulatory blood pressure monitor The effect of GSK1120212 on blood pressure parameters will be determined by blood pressure readings obtained at the same time points relative to dosing on Study Days 1 and 15. Serial blood samples to analyze the concentration of study drug in the subject's blood will be obtained at the same time points relative to dosing on Study Days 1 and 15. Subjects who are eligible for continued treatment with GSK1120212 may continue treatment under the rollover study MEK114375 (drug study number). A post-treatment follow-up visit will be conducted within 28 days of the last dose of study treatment for all subjects who do not continue treatment in the rollover study MEK114375.
Study Results: NO
Conditions: Cancer
Interventions: DRUG: GSK1120212
Primary Outcome Measures: Compare the effect of GSK1120212 on the baseline-adjusted, placebo-corrected, time-matched QTcF(QT interval corrected for heart rate by Fridericia's formula) interval duration in subjects with solid tumor cancers, from baseline to day 15
Secondary Outcome Measures: Evidence of the relationships between the change in QTc(Corrected QT interval) from baseline and the plasma concentrations of GSK1120212 and predicted change in QTc(Corrected QT

interval), From baseline as compared to study day 15|Plasma concentrations and PK (Pharmacokinetic) parameters of GSK1120212, including AUC(Area under concentration-time curve)(0-24), concentration at time t (Ct), Cmax (Maximum observed concentration) and time to Cmax (tmax)., From placebo dosing on day 1 to day 15|Safety parameters: AEs, vital sign (blood pressure, pulse rate and temperature), ECGs, and clinical laboratory assessments, From baseline until follow up(maximum 42 days)|Change in blood pressure parameters, including PP(Pulse pressure) and MABP(Mean arterial blood pressure), from baseline to Study Day 15.
Other Outcome Measures:
Sponsor: GlaxoSmithKline
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 60
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: SINGLE (PARTICIPANT)|Primary Purpose: BASIC_SCIENCE
Other IDs: 114655
Start Date: 2012-09-19
Primary Completion Date: 2014-04-05
Completion Date: 2014-04-05
First Posted: 2012-08-07
Results First Posted:
Last Update Posted: 2017-11-13
Locations: GSK Investigational Site, San Antonio, Texas, 78229, United States|GSK Investigational Site, Salt Lake City, Utah, 84112, United States
Study Documents:

NCT Number: NCT02874664
Study Title: A Study of Rovalpituzumab Tesirine to Study Cardiac Ventricular Repolarization in Subjects With Small Cell Lung Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02874664
Acronym:
Study Status: COMPLETED
Brief Summary: Study to evaluate the effect of rovalpituzumab tesirine on cardiac ventricular repolarization in subjects with small cell lung cancer (SCLC).
Study Results: NO
Conditions: Small Cell Lung Carcinoma
Interventions: DRUG: Rovalpituzumab Tesirine
Primary Outcome Measures: Change in QTcF interval from baseline QTcF following treatment with rovalpituzumab teserine as measured by extracting quantitative ECG parameters from ambulatory Holter monitors., 12 weeks
Secondary Outcome Measures: Change in RR interval from baseline RR

following treatment with rovalpituzumab teserine as measured by extracting quantitative ECG parameters from ambulatory Holter monitors., 12 weeks|Change in PR interval from baseline PR following treatment with rovalpituzumab teserine as measured by extracting quantitative ECG parameters from ambulatory Holter monitors., 12 weeks|Change in QRS duration interval from baseline QRS duration following treatment with rovalpituzumab teserine as measured by extracting quantitative ECG parameters from ambulatory Holter monitors., 12 weeks|Change in waveform composition interval from baseline waveform composition following treatment with rovalpituzumab teserine as measured by extracting quantitative ECG parameters from ambulatory Holter monitors., 12 weeks|Relationship between plasma rovalpituzumab tesirine concentration and change in QTcF interval from baseline., 12 weeks|Incidence of proarrhythmic adverse events stratified by change in QTcF from baseline of less than 10 ms or greater than 10 ms., 12 weeks|Incidence of adverse events., From first dose through 30 days post-last-dose|Objective response rate, Baseline, every 6 weeks until 6 months, then every 12 weeks until disease progression, assessed up to 24 months.|Duration of response, Baseline, every 6 weeks until 6 months, then every 12 weeks until disease progression, assessed up to 24 months.|Progression free survival, Baseline, every 6 weeks until 6 months, then every 12 weeks until disease progression, assessed up to 24 months.|Overall survival, Baseline, every 6 weeks until 6 months, then every 12 weeks until disease progression, assessed up to 24 months.|Clinical benefit ratio, Baseline, every 6 weeks until 6 months, then every 12 weeks until disease progression, assessed up to 24 months.|Maximum Plasma Concentration (Cmax), Cycles 1 and 2: Day 1 (predose, 30 min, 2 and 4 hours postdose) and days 2,3,4,8,15,and 29; Cycles 4,5,7,8: Day 1 predose and 30 min postdose.|Area Under the Curve (AUC), Cycles 1 and 2: Day 1 (predose, 30 min, 2 and 4 hours postdose) and days 2,3,4,8,15,and 29; Cycles 4,5,7,8: Day 1 predose and 30 min postdose.
Other Outcome Measures:
Sponsor: Stemcentrx
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 46
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: SCRX001-007
Start Date: 2016-09
Primary Completion Date: 2018-09-12
Completion Date: 2018-09-12
First Posted: 2016-08-22
Results First Posted:
Last Update Posted: 2018-09-24

Locations: University of California Los Angeles, Los Angeles, California, 90404, United States|Winship Cancer Institute, Emory University, Atlanta, Georgia, 30322, United States|University of Chicago Medical Center, Chicago, Illinois, 60637, United States|Parkview Research Center, Fort Wayne, Indiana, 46845, United States|Baptist Health Lexington, Lexington, Kentucky, 40503, United States|Karmanos Cancer Institute, Detroit, Michigan, 48201, United States|Henry Ford Hospital, Detroit, Michigan, 48202, United States|Roswell Park Cancer Institute, Buffalo, New York, 14263, United States|University of Cincinnati, Cincinnati, Ohio, 45267, United States|University Hospitals Case Medical Center, Cleveland, Ohio, 44106, United States|MetroHealth Medical Center, Cleveland, Ohio, 44109, United States|Greenville Health System Cancer Institute, Greenville, South Carolina, 29605, United States|Mary Crowley Medical Research Center, Dallas, Texas, 75230, United States|Cross Cancer Institute, Edmonton, Alberta, T6G 1Z2, Canada|The Ottawa Hospital-Cancer Centre, Ottawa, Ontario, K1H 8L6, Canada
Study Documents:

NCT Number: NCT04461561
Study Title: Using NPT to Evaluate Providing PPC as ELNEC-PPC WBT for Nurses
Study URL: https://beta.clinicaltrials.gov/study/NCT04461561
Acronym: ELNEC-PPC
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to explain the provision of palliative care at the end of life by the implementation of the ELNEC course, as WBT Program using the Normalization Process Theory, that focus attention on how complex interventions become routinely embedded in practice. In addition to, identify the changes implemented by the participant nurses (intervention group) in their clinical practice, after participating in WBT Program to provide Palliative Care alongside with usual care versus usual care only (control group) for children with life-limiting conditions or in the case of accidents/sudden death, at the end of life. And finally, provide findings that will assist in the interpretation of the trial results.
Study Results: NO
Conditions: Cancer|Cardiac Anomaly|Cystic Fibrosis|Muscular Dystrophy|HIV/AIDS|Batten's Disease|Cerebral Palsy
Interventions: GENETIC: end-of-life nursing education consortium-pediatric palliative care as web based-training plus usual care
Primary Outcome Measures: The NoMAD Instrument, to describe respondents' experiences of using the intervention in the workplace., The data collection instrument is NoMAD \[1\]. The NoMAD translated into Arabic for the purpose of evaluating the normalization of the pediatric palliative care provide by web-based training concept. The Arabic-NoMAD is divided into 3 sections. It begins with section A consisting of 12 questions about the respondent, section B with 3 general questions about the intervention. Section C contains 20 specific questions about the intervention, corresponding to the 4

constructs of the normalization process theory \[2\], with Coherence and Cognitive Participation has 4 items, 7 items for Collective Action, and 5 items for Reflexive Monitoring. The scale consists of 31 Likert-type items. Items in section B are answered with a 10-point Likert scale ranging from "Not at all" to "Completely". The items in part C are answered using a 5-point Likert scale, ranging from "Disagree Strongly" to 'Agree Strongly'. 'Neutral' and 'Not applicable'., 2 weeks after the end of WBT course|The NoMAD Instrument, to describe respondents' experiences of using the intervention in the workplace., The data collection instrument is NoMAD \[1\]. The NoMAD translated into Arabic for the purpose of evaluating the normalization of the pediatric palliative care provide by web-based training concept. The Arabic-NoMAD is divided into 3 sections. It begins with section A consisting of 12 questions about the respondent, section B with 3 general questions about the intervention. Section C contains 20 specific questions about the intervention, corresponding to the 4 constructs of the normalization process theory \[2\], with Coherence and Cognitive Participation has 4 items, 7 items for Collective Action, and 5 items for Reflexive Monitoring. The scale consists of 31 Likert-type items. Items in section B are answered with a 10-point Likert scale ranging from "Not at all" to "Completely". The items in part C are answered using a 5-point Likert scale, ranging from "Disagree Strongly" to 'Agree Strongly'. 'Neutral' and 'Not applicable'., at 3 months for both groups
Secondary Outcome Measures: The interview, using framework analysis, informed by normalization process theory toolkit, Semi-structured face-to-face interviews will be conducted by all nurses on how successful passing ELNEC-PPC WBT course from the selected setting. All participants had direct contact with patients. Three rounds of interviews will be conducted after 3 months. After consenting, participants will be interviewed by the main researcher (MA). All interviews will be audio-recorded and transcribed. They will be asked why they felt the change was significant. During the second round of interviews, will be asked about the most significant developments since the beginning of the program; they will be asked to share their views about pediatric palliative care and to describe the extent to which they were adopting the approach, and if not, why not. Topic guides were informed by NPT \[3\], it will be used the interactive NPT toolkit. It contains 16 questions, for thinking through an implementation problem. The work was embedding improved and edited statements and explanations into a web-enabled tool., For 3-months post-course
Other Outcome Measures:
Sponsor: Altoosi University College
Collaborators: Babylon University
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 172

Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: OTHER
Other IDs: AltoosiUC
Start Date: 2020-07-01
Primary Completion Date: 2020-12-30
Completion Date: 2021-09-01
First Posted: 2020-07-08
Results First Posted:
Last Update Posted: 2020-07-27
Locations: 1) Imam Sadiq (peace be upon him) Teaching Hospital; 2) Babylon Maternity and Children Teaching Hospital; 3) Al-Noor Hospital for Children; 4) Morgan Teaching Hospital; and 5) Babylon Oncology Center, Hilla, Babylon Province, Iraq
Study Documents:

NCT Number: NCT04867564
Study Title: Radiation-induced Cardiac Toxicity After Non-small Cell Lung Cancer Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04867564
Acronym:
Study Status: RECRUITING
Brief Summary: Despite the growing interest in investigating how the radiotherapy (RT) dose to anatomical substructures of the heart links to survival, the heart substructures at risk remain poorly defined. They are not delineated routinely as part of the RT planning process and there is no consensus on their dose constrains. With improving prognosis for non-small cell lung cancer (NSCLC) patients, the evidence relating irradiation of the heart to excess mortality has begun to accumulate.

The study aims to evaluate subclinical cardiac dysfunction in consecutive NSCLC patients treated with definitive RT and to investigate the predictive value of the heart substructures dosimetric parameters for subclinical and overt cardiac toxicity as assessed using traditional and speckle tracking echocardiography (STE). The study will also investigate whether subclinical alterations detected by echocardiography with strain imaging may serve as a marker for future clinical dysfunctions.
Study Results: NO
Conditions: Non-small Cell Lung Cancer|Radiation Toxicity|Cardiac Toxicity
Interventions: DIAGNOSTIC_TEST: Echocardiography
Primary Outcome Measures: RT-induced systolic and diastolic function alterations, Systolic and diastolic function alterations assessed using traditional echocardiographic parameters as well as speckle tracking echocardiography analysis at 1, 6, and 12 months after RT compared to baseline., 1 year
Secondary Outcome Measures: The predictive value of cardiac

substructures dosimetric parameters for cardiac toxicity as evaluated using STE and traditional echocardiographic parameters, Apart from the whole heart, which is routinely contoured, the following substructures will be also contoured on the computed tomography planning CT scans: left ventricle (LV), left ventricle anterior segment (LVant), left ventricle inferior segment (LVinf), left ventricle lateral segment (LVlat), left ventricle septal segment (LVsept), left atrium (LA), right ventricle (RV), right atrium (RA), aortic valve (AV), pulmonic valve (PV), tricuspid valve (TV), mitral valve (MV), left main coronary artery (LMCA), left anterior descending coronary artery (LAD), left circumflex coronary artery (LCxCA), and right coronary artery (RCA). No prespecified dose constrains will be applied for these substructures. RT treatment plan will be prepared using routine whole heart dose constrains according to the institutional protocol, and the pre-specified dose-volume histogram parameters will be extracted for analysis., 1 year|The predictive value of subclinical alterations detected by echocardiography for future clinical dysfunctions, Occurence of the symptomatic cardiac disorders, as classified by Common Terminology Criteria for Adverse Events (CTCAE) v.4.0, in patients with vs. without subclinical alterations detected by echocardiography, 1 year|Cumulative incidence of cardiac disorders, as classified by CTCAE4.0, Cumulative incidence of cardiac disorders, as classified by CTCAE4.0, 1 year
Other Outcome Measures:
Sponsor: Military Institute of Medicine, Poland
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 20/WIM/2021
Start Date: 2021-05-01
Primary Completion Date: 2024-05-01
Completion Date: 2024-05-01
First Posted: 2021-04-30
Results First Posted:
Last Update Posted: 2021-07-23
Locations: Department of Radiotherapy, Military Institute of Medicine, Warsaw, Mazowieckie, 04-141, Poland
Study Documents:

NCT Number: NCT02815553
Study Title: Cardiac Tumors Interventional (Radio Frequency/Laser Ablation) Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT02815553
Acronym: CTIH
Study Status: RECRUITING

Brief Summary: Currently, surgical removal remains the main clinical treatment for cardiac tumor patients. However, part of tumors are hard to completely resect. Also, as thoracoscopic surgeries induce great operation trauma, some patients cannot tolerate or do not will to take the operation. Therefore, new methods and techniques are in urgent need.

Our center have a 12-year experience of intervention treatment for solid tumors and has conducted several animal experiments to verify the effectiveness of transthoracic puncture ablation and radiofrequency ablation for ventricular muscle.

The purpose of this study is to conduct new method of direct transthoracic cardiac tumor-targeted Radiofrequency Ablation (RFA) or Laser induced Interstitial Thermotherapy (LITT), make minimally invasive treatment plans for cardiac tumor patients, and verify the safety and validity of intervention treatment in long term.
Study Results: NO
Conditions: Cardiac Tumors
Interventions: PROCEDURE: Direct Transthoracic Cardiac Tumor Radio Frequency Ablation Therapy|PROCEDURE: Direct Transthoracic Cardiac Tumor Laser Ablation Therapy
Primary Outcome Measures: Mortality, 24 months|Tumor size, If the maximum tumor size increases, the symptom gets deteriorated; If the maximum tumor size decreases, the symptom gets relieved., 24 months|Quantification of obstructive severity, Investigators use the peak velocity and of stenosis (by echocardiography) to quantify obstructive severity caused by the tumor. If the peak velocity increases, the symptom gets deteriorated; if the peak velocity decreases, the symptom gets relieved., 24 months
Secondary Outcome Measures: Quantification of cardiac function, Investigators use ejection fraction(EF) to quantify the cardiac function. If EF is higher after the operation, the cardiac function gets recovered; if EF is lower after the operation,the cardiac function does't get recovered., 24 months|Quantification of tumor blood perfusion, Investigators use contrast-enhanced ultrasonography to quantify tumor blood perfusion. If there is no perfusion observed, the therapy is successful; if there is perfusion, the therapy is ineffective., 24 months
Other Outcome Measures:
Sponsor: Xijing Hospital
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT

Other IDs: KY20162034-1
Start Date: 2016-04
Primary Completion Date: 2022-08
Completion Date: 2022-08
First Posted: 2016-06-28
Results First Posted:
Last Update Posted: 2022-08-31
Locations: Ultrasonic Diagnosis Department of Xijing Hospital, Fourth Military Medical University, Xi'an, Shaanxi, 710032, China
Study Documents:

NCT Number: NCT02962661
Study Title: Donor Bone Marrow Derived Mesenchymal Stem Cells in Controlling Heart Failure in Patients With Cardiomyopathy Caused by Anthracyclines
Study URL: https://beta.clinicaltrials.gov/study/NCT02962661
Acronym:
Study Status: RECRUITING
Brief Summary: This randomized pilot phase I trial studies the side effects of donor bone marrow derived mesenchymal stem cells in controlling heart failure in patients with cardiomyopathy caused by anthracyclines. Donor bone marrow derived mesenchymal stem cells may help to control symptoms of heart failure and improve heart function.
Study Results: NO
Conditions: Cardiomyopathy|Heart Failure|Hematopoietic and Lymphoid Cell Neoplasm|Malignant Solid Neoplasm
Interventions: OTHER: Best Practice|OTHER: Laboratory Biomarker Analysis|DRUG: Mesenchymal Stem Cell Transplantation|DRUG: Mesenchymal Stem Cell Transplantation
Primary Outcome Measures: Incidence of adverse events, Statistical analyses of safety will be descriptive., Up to 6 months|Change in left ventricular ejection fraction (LVEF), The comparison will be between the two groups of patients., Baseline to 6 months
Secondary Outcome Measures: Change in improvement of left ventricular (LV) systolic function as assessed by LVEF, As regards statistical analyses, the results of the trial will be displayed in table format. Will provide confidence intervals of the differences in change from baseline between each investigational group and the control group. If both investigation groups are significant at the p \< .05 level, then the two investigational drugs can be compared using a gatekeeping procedure. These intervals and the associated p-values will be calculated using two-sample t-tests, with no adjustments for multiple comparisons., Baseline up to 6 months|LV end-systolic and end-diastolic volumes as determined by contrast-enhanced 2-dimensional(D)/3D echography, As regards statistical analyses, the results of the trial will be displayed in table format. Will provide confidence intervals of the differences in change from baseline between each investigational group and the control group. If both investigation groups are significant at the p \< .05 level, then the two investigational drugs can be compared using a gatekeeping procedure.

These intervals and the associated p-values will be calculated using two-sample t-tests, with no adjustments for multiple comparisons., Up to 6 months|Cardiac death, As regards statistical analyses, the results of the trial will be displayed in table format. Will provide confidence intervals of the differences in change from baseline between each investigational group and the control group. If both investigation groups are significant at the p \< .05 level, then the two investigational drugs can be compared using a gatekeeping procedure. These intervals and the associated p-values will be calculated using two-sample t-tests, with no adjustments for multiple comparisons., Up to 6 months|Re-hospitalization after heart failure, As regards statistical analyses, the results of the trial will be displayed in table format. Will provide confidence intervals of the differences in change from baseline between each investigational group and the control group. If both investigation groups are significant at the p \< .05 level, then the two investigational drugs can be compared using a gatekeeping procedure. These intervals and the associated p-values will be calculated using two-sample t-tests, with no adjustments for multiple comparisons., Up to 6 months|Aborted death from an automatic implantable cardioverter defibrillator (AICD) firing, As regards statistical analyses, the results of the trial will be displayed in table format. Will provide confidence intervals of the differences in change from baseline between each investigational group and the control group. If both investigation groups are significant at the p \< .05 level, then the two investigational drugs can be compared using a gatekeeping procedure. These intervals and the associated p-values will be calculated using two-sample t-tests, with no adjustments for multiple comparisons., Up to 6 months|Nonfatal myocardial infarction, As regards statistical analyses, the results of the trial will be displayed in table format. Will provide confidence intervals of the differences in change from baseline between each investigational group and the control group. If both investigation groups are significant at the p \< .05 level, then the two investigational drugs can be compared using a gatekeeping procedure. These intervals and the associated p-values will be calculated using two-sample t-tests, with no adjustments for multiple comparisons., Up to 6 months|Revascularization, As regards statistical analyses, the results of the trial will be displayed in table format. Will provide confidence intervals of the differences in change from baseline between each investigational group and the control group. If both investigation groups are significant at the p \< .05 level, then the two investigational drugs can be compared using a gatekeeping procedure. These intervals and the associated p-values will be calculated using two-sample t-tests, with no adjustments for multiple comparisons., Up to 6 months
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: PHASE1
Enrollment: 72
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 2015-0835|NCI-2016-01921|2015-0835
Start Date: 2020-07-18
Primary Completion Date: 2023-07-30
Completion Date: 2023-07-30
First Posted: 2016-11-11
Results First Posted:
Last Update Posted: 2023-06-15
Locations: M D Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT02472353
Study Title: Use of Metformin to Reduce Cardiac Toxicity in Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02472353
Acronym:
Study Status: TERMINATED
Brief Summary: The goal of this study is to determine if co-administration of metformin and doxorubicin in breast cancer patients receiving neoadjuvant or adjuvant therapy will reduce the number of patients who develop a significant change in left ventricle ejection fraction (LVEF).
Study Results: YES
Conditions: Breast Cancer|Breast Tumors
Interventions: DRUG: Metformin|DRUG: Doxorubicin
Primary Outcome Measures: Number of Participants With Less Than or Equal to 5% Decrease in Left Ventricle Ejection Fraction (LVEF) on Echocardiogram, Determine whether the addition of metformin to standard doxorubicin therapy in breast cancer patients will decrease the incidence of change in left ventricle ejection fraction (LVEF)., 1 year
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Avera McKennan Hospital & University Health Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 30
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: PREVENTION
Other IDs: AMEM-2014-MET001

Start Date: 2014-07
Primary Completion Date: 2018-05-23
Completion Date: 2018-05-23
First Posted: 2015-06-15
Results First Posted: 2019-09-05
Last Update Posted: 2019-10-16
Locations: Avera Cancer Institute, Sioux Falls, South Dakota, 57105, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT04885088
Study Title: Smart Home Care of Cloud Base ECG on the Cardiotoxicity Prevention on the Cancer Patients.
Study URL: https://beta.clinicaltrials.gov/study/NCT04885088
Acronym: AI
Study Status: UNKNOWN
Brief Summary: Thoracic malignancy is the most commonly diagnosed cancer worldwide.1,2 The incidence of thoracic malignancy has decreased in North America, but not in Asia, where it continues to show an increasing trend. A notable manifestation of the bimodal age distribution of thoracic malignancy has been observed in women. The occurrence of early-onset thoracic malignancy in the Asian population is earlier than that in the Western population, resulting in a higher incidence of thoracic malignancy in young Asian women. Moreover, the late onset age distribution of patients with thoracic malignancy in Asia (40-50 years) is earlier than that in Western countries (60-70 years), peaking at the age of 45-50 years in most women. The age-specific incidence rates of thoracic malignancy increase sharply until the menopausal stage.

Cardiovascular morbidity is higher among women with thoracic malignancy involving the thorax who had received radiotherapy (RT) compared with those not involving the thorax but receiving the same treatment. Thus far, the risks and time to onset of cardiac complications have been unclear in both young and old women. The proportion of young women with thoracic malignancy is higher in Asia than in Western countries. Furthermore, whether Asian women with thoracic malignancy are susceptible to RT remains unclear.

Anthracyclines are important therapeutic agents for breast cancer. Anthracycline-based regimens have similar or improved outcomes relative to the standard treatment regimen of cyclophosphamide, methotrexate, and fluorouracil. However, cardiotoxicity is a long-term toxicity associated with these regimens. The combined use of adjuvant anthracycline-based chemotherapy (CT) and RT may result in high cardiotoxicity. Nonetheless, no clear information on the effects of this combined therapy on the time to onset of both cardiac complications and cardiotoxicity is available. Furthermore, whether the cardiotoxicity of adjuvant RT and anthracycline-based CT is associated with age and ethnicity in women with thoracic malignancy

remains unclear.

Therefore, cardiovascular disease is undoubtedly one of the most challenging health problems in the world. More efforts are needed to prevent and better control of this disease. Our proposed monitoring program is to use AI to monitor the basal value variation of personalized cardiovascular disease in cancer patients before and after chemoradiation. In the first year, our team focused on cardiotoxicity associated with cardiovascular disease models and cancer treatments. In the second year, we will apply knowledge in a clinical setting and calculate the severity of cardiac toxicity and its incidence and time response after cancer treatment. In the third year, high-risk groups will be identified to provide preventive intervention to reduce the risk of cancer-treatment related cardiotoxicity.
Study Results: NO
Conditions: Artificial Intelligent|Cardiotoxicity|Cardiac Monitor|Cancer Treatment|ECG
Interventions: DEVICE: Wisdom bracelet
Primary Outcome Measures: death, death, divided into yes or no, Within a year|heart failure, Come back to the hospital for heart failure (Judged by the physician) after discharge, divided into yes or no, Within a year|Acute Coronary Syndrome, Coronary Artery Disease, Come back to the hospital for Acute Coronary Syndrome, Coronary Artery Disease (Judged by the physician) after discharge, divided into yes or no, Within a year|Myocarditis, Come back to the hospital for Myocarditis (Judged by the physician) after discharge, divided into yes or no, Within a year
Secondary Outcome Measures: Arrhythmia, Re-hospitalization for Arrhythmia (Judged by the physician) after discharge, divided into yes or no, Within a year|Valvular Heart Disease, Re-hospitalization for Valvular Heart Disease (Judged by the physician) after discharge, divided into yes or no, Within a year|Physician adjusts medicine, According to the medicine order issued by the doctor, if there is any adjustment of the medicine, make a record,divided into yes or no, Within a year|Physician arranges examination early, If the doctor has arranged to do Cardiac ultrasound or stress \& redistribution myocardial perfusion scan with SPECT During non-table period, divided into yes or no, Within a year|Compliance, Judged by the physician, when the patient returns to the consultation, the patient is asked about the compliance with the drug in the past, divided into yes or no, Within a year|Medical cost, The sum of all medical and health insurance expenses of the patient in the past year, Within a year
Other Outcome Measures:
Sponsor: Ju-Chi Liu
Collaborators: Taipei Medical University WanFang Hospital|Taipei Medical University Hospital|Lotung Poh-Ai Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:

Enrollment: 400
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ShuangHoH
Start Date: 2021-07-01
Primary Completion Date: 2023-06-30
Completion Date: 2023-06-30
First Posted: 2021-05-13
Results First Posted:
Last Update Posted: 2021-05-13
Locations:
Study Documents:

NCT Number: NCT05806138
Study Title: A Study of Vericiguat in People With Breast Cancer and Cancer Therapy-Related Cardiac Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT05806138
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: The purpose of this study is to find out if adding vericiguat to standard treatment for cancer therapy related cardiac dysfunction (CTRCD) is more effective than standard treatment alone. The addition of vericiguat to the usual treatment could help improve cardiac function, but it could also cause side effects. This study will help researchers find out whether this different treatment is better, the same as, or worse than the usual approach.
Study Results: NO
Conditions: Breast Cancer|Cardiac Dysfunction
Interventions: DRUG: Vericiguat|OTHER: Optimal medical therapy
Primary Outcome Measures: change in CRF (measured by VO2peak), For the primary analysis, intervention effect will be evaluated by comparing differences in mean VO2peak changes from baseline to month 6 between the investigational and control groups using the analysis of covariance approach (ANCOVA)., up to 6 months
Secondary Outcome Measures: CRF response rate, assessed by the number of participants with a change in VO2peak ≥ 1.32 ml O2 • kg-1 • min-1 (technical error of CRF measurement) from baseline to month 6. A change in VO2peak ≥ 1.32 ml O2 • kg-1 • min-1 will be considered a response, whereas a change in VO2peak \< 1.32 ml O2 • kg-1 • min-1 will be considered a non-response., up to 6 months
Other Outcome Measures:
Sponsor: Memorial Sloan Kettering Cancer Center
Collaborators: Merck Sharp & Dohme LLC
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL

Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 23-050
Start Date: 2023-06
Primary Completion Date: 2028-04
Completion Date: 2028-04
First Posted: 2023-04-10
Results First Posted:
Last Update Posted: 2023-05-03
Locations: Memorial Sloan Kettering Cancer Center (All Protocol Activities), New York, New York, 10065, United States
Study Documents:

NCT Number: NCT05184088
Study Title: Efficacy of [18F]Florbetaben PET for Diagnosis of Cardiac AL Amyloidosis
Study URL: https://beta.clinicaltrials.gov/study/NCT05184088
Acronym: CArdiag
Study Status: RECRUITING
Brief Summary: This is an open-label, multi-center pivotal Phase 3 study to visually and quantitatively assess PET images obtained after single application of 300 MBq \[18F\]florbetaben and PET scanning of patients with suspected cardiac amyloidosis.
Study Results: NO
Conditions: Cardiac Amyloidosis|AL Amyloidosis|ATTR Amyloidosis
Interventions: DRUG: [18F]florbetaben
Primary Outcome Measures: Sensitivity and specificity of the visual assessment of [18F]florbetaben PET images for the diagnosis of cardiac AL amyloidosis., The results from the visual assessment of \[18F\]florbetaben PET images are compared to the clinical diagnosis established through histological verification of the presence or absence of AL amyloidosis with cardiac involvement determined either through endomyocardial biopsy or through extracardiac biopsy in conjunction with typical CMR or echocardiography imaging features as the standard of truth., Up to 12 weeks
Secondary Outcome Measures: Sensitivity and specificity of [18F]florbetaben PET for the diagnosis of cardiac AL amyloidosis using quantification., The sensitivity and specificity of \[18F\]florbetaben PET for the diagnosis of cardiac AL amyloidosis will be determined by using quantitative image analysis., Up to 12 weeks|Correlation of quantitative [18F]florbetaben PET results with left ventricular ejection fraction (LV EF) and left ventricular mass (LV mass)., Correlation of quantitative \[18F\]florbetaben PET results with left ventricular ejection fraction (LV EF) and left ventricular mass (LV mass)., Up to 12 weeks|Correlation of quantitative [18F]florbetaben PET results with AL CA stage I - IV based on FLC-diff, cTnT and NT-proBNP levels., Correlation of quantitative \[18F\]florbetaben PET results with AL CA stage I - IV based on FLC-diff, cTnT and NT-proBNP levels., Up to 12 weeks|Impact of PET imaging (AL-CA/non AL-CA) on diagnostic thinking and patient management will be assessed with

physician's questionnaires before and after the diagnostic work-up, and after receipt of the PET results., The impact of PET imaging (AL-CA/non AL-CA) on diagnostic thinking and patient management will be assessed with physician's questionnaires before and after the diagnostic work-up, and after receipt of the PET results., Up to 14 weeks|Number of adverse events, Safety will be evaluated by collection of Adverse Events., Up to 17 days after imaging visit
Other Outcome Measures: Sensitivity and specificity of [18F]florbetaben PET images for a differential diagnosis between AL CA, ATTR CA and non CA will be assessed., In this exploratory endpoint the sensitivity and specificity of \[18F\]florbetaben PET images for a differential diagnosis between AL CA, ATTR CA and non CA will be assessed., Up to 12 weeks
Sponsor: Life Molecular Imaging GmbH
Collaborators: pharmtrace klinische Entwicklung GmbH
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 200
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: FBB-02-01-21
Start Date: 2023-01-13
Primary Completion Date: 2024-06
Completion Date: 2024-09
First Posted: 2022-01-11
Results First Posted:
Last Update Posted: 2023-02-16
Locations: Clínica Universidad de Navarra, Pamplona, 31008, Spain
Study Documents:

NCT Number: NCT00799188
Study Title: CERTICOEUR: A Secondary Prevention Study of Skin Cancers in Heart Transplant Patients. Everolimus Versus Calcineurin Inhibitors Multicenter Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT00799188
Acronym: CERTICOEUR
Study Status: UNKNOWN
Brief Summary: Heart transplant is a recognized therapeutic strategy in refractory heart failure. Its success is however hampered by severe cancer occurrence and recurrence. The new m-tor inhibiting drugs Sirolimus and Everolimus have shown potential for reducing the incidence of cancer in animal models. They are potent immunosuppressant, antiproliferative and antiangiogenic drugs. This open labelled randomized multicenter study aims at evaluating the beneficial antineoplastic effect of Everolimus in 159 heart transplant patients suffering of recurrent skin cancer. Primary objective is to demonstrate a reduction in the number of new skin cancers. Secondary

end point will be time of recurrence, incidence of non skin cancer, graft function following switch (including death), renal function evolution following calcineurin inhibitors reduction or withdrawal, Everolimus tolerance profile, schemes of calcineurin inhibitors reduction management in centers.
Study Results: NO
Conditions: Cardiac Transplantation|Skin Cancer
Interventions: DRUG: Everolimus
Primary Outcome Measures: Number of skin tumors per patients requiring surgery with histology control within 2 years, 2 years
Secondary Outcome Measures: New skin cancer, 2 years|Number of patients with new skin cancers, 2 years|Time of recurrence, 2 years|Number and histology of other types of skin cancer, 2 years|Graft function (including acute rejection, graft loss, death), 2 years|Renal function evolution as assessed using Cockcroft creatinine clearance and proteinuria, 2 years|Adverse events and serious adverse events, 2 years|Non skin cancer (Number and diagnostic), 2 years|Schemes of calcineurin inhibitors reduction/withdrawal, 2 years|Immune response assessment through regulatory or effector function of blood and in situ T lymphocytes at baseline and following immunosuppression switch, 2 years
Other Outcome Measures:
Sponsor: Hospices Civils de Lyon
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 175
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 2007.489/32
Start Date: 2008-10
Primary Completion Date: 2014-09
Completion Date:
First Posted: 2008-11-27
Results First Posted:
Last Update Posted: 2013-12-12
Locations: HOSPICES CIVILS de LYON, Lyon, France
Study Documents:

NCT Number: NCT04669730
Study Title: Baduanjin Exercise on Meridian Energy, Lung Function and Heart Rate Variability in Patients Undergoing Lung Operative.
Study URL: https://beta.clinicaltrials.gov/study/NCT04669730
Acronym:
Study Status: UNKNOWN
Brief Summary: Lung cancer (LC) is the leading cause of cancer-related death and is the most frequent cancer in both sexes.Respectable lung

tumor with abnormal lung function, usually because of tobacco use, have chronic obstructive pulmonary disease (COPD), coronary artery disease, and/or old age as underlying comorbidities. Until recent, most exercise prescribed using aerobic exercise programs. Baduanjin is a type of movement-based mind-body intervention. It is a form of traditional practice designed to promote physical and psychological health, manage symptoms, and relieve stress during illness. The impacts of a Baduanjin exercise-based cardiopulmonary rehabilitation program for patients recovering from respectable lung tumor on Meridian Energy Analysis Device (MEAD100, Med- Pex Enterprises, Taichung, Taiwan), lung function and heart rate variability has yet to be assessed. This trial evaluates whether the Baduanjin exercise would provide effective lung function, meridian energy and HRV in patients following lung operative.
Study Results: NO
Conditions: Lung Cancer Non Small Cell
Interventions: OTHER: usual care|BEHAVIORAL: Walk|BEHAVIORAL: Baduanjin|BEHAVIORAL: Baduanjin plus walk
Primary Outcome Measures: The 24 points skin electric conductance over bilateral wrist and foot in patients undergoing lung operative, after admission baseline evaluation before lung operative as assessed using M.E.A.D (Meridian Energy Analysis Device): Baseline, The electrical conductance of the acupuncture points of human subject can be measured by a computerized testing instrument with a very low electrical current. Ryodoraku theory has been shown to be a supplementary diagnostic method for selective diseases and a useful parameter for evaluating therapeutic effects of acupuncture. The electrical conductance of an acupoint was measured using a Meridian Energy Analysis Device (MEAD100, Med- Pex Enterprises, Taichung, Taiwan) operating at DC 12V and 0 to 200A. The method and procedure of the MEAD is based on the Ryodoraku theory and is similar to equipment used in previous studies., Baseline|The change of 24 points skin electric conductance over bilateral wrist and foot in patients undergoing lung operative as assessed using M.E.A.D (Meridian Energy Analysis Device): 2 weeks, The electrical conductance of the acupuncture points of human subject can be measured by a computerized testing instrument with a very low electrical current. Ryodoraku theory has been shown to be a supplementary diagnostic method for selective diseases and a useful parameter for evaluating therapeutic effects of acupuncture. The electrical conductance of an acupoint was measured using a Meridian Energy Analysis Device (MEAD100, Med- Pex Enterprises, Taichung, Taiwan) operating at DC 12V and 0 to 200A. The method and procedure of the MEAD is based on the Ryodoraku theory and is similar to equipment used in previous studies., 2 weeks|The change of 24 points skin electric conductance over bilateral wrist and foot in patients undergoing lung operative as assessed using M.E.A.D (Meridian Energy Analysis Device): 4 weeks, The electrical conductance of the acupuncture points of human subject can be measured by a computerized testing instrument with a very low electrical current. Ryodoraku theory has been shown to be a supplementary diagnostic method for

selective diseases and a useful parameter for evaluating therapeutic effects of acupuncture. The electrical conductance of an acupoint was measured using a Meridian Energy Analysis Device (MEAD100, Med- Pex Enterprises, Taichung, Taiwan) operating at DC 12V and 0 to 200A. The method and procedure of the MEAD is based on the Ryodoraku theory and is similar to equipment used in previous studies., 4 weeks|The change of 24 points skin electric conductance over bilateral wrist and foot in patients undergoing lung operative as assessed using M.E.A.D (Meridian Energy Analysis Device): 12 weeks, The electrical conductance of the acupuncture points of human subject can be measured by a computerized testing instrument with a very low electrical current. Ryodoraku theory has been shown to be a supplementary diagnostic method for selective diseases and a useful parameter for evaluating therapeutic effects of acupuncture. The electrical conductance of an acupoint was measured using a Meridian Energy Analysis Device (MEAD100, Med- Pex Enterprises, Taichung, Taiwan) operating at DC 12V and 0 to 200A. The method and procedure of the MEAD is based on the Ryodoraku theory and is similar to equipment used in previous studies., 12 weeks|The change of 24 points skin electric conductance over bilateral wrist and foot in patients undergoing lung operative as assessed using M.E.A.D (Meridian Energy Analysis Device): 16 weeks, The electrical conductance of the acupuncture points of human subject can be measured by a computerized testing instrument with a very low electrical current. Ryodoraku theory has been shown to be a supplementary diagnostic method for selective diseases and a useful parameter for evaluating therapeutic effects of acupuncture. The electrical conductance of an acupoint was measured using a Meridian Energy Analysis Device (MEAD100, Med- Pex Enterprises, Taichung, Taiwan) operating at DC 12V and 0 to 200A. The method and procedure of the MEAD is based on the Ryodoraku theory and is similar to equipment used in previous studies., 16 weeks
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Tzu Chi University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: FACTORIAL|Masking: DOUBLE (CARE_PROVIDER, INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: TCU-CHHuang-BaduanjinLungCa
Start Date: 2020-11-26
Primary Completion Date: 2021-05-27
Completion Date: 2022-11-27
First Posted: 2020-12-17
Results First Posted:

Last Update Posted: 2020-12-17
Locations: Tzu Chi University, Hualien City, 90093, Taiwan|Tzu Chi University, Hualien City, Taiwan
Study Documents:

NCT Number: NCT02079272
Study Title: REBECCA Study (RadiothErapy for BrEast Cancer and CArdiotoxicity)
Study URL: https://beta.clinicaltrials.gov/study/NCT02079272
Acronym: REBECCA
Study Status: WITHDRAWN
Brief Summary: The purpose of this study is to determine whether a new technique of radiotherapy for breast cancer (helical tomotherapy) can induce cardiac toxicity that would be detected in the first two years after treatment. Screening of subclinical cardiac lesions with non-invasive cardiac imaging techniques combined with measures of circulating biomarkers of cardiac tissue lesions and coronary lesions would allow assessing radiation-induced cardiac toxicity at an early stage.
Study Results: NO
Conditions: Toxicity Due to Radiotherapy|Breast Cancer|Lesion; Cardiac
Interventions: OTHER: Helical tomotherapy for breast cancer
Primary Outcome Measures: Number of participants with subclinical cardiac lesions in myocardial levels and/or coronary levels, The primary outcome is defined as a decrease of at least 5% in strain or strain rate measures based on cardiac ultrasound exam"2D strain" between the measurement before radiotherapy and measures 24 months after radiotherapy and / or an increase of at least 15% in the average index of coronary plaques measured with CT coronary angiogram between the measurement before radiotherapy and measures 24 months after radiotherapy ., within the first 2 years after tomotherapy
Secondary Outcome Measures: Number of participants with decrease in myocardial contractility (strain or strain rate measured with cardiac ultrasound exam"2D strain"), within the first 6 months after tomotherapy|Number of participants with modified measures of circulating biomarkers, within the first 2 years after tomotherapy (at the end of radiotherapy, 6 months after radiotherapy and 24 months maximum after radiotherapy)
Other Outcome Measures:
Sponsor: Sophie JACOB
Collaborators: Institut de Radioprotection et de Surete Nucleaire|Institut Claudius Regaud|University Hospital, Toulouse|Institut National de la Santé Et de la Recherche Médicale, France
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 0
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking:

NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 2013-A00929-36
Start Date: 2014-11
Primary Completion Date: 2018-11
Completion Date: 2019-11
First Posted: 2014-03-05
Results First Posted:
Last Update Posted: 2015-04-06
Locations: Institut Claudius Regaud, Toulouse, 31000, France
Study Documents:

NCT Number: NCT04044872
Study Title: Hyperpolarized Carbon 13-Based Metabolic Imaging to Detect Radiation-Induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT04044872
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Patients enrolled in the study will receive standard of care adjuvant or definitive breast, chest wall or thoracic radiation therapy.Cardiac mitochondrial dysfunction is a hallmark of radiation-induced cardiac injury. Reactive oxygen species (ROS) produced by ionizing radiation cause oxidation of mitochondrial proteins and alter oxidative phosphorylation and pyruvate metabolism(5). The goal of this study is to detect early changes in the mitochondrial metabolism in situ as a marker for subclinical radiation-induced cardiotoxicity.
Study Results: NO
Conditions: Thoracic Cancer|Left Sided Breast Cancer
Interventions: DIAGNOSTIC_TEST: [1-13C]pyruvate along with MRI imaging
Primary Outcome Measures: To determine if radiation-induced cardiac injury causes myocardial mitochondrial dysfunction, To determine if radiation-induced cardiac injury causes myocardial mitochondrial dysfunction as measured by increase in \[1-13C\]lactate/ \[13C\]bicarbonate ratio and a decrease in \[5-13C\]glutamate formation in patients receiving radiotherapy to the thorax, at 1 month before the radiation
Secondary Outcome Measures: Determination of the prognostic value decreased of myocardial mitochondrial pyruvate flux in predicting clinically significant radiation induced cardiotoxicity., As a secondary outcome, we will measure if decreased myocardial mitochondrial pyruvate flux results in changes in myocardial mechanical functional parameters. Towards this goal, we will measure myocardial mechanical functional parameters, including left ventricular global longitudinal strain and left ventricular myocardial deformation using cardiac MRI and correlate them with \[1-13C\] lactate/ \[13C\] bicarbonate ratio. Prior studies that cardiac MRI can detect changes in myocardial strain in patients who received whole breast radiotherapy for treatment of breast cancer., At 1 month after the radiation
Other Outcome Measures:
Sponsor: University of Texas Southwestern Medical Center

Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: EARLY_PHASE1
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: STU 2019-1099
Start Date: 2019-12-17
Primary Completion Date: 2023-12
Completion Date: 2023-12
First Posted: 2019-08-05
Results First Posted:
Last Update Posted: 2023-05-25
Locations: Department of Radiation Oncology; UT Southwestern Medical Center, Dallas, Texas, 75390, United States
Study Documents:

NCT Number: NCT05271162
Study Title: Empagliflozin in the Prevention of Cardiotoxicity in Cancer Patients Undergoing Chemotherapy Based on Anthracyclines
Study URL: https://beta.clinicaltrials.gov/study/NCT05271162
Acronym: EMPACT
Study Status: NOT_YET_RECRUITING
Brief Summary: EMPACT (EMPAgliflozin in prevention of chemotherapy-related CardioToxicity) study is a randomized, multi-center, placebo-controlled, double-blind trial to evaluate efficacy of empagliflozin in prevention of left ventricular (LV) dysfunction in patients receiving high cumulative doses of anthracyclines. Diagnosed with cancer, 220 patients without history of heart failure and LV ejection fraction (EF) ≥ 50%, scheduled for high dose anthracyclines (doxorubicin ≥240 mg/m2 or epirubicin ≥540 mg/m2), will be included in the study. They will be randomized to a 10 mg of empagliflozin once daily or to matching placebo in a 1:1 ratio. The primary objective of the EMPACT study is to assess whether prophylactic SGLT-2 inhibitors may prevent a reduction in LVEF after high doses anthracyclines, as evaluated by serial echocardiography on each visit and cardiovascular magnetic resonance (CMR) performed at randomization and on its completion. The secondary composite endpoint includes: all-cause death, cardiovascular (CV) death, myocardial infarction and ischemic stroke. Additional secondary outcome measures include structural myocardial alterations assessed by CMR, decrease in GLS (global longitudinal strain) in echocardiography and changes in cardiac biomarkers. The study will be carried out in accordance with GCP and monitoring will be outsourced to a subcontractor - CRO. The examination will be insured and will begin as soon as the required approvals are obtained.
Study Results: NO

Conditions: Cardiotoxicity
Interventions: DRUG: Empagliflozin 10 MG|OTHER: Placebo
Primary Outcome Measures: Number of participants with left ventricular systolic dysfunction, echocardiography, cardiovascular magnetic resonance, from date of randomization until the end of study, up to 24 months
Secondary Outcome Measures: Rate of episodes of all-cause death, cardiovascular death, myocardial infarction, and stroke, medical records, from date of randomization until the end of study, up to 24 months|Percentage decrease in left ventricular ejection fraction, GLS (global longitudinal strain), echocardiography, from date of randomization until the end of study, up to 24 months|Rate of structural myocardial alterations in CMR, cardiovascular magnetic resonance, from date of randomization until the end of study, up to 24 months|Changes in the concentration of biomarkers, blood samples, Troponina, NTproBNP, from date of randomization until the end of study, up to 24 months|The difference in scores in the KCCQ (Kansas City Cardiomyopathy Questionnaire) assessing the quality of life of patients., Kansas City Cardiomyopathy Questionnaire, the minimum and maximum values:0-100, higher scores mean a better outcome., from date of randomization until the end of study, up to 24 months
Other Outcome Measures:
Sponsor: Maria Sklodowska-Curie National Research Institute of Oncology
Collaborators: Medical Research Agency, Poland
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 220
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: ABM/03/00012
Start Date: 2023-05
Primary Completion Date: 2028-01-01
Completion Date: 2028-02-01
First Posted: 2022-03-08
Results First Posted:
Last Update Posted: 2023-03-14
Locations: Institute of Hematology and Transfusion Medicine, Warsaw, Poland|National Institute of Oncology, Warsaw, Poland
Study Documents:

NCT Number: NCT03750110
Study Title: Yorkshire Enhanced Stop Smoking Study
Study URL: https://beta.clinicaltrials.gov/study/NCT03750110
Acronym: YESS
Study Status: COMPLETED

Brief Summary: Lung cancer rates are higher in Yorkshire than the rest of the UK, and this is due to higher rates of smoking. Deaths from lung cancer can be reduced using regular lung scans (screening) and by helping people stop smoking. As well as detecting cancers, scans can also show evidence of damage to lungs (emphysema) and heart arteries (calcification). This study will test whether people can be encouraged to quit smoking by giving them pictures from their own scans showing possible lung and heart damage, along with information about how stopping smoking reduces their risk of cancer and heart attacks.
Study Results: NO
Conditions: Cancer, Lung|Respiratory Disease|Heart Diseases
Interventions: OTHER: Intervention|OTHER: Usual Care
Primary Outcome Measures: 7-day point prevalent CO validated smoking cessation., Exhaled Carbon Monoxide reading of 6ppm or less to validate smoking cessation, Three months after lung screening
Secondary Outcome Measures: Self-reported continuous smoking cessation at three months, Participant self-report being quit continuously for three months after Lung Screening. Binary question " Have you smoked in the 3 months since Lung Screening, yes or no?", Three months after lung screening|Self-reported continuous cessation at 12 months, Participant self-reports being quit continuously for 12 months following Lung Screening. Binary question " Have you smoked in the 12 months since Lung Screening, yes or no?", 12 months after Lung Screening|CO validated cessation at 12 months, Exhaled Carbon Monoxide reading of 6ppm or less to validate smoking cessation, 12 Months after lung screening|Self-reported continuous cessation at 4 weeks, Participant self-reports being quit continuously for 4 weeks following Lung Screening. Binary question " Have you smoked in the 4 weeks since Lung Screening, yes or no?", four weeks after lung screening|CO validated cessation at 4 weeks, Exhaled Carbon Monoxide reading of 6ppm or less to validate smoking cessation, four weeks after lung screening|Changes in perceived risk of lung cancer, Cancer worry score (UKLS adapted version), 4 weeks after lung screening|Changes in perceived risk of lung cancer, Cancer worry score (UKLS adapted version), 3 months after lung screening|Changes in perceived risk of lung cancer, Cancer worry score (UKLS adapted version), 12 months after lung screening|Changes in motivation to quit smoking tobacco, Motivation to stop smoking - questionnaire, 12 months after lung screening|Changes in motivation to quit smoking tobacco, Motivation to stop smoking - questionnaire, 3 months after lung screening|Changes in motivation to quit smoking tobacco, Motivation to stop smoking - questionnaire, 4 weeks after lung screening|Changes in confidence and efficacy beliefs of stopping smoking, Response efficacy (of stopping smoking) - questionnaire, 12 months after lung screening|Changes in confidence and efficacy beliefs of stopping smoking, Response efficacy (of stopping smoking) - questionnaire, 3 months after lung screening|Changes in confidence and efficacy beliefs of stopping smoking, Response efficacy (of stopping smoking) - questionnaire, 4 weeks after lung health screening|Confidence and efficacy beliefs of stopping smoking, Self efficacy (of stopping smoking) - Questionnaire, 4 weeks

after lung screening|Confidence and efficacy beliefs of stopping smoking, Self efficacy (of stopping smoking) - Questionnaire, 3 months after lung screening|Confidence and efficacy beliefs of stopping smoking, Self efficacy (of stopping smoking) - Questionnaire, 12 months after lung screening|Self -reported changes in health, Health questionnaire (EQ-5D-5L), 3 months after lung screening|Self -reported changes in health, Health questionnaire (EQ-5D-5L), 12 months after lung screening|7-day point prevalent self reported smoking cessation at 3 months, Exhaled Carbon Monoxide reading of 6ppm or less to validate smoking cessation, Three months after lung screening
Other Outcome Measures:
Sponsor: University of Nottingham
Collaborators: The Leeds Teaching Hospitals NHS Trust|University of Leeds|Cardiff University|University of Manchester|University College, London|University of York|Yorkshire Cancer Research
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1001
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 18046
Start Date: 2017-07-01
Primary Completion Date: 2022-03-21
Completion Date: 2022-03-21
First Posted: 2018-11-21
Results First Posted:
Last Update Posted: 2022-05-19
Locations: Leeds Teaching Hospitals NHS Trust, Leeds, West Yorkshire, LS9 7TF, United Kingdom
Study Documents:

NCT Number: NCT04718610
Study Title: Heart Rate Variability, Vagus Nerve and Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT04718610
Acronym:
Study Status: UNKNOWN
Brief Summary: In France, new cancer cases keep on increasing with around 150 000 deaths yearly. Cancer therapy research is constantly evolving. Indeed, several studies explore new treatments or their combination with conventional cancer treatments. But, at the same time, complementary and alternative medicines, as osteopathy, remain little explored upon their role in the combination with conventional therapy.

Several studies showed indirect interaction between vagus nerve and cancer. Firstly, vagus nerve regulates homeostasis and immunity by reducing systemic inflammation while maintaining local inflammation

and antitumor effects. Secondly, vagus nerve stimulation increases Heart Rate Variability (HRV). Moreover, a higher HRV is associated with an improvement of vital prognosis in cancer patients. Vagus nerve could be stimulated by noninvasive osteopathic manipulations.

This prospective, monocentric and randomized study is a collaboration between the Centre Hospitalier d'Avignon and the Institut de Formation en Ostéopathie du Grand Avignon. It focuses on using noninvasive osteopathic mobilizations to stimulate vagus nerve. Indeed, this study aims to evaluate effects of vagus nerve osteopathic stimulations on HRV in patients with lung cancer, colorectal cancer, Non Hodgkin Lymphoma or Multiple Myeloma. More specifically, this study will tell us whether vagus nerve noninvasive osteopathic stimulations induce increase of HRV associated with a decrease of systemic inflammation and an improvement of patient's quality of life.
Study Results: NO
Conditions: Lung Cancer|Colorectal Cancer|Multiple Myeloma|Non Hodgkin Lymphoma
Interventions: OTHER: Osteopathic intervention|BIOLOGICAL: CRP assessment|BEHAVIORAL: QLQ-C30 questionnaire
Primary Outcome Measures: Change of Heart Rate Variability measured by SDNN (Standard Deviation of all NN intervals) from baseline to the end of osteopathic treatment, To assess the effect of vagus nerve osteopathic stimulations on Heart Rate Variability, up to 84 days
Secondary Outcome Measures: Serum concentration of C-Reactive Protein, To assess the effect of vagus nerve osteopathic stimulations on systemic inflammatory, up to 84 days|Time to definitive improvement in global health status / QoL, To assess the effect of vagus nerve osteopathic stimulations on health related quality of life, up to 84 days
Other Outcome Measures:
Sponsor: Centre Hospitalier Henri Duffaut - Avignon
Collaborators: Institut de Formation en Ostéopathie du Grand Avignon
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: OSTEOCAN
Start Date: 2021-01-12
Primary Completion Date: 2023-01-12
Completion Date: 2023-01-12
First Posted: 2021-01-22
Results First Posted:
Last Update Posted: 2021-01-22
Locations: Centre Hospitalier Henri Duffaut, Avignon, 84000, France
Study Documents:

NCT Number: NCT01425710
Study Title: Non-invasive Evaluation of Fluid Status and Cardiac Output During Operative Treatment of Pheochromcytoma
Study URL: https://beta.clinicaltrials.gov/study/NCT01425710
Acronym:
Study Status: COMPLETED
Brief Summary: Non-invasive measurements of cardiac output (CO), systemic vascular resistance (SVR), corrected aortic flow time (FTc) and stroke volume (SV) are useful parameters during laparoscopic resection of pheochromocytoma (adrenalectomy) to document the intraoperative changes in volume status and to estimate the volume depletion.
Study Results: NO
Conditions: Pheochromocytoma
Interventions:
Primary Outcome Measures: Cardiac output (CO), measured using esophageal doppler, parameter will be measured continously for the duration of adrenalectomy, an expected average of 3 hours|Systemic vascular resistance (SVR), measured using esophageal doppler, parameter will be measured continously for the duration of adrenalectomy, an expected average of 3 hours|Stroke volume (SV), measured using esophageal doppler, parameter will be measured continously for the duration of adrenalectomy, an expected average of 3 hours|Corrected aortic flow time(FTc), measured using esophageal doppler, parameter will be measured continously for the duration of adrenalectomy, an expected average of 3 hours|Central venous pressure, Measured using esophageal doppler, parameter will be measured continously for the duration of adrenalectomy, an expected average of 3 hours|Heart rate, parameter will be measured continously for the duration of adrenalectomy, an expected average of 3 hours|Arterial blood pressure, systolic, diastolic, mean; continuous invasive measurement, parameter will be measured continously for the duration of adrenalectomy, an expected average of 3 hours
Secondary Outcome Measures: Changes in serum Concentration: Epinephrine, 7 timepoints during anesthesia (Administration of rocuronium, intubation, cut, intraabdominal air insufflation, ligature of v. suprarenalis, tumor exstirpation, end of operation)|Changes in serum concentration: Norepinephrine, 7 timepoints during anesthesia (Administration of rocuronium, intubation, cut, intraabdominal air insufflation, ligature of v. suprarenalis, tumor exstirpation, end of operation)|Changes in serum concentration: Dopamin, 7 timepoints during anesthesia (Administration of rocuronium, intubation, cut, intraabdominal air insufflation, ligature of v. suprarenalis, tumor exstirpation, end of operation)|Changes in plasma concentration: Metanephrines, 7 timepoints during anesthesia (Administration of rocuronium, intubation, cut, intraabdominal air insufflation, ligature of v. suprarenalis, tumor exstirpation, end of operation)
Other Outcome Measures:
Sponsor: Medical University of Vienna

Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 15
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: pheo
Start Date: 2011-08
Primary Completion Date: 2013-07
Completion Date: 2013-07
First Posted: 2011-08-30
Results First Posted:
Last Update Posted: 2014-02-13
Locations: Medical University of Vienna, Vienna, 1050, Austria
Study Documents:

NCT Number: NCT05414162
Study Title: Multiparametric Cardiac MRI in Patients Under CAR T-cell Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT05414162
Acronym:
Study Status: RECRUITING
Brief Summary: Recently chimeric antigen receptor (CAR) T-cell therapy, a new class of chemo therapy, has gained regulatory approval for the treatment of diseases such as B-cell lymphoma. Known side effects include cytokine release syndrome, which has been described to lead to myocarditis, but larger studies exploring this relationship are currently lacking. In this prospective study, the investigators aim to explore the potential effects of CAR T-cell therapy using cardiac MRI on the heart.
Study Results: NO
Conditions: DLBCL|Multiple Myeloma|Cytokine Release Syndrome|Myocarditis|CAR T-cell Therapy|ALL|PCBCL|Follicular Lymphoma|MCL
Interventions: DIAGNOSTIC_TEST: Cardiac MRI
Primary Outcome Measures: Extent and pattern of acute cardiac effects of CAR T-cell therapy, To investigate to what extent and with which patterns CAR T cell therapy leads to acute cardiac effects in terms of inflammation, fibrosis, and myocardial dysfunction that can be detected with cardiac MRI., 2 weeks|Long-term cardiac remodeling effects of CAR T-cell therapy, To explore whether CAR T cell therapy leads to long-term cardiac remodeling effects in terms of inflammation, fibrosis, and myocardial dysfunction that can be detected with cardiac MRI., 6 months|Correlate MRI findings with clinical course, To assess whether changes in cardiac MRI parameters obtained from objectives 1 and 2 correlate with the clinical course (e.g., CRS development), cytokines and immunological markers and might predict major adverse cardiac events (MACE)., 6 months
Secondary Outcome Measures:

Other Outcome Measures:
Sponsor: University Hospital, Bonn
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 60
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 81/22
Start Date: 2022-05-16
Primary Completion Date: 2024-05
Completion Date: 2025-12
First Posted: 2022-06-10
Results First Posted:
Last Update Posted: 2022-06-15
Locations: University Hospital Bonn, Bonn, NRW, 53127, Germany
Study Documents:

NCT Number: NCT03711110
Study Title: Cardiovascular Prevention Strategies in Elderly Patients With Cancer (CARTIER Clinical Trial)
Study URL: https://beta.clinicaltrials.gov/study/NCT03711110
Acronym: CARTIER
Study Status: RECRUITING
Brief Summary: The CARTIER study is a randomized, multicenter, open-label clinical trial comparing, in elderly patients with cancer under anti-tumoral treatment, two different cardiotoxicity prevention strategies: primary (intensive cardiovascular monitoring focused on prevention and early diagnosis and treatment of cardiotoxicity based in cardio-onco-hematology teams involved in cancer patient care) vs. secondary (current clinical practice where intensive cardiovascular monitoring is not routinely performed and cardiotoxicity patient care is based on the onco-hematologist criteria).

The primary endpoint is to determine whether this primary prevention englobing cardiovascular monitoring plus intensive multidisciplinary management is superior to the current clinical practice in reducing all cause mortality.

Other secondary objectives of the study are to analyze the impact of this intensive cardiovascular monitoring strategy on the incidence of cardiovascular mortality, oncological mortality, hospitalization and/or urgent care due to cardiovascular complications, hospitalization and/or urgent oncological care due to cancer complications, tumor progression and cost-effectiveness analysis.

A total of 514 patients ≥ 65 years old diagnosed with any of the following onco-hematological cancers, colon, breast, lymphoma, chronic

lymphoma leukemia, chronic myeloid leukemia or myeloma, undergoing standardized anti-tumoral treatment, will be recruited.

The incidence of primary and secondary outcomes will be measured at 2 and 5 years
Study Results: NO
Conditions: Cancer (Colon Cancer, Breast Cancer, Lymphoma, Chronic Lymphoma Leukemia, Multiple Myeloma)|Elderly|Antineoplastic Agents|Cardiotoxicity
Interventions: OTHER: Intensive cardiovascular monitoring|OTHER: No intervention
Primary Outcome Measures: All-cause mortality, Cumulative incidence of all-cause mortality, Two (mid-term analysis) and five years of follow-up
Secondary Outcome Measures: Oncological mortality, Cumulative incidence of oncological mortality, Two and five years of follow-up|Cardiovascular mortality, Cumulative incidence of cardiovascular mortality, Two and five years of follow-up|Hospitalization, Cumulative incidence of hospitalization, Two and five years of follow-up|Hospitalization/emergency cardiovascular cause, Cumulative incidence of hospitalization and/or emergency care for cardiovascular cause, Two and five years of follow-up|Hospitalization/emergency cancer cause, Cumulative incidence of hospitalization and/or emergency care for cancer cause, Two and five years of follow-up|Tumor recurrence or progression, Incidence of tumoral recurrence or progression, Two and five years of follow-up
Other Outcome Measures:
Sponsor: Fundación Instituto de Estudios de Ciencias de la Salud de Castilla y León
Collaborators: Instituto de Investigación Biomédica de Salamanca|Instituto de Salud Carlos III
Sex: ALL
Age: OLDER_ADULT
Phases: NA
Enrollment: 514
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: CARTIER
Start Date: 2019-08-02
Primary Completion Date: 2024-08-02
Completion Date: 2025-11-30
First Posted: 2018-10-18
Results First Posted:
Last Update Posted: 2022-05-31
Locations: Hospital Clínico Universitario de Santiago de Compostela, Santiago De Compostela, A Coruña, 15706, Spain|Hospital de Galdakao-Usansolo, Galdakao, Vizcaya, 48960, Spain|Hospital Universitario Vall d´Hebron, Barcelona, 08035, Spain|Hospital Universitario Reina Sofía,

Córdoba, 14004, Spain|Hospital Universitario de La Princesa, Madrid, 28006, Spain|Hospital G. Universitario Gregorio Marañón, Madrid, 28009, Spain|Hospital Universitario Ramón y Cajal, Madrid, 28034, Spain|Hospital Universitario Fundación Jiménez Díaz, Madrid, 28040, Spain|Hospital Universitario 12 de Octubre, Madrid, 28041, Spain|Hospital Universitario Puerta de Hierro, Madrid, 28222, Spain|Hospital Universitario Virgen de la Victoria, Málaga, 29010, Spain|Complejo Asistencial Universitario de Salamanca, Salamanca, 37007, Spain|Hospital Universitario Virgen del Rocío, Sevilla, 41013, Spain|Hospital Universitario Río Hortega, Valladolid, 47012, Spain
Study Documents:

NCT Number: NCT04030546
Study Title: Ivabradine to Prevent Anthracycline-induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT04030546
Acronym:
Study Status: UNKNOWN
Brief Summary: The aim of this study is to investigate protective effects of ivabradine in adult cancer patients undergoing anthracycline-based chemotherapy.
Study Results: NO
Conditions: Patients With Cancer
Interventions: DRUG: Ivabradine
Primary Outcome Measures: Change in left venticular dysfunction by global longitudinal strain (GLS)., Change in global longitudinal strain (GLS) at least by 3%., 1, 3 and 6 months
Secondary Outcome Measures: Incidence of myocardial injury according to levels of high-sensitivity cardiac troponin T and NT-proBNP, Incidence of myocardial injury according to levels of high-sensitivity cardiac troponin T and NT-proBNP., 1, 3 and 6 months|Incidence of left ventricular systolic and diastolic dysfunction by 2D and 3D echocardiography., Incidence of left ventricular (LV) dysfunction defined as drop of LV ejection fraction by ≥ 10%., 1, 3 and 6 months
Other Outcome Measures: Incidence of symptomatic heart failure., Incidence of symptomatic heart failure., 1, 3 and 6 months|Changes in left ventricular and right ventricular dimensions by 2D and 3D echocardiography., Changes in left ventricular and right ventricular dimensions by 2D and 3D echocardiography., 1, 3 and 6 months
Sponsor: Vilnius University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 128
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: TREATMENT
Other IDs: ICO

Start Date: 2019-06-01
Primary Completion Date: 2020-06-01
Completion Date: 2020-12-31
First Posted: 2019-07-24
Results First Posted:
Last Update Posted: 2019-12-18
Locations: Vilnius University Hospital Santaros klinikos, Vilnius, 08661, Lithuania
Study Documents:

NCT Number: NCT01219010
Study Title: A Study Evaluating the Effects of Siltuximab on the Heart in Patients With Monoclonal Gammopathy of Undetermined Significance, Smoldering Multiple Myeloma, or Indolent Multiple Myeloma
Study URL: https://beta.clinicaltrials.gov/study/NCT01219010
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine if siltuximab has an effect on the heart function measured by ECG recordings and more specifically to determine if siltuximab has an effect on the QT interval in patients with Monoclonal Gammopathy of Undetermined Significance (MGUS), Smoldering Multiple Myeloma (SMM) or Indolent Multiple Myeloma (IMM). The study will also look to see if siltuximab may be useful in treating patients with MGUS, SMM or IMM.
Study Results: NO
Conditions: Monoclonal Gammopathy of Undetermined Significance|Multiple Myeloma|Plasma Cell Neoplasm
Interventions: BIOLOGICAL: Siltuximab
Primary Outcome Measures: QTc interval, Screening through Week 10
Secondary Outcome Measures: Additional safety evaluations, 6 months and, if eligible, up to 2 years of extended treatment|Efficacy evaluations, 6 months and, if eligible, up to 2 years of extended treatment|Pharmacokinetic and Pharmacodynamic evaluations, 6 months and, if eligible, up to 2 years of extended treatment
Other Outcome Measures:
Sponsor: Janssen Research & Development, LLC
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 30
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CR017452|CNTO328SMM1001
Start Date: 2010-10
Primary Completion Date: 2012-06
Completion Date: 2014-03
First Posted: 2010-10-13

Results First Posted:
Last Update Posted: 2015-01-19
Locations: Chicago, Illinois, United States|Dallas, Texas, United States|Houston, Texas, United States|Antwerpen, Belgium|Gent, Belgium|Izhevsk, Russian Federation|Moscow N/A, Russian Federation|Nizhni Novgorod, Russian Federation
Study Documents:

NCT Number: NCT01110031
Study Title: Ofatumumab Cardiac Repolarization (QTc) Study in Fludarabine-Refractory Chronic Lymphocytic Leukemia Subjects
Study URL: https://beta.clinicaltrials.gov/study/NCT01110031
Acronym:
Study Status: COMPLETED
Brief Summary: Ofatumumab is a fully-human monoclonal antibody that exhibits high binding affinity to an antigen on the surface of B lymphocytes. Antigen engagement by ofatumumab results in maximal B-cell killing through complement-dependent cytotoxicity and antigen-dependent cellular cytotoxicity in both antigen high- and low-expressing cells. Recent research has shown that ofatumumab-dependent B-cell depletion provides clinical benefit to subjects with CD20-positive cancers such as chronic lymphocytic leukemia (CLL). The purpose of the current study is to assess the impact of ofatumumab on electrocardiographic parameters with particular focus on cardiac repolarization (QTc interval duration) in subjects with refractory CLL. Subjects enrolled in this open-label, single-arm trial will receive ofatumumab at the highest clinical dose (2000 mg) studied or planned for study. Ofatumumab will be administered as eight weekly intravenous (IV) infusions followed by four monthly infusions, beginning in Week 13, across a 25-week treatment period. Cardiovascular effects will be evaluated during treatment through routine 12-lead electrocardiographic (ECG) monitoring. The pharmacokinetic relationship between plasma concentration of ofatumumab and its effect on QTc interval duration will be examined. Specifically, ECG assessments will be collected in triplicate at baseline, at the time of maximum ofatumumab concentrations periodically on-therapy, and at the end of treatment. After completion of the final ofatumumab infusion, subjects will continue to be followed for safety and efficacy for six months relative to the last ofatumumab dose.
Study Results: NO
Conditions: Leukaemia, Lymphocytic, Chronic
Interventions: BIOLOGICAL: Ofatumumab
Primary Outcome Measures: Cardiac Repolarization (Fredericia's QTc), ECGs are collected in triplicate during the study to assess QTc effect., 25-week ofatumumab treatment period
Secondary Outcome Measures: Plasma concentrations of ofatumumab and electrocardiogram (ECG) parameters, The pharmacokinetic results will be correlated to ECG findings to determine if drug concentrations relate to any ECG effects., 25-week ofatumumab treatment period|Vital

signs, weight, adverse events, Safety and tolerability of ofatumumab therapy will be determined by analysing changes in vital signs, weight, or development of adverse events., 25-week ofatumumab treatment period plus 6-month follow-up after final ofatumumab infusion|Flow cytometry, Efficacy of ofatumumab therapy will be measured by the number of CD20 positive cells in the blood, 25-week ofatumumab treatment period plus 6-month follow-up after final ofatumumab infusion|Cytokine, chemokine, human anti-human antibodies, Effect of ofatumumab on circulating biomarkers in refractory Chronic Lymphocytic Leukemia (CLL) subjects will be determined by measuring changes in the cytokine, chemokine, human anti-human antibody levels., 25-week ofatumumab treatment period plus 6-month follow-up after final ofatumumab infusion
Other Outcome Measures:
Sponsor: GlaxoSmithKline
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 12
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: OTHER
Other IDs: 112855
Start Date: 2010-05-13
Primary Completion Date: 2012-04-12
Completion Date: 2012-06-26
First Posted: 2010-04-23
Results First Posted:
Last Update Posted: 2017-11-13
Locations: GSK Investigational Site, La Jolla, California, 92093, United States|GSK Investigational Site, Randwick, New South Wales, 2031, Australia|GSK Investigational Site, Auckland, 1150, New Zealand|GSK Investigational Site, Christchurch, 8011, New Zealand
Study Documents:

NCT Number: NCT04275830
Study Title: The Effects of Heart Rate Variability Biofeedback Training on Hematopoietic Cell Transplantation Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04275830
Acronym:
Study Status: COMPLETED
Brief Summary: Patients undergoing hematopoietic stem cell transplantation (HCT) often continue to experience anxiety, depression, isolation, and other psychosocial distress due to the severe nature of the transplant experience. Storytelling interventions that provide an opportunity for emotional disclosure have shown preliminary efficacy to alleviate psychosocial distress and improve emotion regulation during health challenges. Not only are these

changes observed in response to such interventions, but they can also be directly strengthened with HRV biofeedback (HRVB) training, a device-driven breath pacing practice that uses colored light signals to provide feedback to increase vagal tone and improve emotional responses and sleep quality by regulating negative affect and stress. This randomized controlled trial will explore the effects of HRV biofeedback (HRVB) training combined with a digital storytelling intervention and changes in psychosocial distress with a modified waitlist control in a population of Hematopoietic cell transplantation (HCT) patients.
Study Results: NO
Conditions: Hematopoietic Stem Cell Transplantation|Bone Marrow Transplant|Heart Rate Variability|Autonomic Nervous System|Stress|Mood|Psychological Distress|Emotion Regulation|Communication Research|Narrative
Interventions: BEHAVIORAL: Baseline Surveys|BEHAVIORAL: Heart rate variability biofeedback|BEHAVIORAL: Heart rate variability waitlist and Digital storytelling Control intervention
Primary Outcome Measures: Changes from Baseline Heart Rate Variability (HRV and coherence scores) at 2 weeks, The Emwave Pro Plus device from HeartMath will be used to collect HRV data and heart rate using a 3-minutes "neutral" protocol (we call "waiting at the bus stop" implying that no particular intent for breath or mindful state is to be evoked) to understand the benefits of DS+ HRVB. In addition, HRV measures will be obtained for the 1-minute paced breathing period to understand the effects of paced breathing on HRV. The following precautions will be provided as instructions to participants prior to data collection: no coffee, tea, or caffeinated drinks such as energizing drinks in the 2 hours before the data collection, and no alcohol consumption during 24 hours prior to the data collection., Baseline (T1), 2 weeks after (T2)
Secondary Outcome Measures: Changes from Baseline Profile of Mood States (POMS) short version (Psychological Distress) at 2 weeks, Psychological distress will be measured using the Profile of Mood States (POMS) short version (15 items, 5-point Likert scale; 0=not at all, 4=extremely). The POMS is one of the most frequently used and validated scales in studies of psychosocial interventions for cancer patients. The POMS Total Mood Disturbance (TMD) score has been shown to be most sensitive to interventions designed to facilitate emotional expression. The POMS consists of the TMD dimensions (tension-anxiety; depression-dejection; anger-hostility; and confusion-bewilderment) (Cronbach's a = .93) to be used in the current study as the primary outcome measure; and two others (fatigue-inertia; vigor-activity) will be documented. Total of Mood Disturbance= (anxious+depression+anger+fatigue)- vigor (Range from 12 to 48). The higher values represent a worse emotional well-being., Baseline (T1), 2 weeks after (T2)
Other Outcome Measures: Changes from Baseline Depression at 2 weeks, Depression will be measured using the Center for Epidemiological Studies Depression Scale Revised (CESD-R-10) scale (10 items, 4-point Likert scale (0 = rarely or none of the time, 3= all of the times,

Cronbach's a = .86). The higher values represent a worse depression., Baseline (T1), 2 weeks after (T2)
Sponsor: Arizona State University
Collaborators: HonorHealth Research Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 18
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: STUDY00010085|PG12840
Start Date: 2020-02-04
Primary Completion Date: 2021-12-31
Completion Date: 2022-02-04
First Posted: 2020-02-19
Results First Posted:
Last Update Posted: 2022-05-23
Locations: HonorHealth, Scottsdale, Arizona, 85258, United States
Study Documents:

NCT Number: NCT04995848
Study Title: Telepalliation - Digital Platform for Patients in Palliation and Their Relatives
Study URL: https://beta.clinicaltrials.gov/study/NCT04995848
Acronym:
Study Status: RECRUITING
Brief Summary: This project has focus on patients in palliation testing a digital platform TelePal.dk.
Study Results: NO
Conditions: Cancer|Heart Failure|Chronic Obstructive Pulmonary Disease|Neurological Diseases
Interventions: OTHER: Telepalliation
Primary Outcome Measures: Changes in Quality of life, Measured by the European Organization for Research and Treatment of Cancer, questionnaire regarding quality of life in palliative cancer care patients (EORTC QLQ-C15-PAL)., At baseline, week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, and 26
Secondary Outcome Measures: Changes in medicine, Information on medicine for both groups will be collected at enrolment and every week from the electronic patient record (EPR). Changes in medicine over time will be analyzed., At enrolment and week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, and 26|Changes in feeling of security, Measured on a likert scale, At baseline, twice every week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, and 26|Experiences of pain, Numerical Rating Scale (NRS), At baseline, week 1, 2, 3, 4, 5,

6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, and 26|Experience of pain (brief), Brief Pain Inventory, short form (BPI-sf), At baseline, week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, and 26|Experiences of patients on the actual use of the TelePal.dk platform and their experiences of being a part of a telepalliation program, Qualitative interviews, Week 4|Experiences of relatives on the actual use of the TelePal.dk platform and their experiences of being a part of a telepalliation program, Qualitative interviews, Week 4 and 3 months|Experiences of health care professionals on the actual use of the TelePal.dk platform and their experiences of being a part of a telepalliation program, Qualitative interviews, 6 months and 12 months|Perceptions on usability of a cross-sector communication platform and telerehabilitation program by patients, relatives and health care professionals, Qualitative interviews, 12 months|Observations on usability of a cross-sector communication platform and telerehabilitation program by patients, relatives and health care professionals, Observations, 12 months|Health related quality of life, Measured by EQ-5D Health Questionnaire, week 1 and week 4|Cost of healthcare services, Cost-effectiveness analysis ((number of phone/video calls, equipment, driving, personal use in palliative care (video and home visits), visits to general practitioner and outpatient clinic, hospitalizations, readmissions and length of stay, visits from palliative team)), 24 months
Other Outcome Measures:
Sponsor: Aalborg University
Collaborators: Palliative Team,Hospital of South West Jutland|Center for Innovative Medical Technologies (CIMT), Odense University Hospital|Danish Cancer Society|Laboratory of Welfare Technology, Department of Health Science and Technology, Aalborg University
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 182
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: N-20200094
Start Date: 2021-05-26
Primary Completion Date: 2024-01-01
Completion Date: 2024-06-30
First Posted: 2021-08-09
Results First Posted:
Last Update Posted: 2021-08-12
Locations: Palliative Team, South West Jutland Hospital, ESbjerg, Denmark
Study Documents:

NCT Number: NCT03866148

Study Title: Obstructive Sleep Apnoea and Cardiac Arrhythmias
Study URL: https://beta.clinicaltrials.gov/study/NCT03866148
Acronym: OSCA
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This study is a prevelance trial looking at how sleep apnoea affects the heart especially heart rhythms.

Previous research shows that patients suffering from sleep apnoea are much more likely to get heart disease and abnormal heart rhythms (arrhythmias). These defects are sometimes missed by the traditional methods of monitoring i.e. 24-hour Holter monitor and ECGs. This means potentially dangerous arrhythmias may not be detected. Additionally, standard therapy for sleep apnoea does not significantly reduce the risk of heart disease.

This study will recruit 200 participants over a period of 18 months. The research team will observe the heart rhythms of sleep apnoea patients by inserting an implantable loop recorder (ILR) in up to 100 participants. The other 100 patients will simply have standard care. This device will monitor the heart continuously for 3 years allowing us to detect abnormal heart rhythms and treat as necessary.

Demonstrating the incidence of arrhythmia can lead onto a larger study which may change future sleep apnoea management improving their cardiovascular outcomes. Other markers of heart disease such as; blood tests, Magnetocardiography and Echocardiography will be performed on participants to shed more light on the mechanisms which link sleep apnoea and heart disease/arrhythmia.
Study Results: NO
Conditions: Obstructive Sleep Apnea|Cardiovascular Diseases|Arrhythmia|Atrial Fibrillation New Onset
Interventions: DEVICE: Reveal LINQ
Primary Outcome Measures: Incidence of arrhythmia, Incidence of arrhythmia in sleep apnoea patients as recorded by ILR vs a no ILR group, 3 years|Autonomic function before and after CPAP, Assess the changes to the heart in sleep apnoea patients before and after CPAP in terms of heart rate variability as measured on 24 hour holter monitors. The raw data is taken from the monitor and then analysed manually. The first data set will be from baseline studies which will be compared to studies done at the 1 year follow-up., 3 years
Secondary Outcome Measures: Onset and frequency of atrial fibrillation, Explore the onset and frequency of atrial fibrillation in sleep apnoea patients in order to determine what method of detection is efficient and cost effective., 3 years|Rate of Cardiovascular Morbidity, Explore the impact of inserting an ILR in patients with sleep apnoea on cardiovascular morbidity (stroke and myocardial infarction) compared to those without ILR, 3 years|Rate of Cardiovascular Mortality, Explore the impact of inserting an ILR in patients with sleep apnoea on cardiovascular mortality (stroke and/or myocardial infarction resulting in death) compared to those without

ILR, 3 years|Cardiovascular biomarkers before and after CPAP, Explore the changes to the heart in sleep apnoea patients before and after CPAP in terms of vascular biomarkers - high sensitivity C-Reactive Protein, high sensitivity Troponin-T, N-terminal pro B-type Natriuretic Peptide, Tumour Necrosis Factor-alpha, Matrix Metalloproteinase-9, Interleukin-6, Fibroblast Growth Factor-23. The first data set will be from baseline studies which will be compared to studies done at the 1 year follow-up., 3 years|Echocardiography before and after CPAP, Explore the changes to the heart in sleep apnoea patients before and after CPAP in terms of echocardiogram measures., 3 years|Quality of life: EQ-5D-5L questionnaire, Quality of life measures before and after CPAP as measured by the EQ-5D 5 level questionnaire. This measures various quality of life points from a scale of 1-5. 1 represents poor quality of life and 5 represents good quality of life for each factor. This data will be analysed as per the EuroQol algorithm. The first data set will be from baseline studies which will be compared to studies done at the 1 year follow-up., 3 years
Other Outcome Measures:
Sponsor: University Hospitals Coventry and Warwickshire NHS Trust
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: FO409918
Start Date: 2019-10-03
Primary Completion Date: 2023-04-15
Completion Date: 2025-04-15
First Posted: 2019-03-07
Results First Posted:
Last Update Posted: 2023-06-02
Locations: University Hospital Coventry & Warwickshire, Coventry, CV2 2DX, United Kingdom
Study Documents:

NCT Number: NCT01531751
Study Title: High Cut-off Hemodialysis in Patients With Advanced Cardiac AL Amyloidosis and End Stage Renal Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT01531751
Acronym: DIACAL
Study Status: WITHDRAWN
Brief Summary: The aim of the study is to assess survival of patients with advanced cardiac AL amyloidosis treated with high cut-off hemodialysis (HCO-HD) combined with chemotherapy.
Study Results: NO

Conditions: Primary Amyloidosis of Light Chain Type
Interventions: DEVICE: High Cut-off Hemodialysis|DRUG: Chemotherapy
Primary Outcome Measures: Survival, The primary objective will be to assess survival of patients with advanced cardiac AL amyloidosis treated with HCO-HD combined with chemotherapy., 6 months
Secondary Outcome Measures: tolerability of the experimental device, Secondary objectives will be to assess the feasibility and tolerability of HCO-HD in patients with advanced cardiac AL amyloidosis, the efficiency of HCO-HD plus chemotherapy in reducing amyloidogenic FLC in this setting, and the ability of this approach to promote improvement of cardiac dysfunction as assessed by biomarkers., 1 month
Other Outcome Measures:
Sponsor: IRCCS Policlinico S. Matteo
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: AC-005-IT
Start Date: 2015-02
Primary Completion Date: 2015-12
Completion Date: 2015-12
First Posted: 2012-02-13
Results First Posted:
Last Update Posted: 2018-03-21
Locations: Centro per lo Studio e la Cura delle Amiloidosi Sistemiche - Fondazione IRCCS Policlinico S.Matteo, Pavia, 27100, Italy
Study Documents:

NCT Number: NCT01280825
Study Title: The 1200 Patients Project: Studying the Implementation of Clinical Pharmacogenomic Testing
Study URL: https://beta.clinicaltrials.gov/study/NCT01280825
Acronym:
Study Status: RECRUITING
Brief Summary: The purpose of this study is to collect DNA samples from patients undergoing routine care at the University of Chicago. These samples will be tested for differences in genes that may suggest greater risk of side effects or chance of increased benefit from certain medications. The results will be made available to the patient's treating physician and the researchers will track whether or not this information is used in routine health care.
Study Results: NO
Conditions: Patients Undergoing Routine Health Care|Heart Diseases|Inflammatory Bowel Diseases|Autoimmune Disease|Inflammatory Disease|

Blood Coagulation Disorders|Hepatitis C|Non-Metastatic Neoplasm
Interventions:
Primary Outcome Measures: Feasibility of incorporating pharmacogenomic testing into routine medical care, 5 years
Secondary Outcome Measures: Find out whether availability of pharmacogenomic information impacts drug decision making in the health care setting, 5 years
Other Outcome Measures: To determine whether access to pharmacogenomic information improves satisfaction with care., 5 years
Sponsor: University of Chicago
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1200
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 10-487-A
Start Date: 2011-01-14
Primary Completion Date: 2023-11-14
Completion Date: 2023-12-14
First Posted: 2011-01-21
Results First Posted:
Last Update Posted: 2023-03-07
Locations: University of Chicago Medical Center, Chicago, Illinois, 60637, United States
Study Documents:

NCT Number: NCT01956773
Study Title: Family Health History in Diverse Care Settings (FHH)
Study URL: https://beta.clinicaltrials.gov/study/NCT01956773
Acronym: FHH
Study Status: COMPLETED
Brief Summary: The outcome of this research will be a demonstration that family health history (FHH) risk data can be used efficiently to deliver more effective healthcare in geographically and ethnically diverse clinical care environments. Although FHH is a standard component of the medical interview its widespread adoption is hindered by three major barriers: (1) a dearth of standard collection methods; (2) the absence of health care provider access to complete FHH information; and (3) the need for clinical guidance for the interpretation and use of FHH. In addition, the time constraints of the busy provider and poor integration of FHH with paper medical records or electronic medical records (EMR) impede its widespread use. The investigators hypothesize that patient-driven and electronic collection of FHH for risk stratification will promote more informed decision-making by patients and providers, and improves adherence to risk-stratified preventive care guidelines. The study team will use an implementation sciences approach to integrate an innovative FHH system

that collects FHH from patients. Intermountain Healthcare will provide the information technology expertise with EMR design to develop an innovative solution to a storage model standard for FHH data as well as a centralized standards-compliant open clinical decision support (OpenCDS) rule development architecture to analyze FHH and to generate evidence-based, individualized, disease risk, preventive care recommendations for both patients and providers.
Study Results: YES
Conditions: Diabetes|Heart Disease|Cancer
Interventions: OTHER: MeTree
Primary Outcome Measures: Number of Participants With Uptake of Genetic Counseling for Those at Risk of Hereditary Conditions at 1 Year, How many patients identified as meeting criteria for genetic counseling, how many providers ordered genetic counseling, and how many patients adhere to the provider recommendation at 1 year., Baseline, 3 and 12 months
Secondary Outcome Measures: Number of Participants Reporting Satisfaction When Using the MeTree Tool, The study will assess satisfaction associated with using the MeTree tool via 3 months survey after completing the family health history collection. The participant were asked their level of satisfaction with their experience using the web-based portal to enter information for their provider before their appointment, 3 months|Number of Participants Reporting Comfort When Using the MeTree Tool, The study will assess comfort associated with using the MeTree tool via 3 months survey after completing the family health history collection. The participant were asked if the MeTree program was easy to use, 3 months|Number of Participants Reporting Anxiety When Using the MeTree Tool, The study will assess anxiety associated with using the MeTree tool via 3 months survey after completing the family health history collection. The participant were asked if answering the questions made them anxious, 3 months|Number of Participants Reporting Preparedness When Using the MeTree Tool, The study will assess preparedness associated with using the MeTree tool via 3 months survey after completing the family health history collection. The participants were asked if they had enough information about some people in their family when completing MeTree, 3 months|Number of Physicians Who Gave Their Perceptions of Satisfaction and the MeTree Tool's Impact on Work Load, Evaluate physicians' perceptions of satisfaction, the MeTree tool's impact on work load and its effectiveness via survey and informal interviews at 3 months., 3 months|Number of Providers Who Were Successfully Using MeTree in Their Clinical Work Flow, Evaluate which providers were successfully using MeTree in their clinical work flow and which patients are successfully using MeTree for their care. (surveys, monitoring of clinical workflow, patient recruitment reflects underlying clinic population), 1 year
Other Outcome Measures:
Sponsor: Duke University
Collaborators:
Sex: ALL

Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 2620
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: Pro00043372|Pro00047666
Start Date: 2014-04-11
Primary Completion Date: 2017-10-31
Completion Date: 2017-10-31
First Posted: 2013-10-08
Results First Posted: 2019-02-18
Last Update Posted: 2019-11-25
Locations: David Grant Medical Center, Fairfield, California, 94535, United States|Essentia Institute of Rural Health, Duluth, Minnesota, 55805, United States|Duke University Medical Center, Durham, North Carolina, 27710, United States|University of North Texas Health Science Center, Fort Worth, Texas, 76107, United States|Medical College of Wisconsin, Milwaukee, Wisconsin, 53226, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT03505164
Study Title: The Role of suPAR Biomarker in Blood Samples of Breast Cancer Patients During and Post Doxorubicin Chemotherapy: Causative vs. Predictor
Study URL: https://beta.clinicaltrials.gov/study/NCT03505164
Acronym:
Study Status: COMPLETED
Brief Summary: This study looks to find a causative or predictive aspect of the suPAR biomarker for heart failure in breast cancer patients receiving Doxorubicin drug chemo regimen.

suPAR is a circulating protein which can be found in blood and/or urine and is associated with both kidney and heart disease.

* Hypothesis 1: Higher suPAR at baseline will predispose to Doxorubicin-induced cardiomyopathy or heart failure, observed by histology (under the microscope and other lab techniques) in mouse models, and tested using heart ultrasound techniques in humans.
* Hypothesis 2: suPAR is a marker of Doxorubicin-induced cardiomyopathy or heart failure after exposure to Doxorubicin, observed by histology (under the microscope and other lab techniques) in mouse models, and tested in humans.

The study will look at suPAR's association with three other biomarkers called troponin, B-Type Natriuretic Peptide (BNP) and C- Reactive Protein (CRP) that are also associated with heart disease.

In this study, the patient will have blood drawn as a routine part of

the cancer treatment. That is prior to starting the cancer therapy, then after the first 2 and last 2 doxorubicin cycles (4 cycles altogether); as well as at 3, 6, \& 12 months after doxorubicin treatment. (6 Visits in total) The patient will also have an echocardiogram (echo, heart ultrasound) at each of these time points. The first of the six study echos is considered part of the routine care.
Study Results: NO
Conditions: Doxorubicin Adverse Reaction|Cardiomyopathies, Secondary|Breast Cancer
Interventions:
Primary Outcome Measures: Causality relationship between the suPAR blood level and doxorubicin-induced cardiomyopathy, A blood draw will be done at baseline for all participants. The blood samples will be processed by Centrifugation, to separate the plasma, and the suPAR level measured using ELISA technique, to stratify the participants that have a higher or normal baseline.

Although there is no current consensus regarding normal suPAR blood level, a level of 3000 pg/mL is considered a high level.

Higher baseline blood level of suPAR, will predispose patients with breast cancer undergoing chemo regimen containing doxorubicin, to develop heart toxicity (heart failure or cardiomyopathy).

Heart failure or Cardiomyopathy will be diagnosed by the clinical evaluation with signs and symptoms, LVEF (Left Ventricular Ejection Fraction) with echocardiograms (heart ultrasound), and surrogate cardiovascular outcome measures as described in humans, and tissue visualization and histology in mouse models, with various staining techniques, whether it was H\&E staining, or other immunological staining., 12 months|Predictive relationship between suPAR blood level and doxorubicin-induced cardiomyopathy, A blood draw will be done at baseline for all participants. The blood samples will be processed by Centrifugation to separate the plasma, and the suPAR level measured using ELISA technique, to stratify the participants having a higher or normal baseline.

Although there is no current consensus regarding normal suPAR blood level, a level less than 3000 pg/mL is considered a normal level.

A normal baseline blood level of suPAR, with progressive elevation following doxorubicin exposure, along with other blood markers for heart failure, will be considered as a predictive marker for doxorubicin-induced cardiomyopathy.

Heart failure or Cardiomyopathy will be diagnosed by the clinical evaluation with signs and symptoms, LVEF (Left Ventricular Ejection Fraction) with echocardiograms (heart ultrasound), and surrogate cardiovascular outcome measures as described in humans, and tissue

visualization and histology in mouse models using H\&E staining, or other immunological staining techniques., 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Rush University Medical Center
Collaborators:
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 42
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 16022426
Start Date: 2017-01-17
Primary Completion Date: 2020-07-06
Completion Date: 2020-07-06
First Posted: 2018-04-23
Results First Posted:
Last Update Posted: 2021-04-27
Locations: Rush University Medical Center, Chicago, Illinois, 60612, United States|Rush Oak Park Hospital, Oak Park, Illinois, 60304, United States
Study Documents:

NCT Number: NCT00019864
Study Title: Combination Chemotherapy Before and After Surgery in Treating Patients With Osteosarcoma
Study URL: https://beta.clinicaltrials.gov/study/NCT00019864
Acronym:
Study Status: TERMINATED
Brief Summary: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Giving chemotherapy before surgery may shrink the tumor so that it can be removed during surgery. Giving chemotherapy after surgery may kill more tumor cells.

PURPOSE: This phase II trial is studying how well giving chemotherapy before and after surgery works in treating patients with osteosarcoma.
Study Results: NO
Conditions: Cardiac Toxicity|Sarcoma
Interventions: BIOLOGICAL: filgrastim|DRUG: cisplatin|DRUG: dexrazoxane hydrochloride|DRUG: doxorubicin hydrochloride|DRUG: leucovorin calcium|DRUG: methotrexate|PROCEDURE: adjuvant therapy|PROCEDURE: conventional surgery|PROCEDURE: neoadjuvant therapy
Primary Outcome Measures: Rate of in vivo histologic response|Event-free survival|Overall survival
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Cancer Institute (NCI)

Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE2
Enrollment: 100
Funder Type: NIH
Study Type: INTERVENTIONAL
Study Design: Allocation: |Intervention Model: |Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CDR0000067263|NCI-99-C-0125I
Start Date: 2000-03
Primary Completion Date: 2006-12
Completion Date: 2011-10
First Posted: 2003-01-27
Results First Posted:
Last Update Posted: 2015-06-08
Locations: Warren Grant Magnuson Clinical Center - NCI Clinical Trials Referral Office, Bethesda, Maryland, 20892-1182, United States| Oklahoma University Cancer Institute, Oklahoma City, Oklahoma, 73104, United States|Cook Children's Medical Center - Fort Worth, Fort Worth, Texas, 76104, United States|Texas Children's Cancer Center and Hematology Service at Texas Children's Hospital, Houston, Texas, 77030-2399, United States
Study Documents:

NCT Number: NCT02123173
Study Title: Hemodynamic Changes During One Lung Ventilation in Non-intubated Vedio-assisted Thoracoscopic Operations
Study URL: https://beta.clinicaltrials.gov/study/NCT02123173
Acronym:
Study Status: COMPLETED
Brief Summary: Non-intubated thoracoscopic surgery has been proved as an adequate alternative for management of many lung conditions such as pneumothorax , lung volume reduction, pulmonary metastasectomy, removal of lung nodules, segmentectomy and lobectomy. However, the hemodynamic changes during one lung ventilation have not been fully investigated. The goals of this study are to compare the changes of hemodynamics (including blood pressure, heart rate, cardiac output, pulse pressure variation, fluid responsiveness) during one lung ventilation between conventional intubated and non-intubated vedio-assisted thoracoscopic (VATS) operations.
Study Results: NO
Conditions: Lung Neoplasms
Interventions:
Primary Outcome Measures: cardiac output after one lung ventilation, record the stroke volume and cardiac output during two lung ventilation till 15 minutes after one lung ventilation, 10-15 minutes
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Taiwan University Hospital

Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 71
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 201401037RINB
Start Date: 2014-05
Primary Completion Date: 2014-11
Completion Date: 2014-12
First Posted: 2014-04-25
Results First Posted:
Last Update Posted: 2014-12-04
Locations: National Taiwan University Hospital, Taipei, 100, Taiwan
Study Documents:

NCT Number: NCT01698164
Study Title: Multi-centre Clinical Trial on Hormone Replacement Treatment in China
Study URL: https://beta.clinicaltrials.gov/study/NCT01698164
Acronym:
Study Status: UNKNOWN
Brief Summary: This study is to evaluate the benefit/risk of hormone replacement treatment among early menopausal women in China. This is a multi-centre, random, prospective study.
Study Results: NO
Conditions: Menopausal Syndrome|Cardiovascular Disease|Osteoporosis|Breast Cancer
Interventions: DRUG: estradiol plus MPA|DRUG: Ximingting Tablet|DRUG: estradiol plus progesterone
Primary Outcome Measures: Change from Baseline in risk factors of cardiovascular disease at 12 months and 24 months, lipid profiles, high-sensitivity C-reactive protein, Hemoglobin A1C, fasting glucose, fasting insulin, blood pressure, waistline, hipline, body composition, electrocardiogram, incidence of coronary heart disease, before the treatment, time point of taking the medicine for 1 year, time point of taking the medicine for 2 years|Change from Baseline in risk factors of breast cancer at 12 months and 24 months, Mammography, palpation of breast, incidence of breast cancer, before the treatment, time point of taking the medicine for 1 year, time point of taking the medicien for 2 years
Secondary Outcome Measures: Change from Baseline in BMD at 12 months and 24 months, DEXA bone mineral density, before the treatment, time point of taking the medicine for 1 year, time point of taking the medicien for 2 years|Change from Baseline in risk factors of senile dementia every three months, mini-mental state examination, hospital anxiety and depression scale, before the recruitment, before handing out the mecidcine, every three months after taking the medicine till

two years later|Change from Baseline in the quality of life every three months, Kupperman menopause index, RAND36 Menopause-Specific quality of life questionaire, before the recruitment, before handing out the mecidcine, every three months after taking the medicine till two years later
Other Outcome Measures: Change from Baseline in thickness of endometrium at 12 months and 24 months, ultrasonography, before the treatment, time point of taking the medicine for 1 year, time point of taking the medicien for 2 years|uterine bleeding, diary, every three months after taking the medicine until two years later|Change from Baseline in vital signs every three months, height, weight, heart rate, BP, gynecological examination, before the recruitment, before handing out the mecidcine, every three months after taking the medicine till two years later|Change from Baseline in general health at 12 months and 24 months, liver function, renal function, before the treatment, time point of taking the medicine for 1 year, time point of taking the medicien for 2 years
Sponsor: Peking Union Medical College Hospital
Collaborators:
Sex: FEMALE
Age: ADULT
Phases: PHASE4
Enrollment: 1200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 2008BAI57B04
Start Date: 2008-12
Primary Completion Date: 2012-10
Completion Date:
First Posted: 2012-10-02
Results First Posted:
Last Update Posted: 2012-10-02
Locations: PUMCH, Peking, Beijing, 100730, China
Study Documents:

NCT Number: NCT05132673
Study Title: Cardiac Autonomic Dysfunction in Childhood Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT05132673
Acronym:
Study Status: SUSPENDED
Brief Summary: This study is being done to evaluate heart rate activity and sleep patterns, among participants in the Long-Term Follow-Up (LTFU) study.

Primary Objective

Using mobile health (mHealth) technologies in a large and well-

characterized cohort of childhood cancer survivors, our primary objective is to understand the magnitude of increased risk of cardiac autonomic dysfunction by (a) comparing prevalence rates among survivors and siblings, and (b) determining the prevalence within specific subgroups of childhood cancer survivors defined by race, sex, cancer type and treatment exposures, and type and severity of chronic health conditions.

Secondary Objectives

Among long-term (≥5 years) survivors of childhood cancer (a) identify demographic, disease, treatment and cognitive-behavioral factors associated with an increased risk of cardiac autonomic dysfunction, (b) develop and validate risk prediction models for future clinical use in identifying individuals who may benefit from targeted interventions, and (c) investigate associations between dysfunction and perceived well-being.
Study Results: NO
Conditions: Autonomic Dysfunction|Childhood Cancer
Interventions:
Primary Outcome Measures: Heart rate variability, Standard deviation of NN (normal to normal RR) intervals (SDNN), Measured over a 24 hour period
Secondary Outcome Measures: Autonomic Symptoms, Self-reported autonomic symptoms via the COMPASS31, Assessed at baseline|Perceived health, Self-reported perceived health via Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), Assessed at baseline|Perceived stress, Cohen's Perceived Stress Scale, Minimum value = 0, Maximum value = 40, Higher scores mean a worse outcome, Assessed at baseline|Cognitive status, Childhood Cancer Survivor Study Neurocognitive Questionnaire, Minimum Value = 33, Maximum value = 99, Higher scores mean a worse outcome, Assessed at baseline|Sleep Onset, Sleep hygiene will be measured via wearable sleep tracker. Sleep onset will be measured in minutes., Measured over 2 weeks|Wake Onset, Sleep hygiene will be measured via wearable sleep tracker. Wake onset will be measured in minutes., Measured daily over 2 weeks|Sleep efficiency, Sleep hygiene will be measured via wearable sleep tracker. Sleep efficient will be measured by dividing the minutes asleep by the total minutes in bed., Measured daily over 2 weeks|Physical activity duration, Intensity and duration of daily activity will be measured via wearable activity tracker. Activity duration will be measured in minutes., Measured daily over 2 weeks|Workout strain, Intensity and duration of daily activity will be measured via wearable activity tracker. Workout strain will be calculated by the duration of time in personal heart rate zones, established from maximum heart rate., Measured daily over 2 weeks|Maximum heart rate, Intensity and duration of daily activity will be measured via wearable activity tracker. Maximum heart rate will be calculated by subtracting age from 220 and is measured in beats per minute., Measured daily over 2 weeks|Average heart rate, Intensity and duration of daily activity will be measured

via wearable activity tracker. Average heart rate will be calculated as number of beats per minute., Measured daily over 2 weeks
Other Outcome Measures:
Sponsor: St. Jude Children's Research Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 6000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: WEARIT|NCT05132673
Start Date: 2023-08
Primary Completion Date: 2025-07-01
Completion Date: 2026-07-01
First Posted: 2021-11-24
Results First Posted:
Last Update Posted: 2023-07-17
Locations: St. Jude Children's Research Hospital, Memphis, Tennessee, 38105, United States
Study Documents:

NCT Number: NCT01071473
Study Title: Resistance and Aerobic Exercise for Subclinical Anthracycline Cardiomyopathy
Study URL: https://beta.clinicaltrials.gov/study/NCT01071473
Acronym:
Study Status: COMPLETED
Brief Summary: This application proposes a prospective, single arm feasibility clinical trial of a 12-week period of combined endurance and resistance training in survivors of childhood cancer who were treated with doxorubicin and/or daunorubicin and have impaired cardiac function.

Baseline and post intervention imaging, laboratory, and neuropsychological evaluations will be used to determine the effects of the intervention on body composition, serum lipid profile, exercise tolerance, and neurocognitive functioning. Participants will be called weekly to monitor compliance with the intervention. Incentives will be given at intervals during the trial to optimize compliance with the intervention.
Study Results: NO
Conditions: Cardiomyopathy
Interventions: OTHER: 12 Week Exercise Intervention
Primary Outcome Measures: The primary aim of this proposal is to evaluate the feasibility of a 12-week exercise intervention among survivors of childhood cancer treated with anthracyclines and known to have cardiomyopathy., 12 Weeks
Secondary Outcome Measures:

Other Outcome Measures:
Sponsor: St. Jude Children's Research Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 22
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: CARHAB
Start Date: 2010-02
Primary Completion Date: 2012-10
Completion Date: 2012-10
First Posted: 2010-02-19
Results First Posted:
Last Update Posted: 2014-02-10
Locations: St. Jude Children's Research Hospital, Memphis, Tennessee, 38105, United States
Study Documents:

NCT Number: NCT05559164
Study Title: Statins for Reduction of Cardiac Toxicity in Patients Receiving HER2 Targeted
Study URL: https://beta.clinicaltrials.gov/study/NCT05559164
Acronym:
Study Status: RECRUITING
Brief Summary: This study proposes that the addition of statins reduces the treatment delays or early discontinuations secondary to cardiotoxicity in patients with Stage I-III HER2 positive breast being treated with anti-HER2 therapy.
Study Results: NO
Conditions: Cardiac Toxicity|Early-stage Breast Cancer
Interventions: DRUG: Lipitor 40mg Tablet
Primary Outcome Measures: Number of Participants With at Least One Adverse Event will be measured using Common Terminology Criteria for Adverse Events (CTCAE) v5.0 for five years, Adverse events (AEs) will be measured using Common Terminology Criteria for Adverse Events (CTCAE) v5.0 for five years, Five years
Secondary Outcome Measures: Patient reported outcome (PRO) for pain measured by the quality of Life questionnaire using PROMIS to measure pain, Quality of Life questionnaire using PROMIS will be administered at baseline, six, twelve and fifteen months, Baseline, six, twelve and fifteen months
Other Outcome Measures: Patient reported outcome (PRO) for pain measured by the quality of Life questionnaire using PROMIS to measure fatigue, Quality of Life questionnaire using PROMIS will be administered at baseline six, twelve and fifteen months, Baseline, six, twelve and fifteen months|Patient reported outcome (PRO) for pain

measured by the quality of Life questionnaire using PROMIS to measure physical functioning, Quality of Life questionnaire using PROMIS will be administered at baseline six, twelve and fifteen months to measure physical functioning, Baseline, six, twelve and fifteen months|Patient reported outcome (PRO) for pain measured by the quality of Life questionnaire using PROMIS to measure emotional distress, Quality of Life questionnaire using PROMIS will be administered at baseline six, twelve and fifteen months to measure emotional distress, Baseline, six, twelve and fifteen months|Patient reported outcome (PRO) for pain measured by the quality of Life questionnaire using PROMIS to measure social participation, Quality of Life questionnaire using PROMIS will be administered at baseline six, twelve and fifteen months to measure social participation, Baseline, six, twelve and fifteen months
Sponsor: Rutgers, The State University of New Jersey
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 042201|Pro2022000290
Start Date: 2022-09-19
Primary Completion Date: 2026-09-01
Completion Date: 2027-03-01
First Posted: 2022-09-29
Results First Posted:
Last Update Posted: 2023-06-18
Locations: Trinitas Hospital and Comprehensive Cancer Center, Elizabeth, New Jersey, 07202, United States|RWJBarnabas Health - Robert Wood Johnson University Hospital, Hamilton, Hamilton, New Jersey, 08690, United States|RWJBarnabas Health - - Jersey City Medical Medical, Jersey City, New Jersey, 07097, United States|Monmouth Medical Center Southern Campus, Lakewood, New Jersey, 08701, United States|RWJBarnabas Health - Monmouth Medical Center, Long Branch, New Jersey, 07740, United States|Monmouth Community Medical, Long Branch, New Jersey, 07764, United States|Rutgers Cancer Institute of New Jersey, New Brunswick, New Jersey, 08903, United States|RWJBarnabas Health - Robert Wood Johnson University Hospital, New Brunswick, New Jersey, 08903, United States|RWJBarnabas Health - Newark Beth Israel Medical Center, Newark, New Jersey, 07112, United States|RWJBarnabas Health - Robert Wood Johnson University Hospital, Somerset, New Jersey, 08873, United States
Study Documents:

NCT Number: NCT02841046
Study Title: The Effect of Goal-directed Therapy Guided by Stroke Volume Variation and Cardiac Index in Non-severe Surgical Patients

Study URL: https://beta.clinicaltrials.gov/study/NCT02841046
Acronym:
Study Status: COMPLETED
Brief Summary: To evaluate the application of fluid-infusion therapy with the combination of stroke volume variation (SVV) and cardiac index (CI) as the primary judgment in non-severe patients underwent resection of gastrointestinal tumor. Fifty patients (ASA I-II, 26-55 years old, cardiac functional gradingI) scheduled for gastrointestinal tumor surgery were divided into two groups randomly: group C with CI as the primary judgment and group S with the combination of SVV and CI as the primary judgment.
Study Results: YES
Conditions: Fluid Therapy
Interventions: DEVICE: cardiac index|DEVICE: Stroke Volume Variation
Primary Outcome Measures: Number of Days Needed for Anal Exsufflation After Surgery, record the number of days needed for anal exsufflation in non-severe patients after gastrointestinal tumor surgery, up to 8 weeks
Secondary Outcome Measures: the Incidence of Adverse Cardiovascular Events, including hypertension,hypotension,tachycardia,bradycardia, during the surgery|Oxygen Delivery (DO2) , oxygen delivery (DO2) in ml•min-1•m-2.Record the data of DO2 at the moment after anaesthetized immediately and at the moment when abdomen was closed., during the surgery|Oxygen Consumption (VO2) , oxygen delivery (VO2) in ml•min-1•m-2.Record the data of VO2 at the moment after anaesthetized immediately and at the moment when abdomen was closed., during the surgery|Oxygen Extraction Rate (ERO2) , oxygen extraction rate(ERO2) in percentage.Record the data of ERO2 at the moment after anaesthetized immediately and at the moment when abdomen was closed., during the surgery|Number of Days in Hospital, The number of days from the admission to hospital until the discharge from hospital, up to 10 weeks
Other Outcome Measures: The Volume of Crystalloid Infusion, Volume of crystalloid infusion in milliliter., during the surgery|The Volume of Colloid Infusion, Volume of colloid infusion in milliliter., during the surgery|Complication After Surgery, From the end of surgery to the time of discharge from hospital.including ileus,abdominal infection,infection of incisional wound,pulmonary infection, up to 8 weeks
Sponsor: First Affiliated Hospital, Sun Yat-Sen University
Collaborators:
Sex: ALL
Age: ADULT
Phases: NA
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT

Other IDs: [2014]No.60
Start Date: 2016-07-27
Primary Completion Date: 2019-05-18
Completion Date: 2019-06-25
First Posted: 2016-07-21
Results First Posted: 2020-02-18
Last Update Posted: 2020-03-03
Locations:
Study Documents: Study Protocol, Statistical Analysis Plan, and Informed Consent Form

NCT Number: NCT02951273
Study Title: Cerebral Blood Flow During Propofol Anaesthesia
Study URL: https://beta.clinicaltrials.gov/study/NCT02951273
Acronym:
Study Status: COMPLETED
Brief Summary: General anaesthesia often reduces blood pressure whereby blood flow to the brain and other vital organs may become insufficient. Thus, medicine is often administered during anaesthesia to maintain blood pressure. However, it is unclear at what level blood pressure should be aimed at during anaesthesia.

Several factors may affect blood flow to the brain during anaesthesia. During surgery on the internal organs, a hormone may be released that dilates blood vessels and causes a so-called mesenteric traction syndrome characterised by a decrease in blood pressure and flushing. This reaction lasts for approximately thirty minutes and is observed in about half of the patients who undergo surgery on the stomach and intestines. It is unknown whether a mesenteric traction syndrome affects blood flow to the brain. Ventilation is also of importance for blood flow to the brain. Thus, blood flow to the brain is reduced by hyperventilation and increases if breathing is slower. It is unclear whether the relation between blood flow to the brain and ventilation is affected during anaesthesia.

This study will evaluate how blood flow to the brain is affected by anaesthesia and standard treatment of a possible reduction in blood pressure. Further, the study will assess whether blood flow to the brain is affected by development of a mesenteric traction syndrome. Lastly, the project will evaluate blood flow to the brain during short-term changes in the patient's ventilation by adjustments on the ventilator.

Thirty patients planned for major abdominal surgery will be included in the project. The study will take place from the patient's arrival at the operation room and until two hours after the start of surgery. Placement of catheters and anaesthesia are according to standard care. Blood flow to the brain will be evaluated using ultrasound. Oxygenation of the brain, skin and muscle will be evaluated by probes that emit light. Depth of anaesthesia is assessed by recording the

electrical activity of the brain. Blood pressure is measured by a catheter placed in an artery at the wrist and blood samples will be drawn from the catheter.
Study Results: YES
Conditions: Gastrointestinal Neoplasms
Interventions: OTHER: Study of cerebral blood flow
Primary Outcome Measures: Changes in Internal Carotid Artery Blood Flow by Treatment of Anaesthesia-induced Hypotension, Unilateral internal carotid artery blood flow \[ml/min\] assessed by duplex ultrasound., Two measurements; one measurement during anaesthesia-induced hypotension (mean arterial pressure < 65 mmHg) before administration of phenylephrine and one measurement 3-5 min after administration of phenylephrine.
Secondary Outcome Measures: Changes in Internal Carotid Artery Blood Flow by Induction of Anaesthesia., Unilateral internal carotid artery blood flow \[ml/min\] assessed by duplex ultrasound., Two measurements; one measurement 5-10 min before induction of anaesthesia and one measurement 5-20 min after induction of anaesthesia.| Association by Multiple Regression Between Changes in Internal Carotid Artery Blood Flow, Mean Arterial Pressure and Cardiac Output by Treatment of Anaesthesia-induced Hypotension., Association by multiple regression between changes in unilateral internal carotid artery blood flow \[ml/min\] as outcome variable and changes in mean arterial pressure \[mmHg\] and cardiac output \[l/min\] as covariates.

Internal carotid artery blood flow \[ml/min\] was assessed by duplex ultrasound. Mean arterial pressure \[mmHg\] was recorded by a transducer connected to an arterial line. Cardiac output \[l/min\] was evaluated by pulse contour analysis (Modelflow) that estimates cardiac output by analysis of the arterial pressure curve taking age, gender, height and weigth into account., Two measurements; one measurement during anaesthesia-induced hypotension (mean arterial pressure < 65 mmHg) before administration of phenylephrine and one measurement 3-5 min after administration of phenylephrine.|Changes in Frontal Lobe Oxygenation by Development of Mesenteric Traction Syndrome (MTS)., Near-infrared spectroscopy determined frontal lobe oxygenation \[%\] as compared between those patients who develop a MTS (defined as flushing within 60 min after the start of surgery) and those who do not. An effect of a MTS was evaluated by a repeated measure mixed model with the fixed effects time point, group according to development of MTS, and interaction between time and group. The reported result is the interaction factor for the time point 0 min after flushing and 20 min after the start of surgery in patients who did not develop MTS., Six measurements during anaesthesia; 5 min before and after incision and 0, 20, 40, and 70 min after flushing and 20, 40, 60, and 90 min after the start of surgery in those patients who do not develop mesenteric traction syndrome.|Changes in Forehead Skin Blood Flow by Development of Mesenteric Traction Syndrome (MTS)., Forehead skin blood flow \[PU\] assessed by laser Doppler flowmetry as compared between those patients who develop mesenteric traction

syndrome (defined as flushing within 60 min after the start of surgery) and those who do not. Laser Doppler flowmetry applies a laser placed on the forehead that penetrates the skin and is scattered with a Doppler shift by the red blood cells and return to a detector that evaluates the amount of backscattered light and Doppler shift. An effect of a MTS was evaluated by a repeated measure mixed model with the fixed effects time point, group according to development of MTS, and interaction between time and group. The reported result is the interaction factor for the time point 0 min after flushing and 20 min after the start of surgery in patients who did not develop MTS., Six measurements during anaesthesia; 5 min before and after incision and 0, 20, 40, and 70 min after flushing and 20, 40, 60, and 90 min after the start of surgery in those patients who do not develop mesenteric traction syndrome.|Changes in Forehead Skin Oxygenation by Development of Mesenteric Traction Syndrome (MTS)., Forehead skin oxygenation \[% \] assessed by laser Doppler flowmetry as compared between those patients who develop a MTS (defined as flushing within 60 min after the start of surgery) and those who do not. An effect of a MTS was evaluated by a repeated measure mixed model with the fixed effects time point, group according to development of MTS, and interaction between time and group. The reported result is the interaction factor for the time point 0 min after flushing and 20 min after the start of surgery in patients who did not develop MTS., Six measurements during anaesthesia; 5 min before and after incision and 0, 20, 40, and 70 min after flushing and 20, 40, 60, and 90 min after the start of surgery in those patients who do not develop mesenteric traction syndrome.|Changes in Internal Carotid Artery Blood Flow by Development of Mesenteric Traction Syndrome (MTS)., Unilateral internal carotid artery blood flow \[ml/min\] assessed by duplex ultrasound as compared between those patients who develop a MTS (defined as flushing within 60 min after the start of surgery) and those who do not. An effect of a MTS was evaluated by a repeated measure mixed model with the fixed effects time point, group according to development of MTS, and interaction between time and group. The reported result is the interaction factor for the time point 0 min after flushing and 20 min after the start of surgery in patients who did not develop MTS., Six measurements during anaesthesia; 5 min before and after incision and 0, 20, 40, and 70 min after flushing and 20, 40, 60, and 90 min after the start of surgery in those patients who do not develop mesenteric traction syndrome.|Changes in the CO2 Reactivity of the Internal Carotid Artery From Before to After Induction of Anaesthesia., Unilateral internal carotid artery blood flow \[ml/min\] assessed by duplex ultrasound and arterial CO2 tension (PaCO2) \[kPa\] was evaluated by gas analysis. Changes in PaCO2 are guided by evaluation of end-tidal CO2 tension.

The CO2 reactivity to hypocapnia when awake and during anaesthesia is calculated as the percentage change in internal carotid artery blood flow per kPa change in PaCO2. The CO2 reactivity when awake and when anaesthetized is compared., Four measurements; before induction of

anaesthesia during normoventilation and during hyperventilation to reduce PaCO2 by 1.5 kPa and during anaesthesia at a PaCO2 at the value before induction of anaesthesia and 1.5 kPa below that value.|Changes in Heart Rate From Baseline Before Induction of Anaesthesia., Heart rate \[bpm\] as recorded continuously by a transducer connected to an arterial line., Continuous measurements from before induction of anaesthesia and until 2 hours after start of surgery.|Changes in Mean Arterial Pressure From Baseline Before Induction of Anaesthesia., Mean arterial pressure \[mmHg\] as recorded continuously by a transducer connected to an arterial line., Continuous measurements from before induction of anaesthesia and until 2 hours after start of surgery.|Changes in Cardiac Output From Baseline Before Induction of Anaesthesia., Cardiac output \[l/min\] as evaluated continuously by pulse contour analysis of the arterial pressure curve (Modelflow)., Continuous measurements from before induction of anaesthesia and until 2 hours after start of surgery.|Changes in Stroke Volume From Baseline Before Induction of Anaesthesia., Stroke volume \[ml\] as evaluated continuously by pulse contour analysis of the arterial pressure curve (Modelflow)., Continuous measurements from before induction of anaesthesia and until 2 hours after start of surgery.
Other Outcome Measures:
Sponsor: Rigshospitalet, Denmark
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 30
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: H-16036250
Start Date: 2016-12-08
Primary Completion Date: 2017-07-06
Completion Date: 2017-07-06
First Posted: 2016-11-01
Results First Posted: 2017-10-06
Last Update Posted: 2018-01-17
Locations: Department of Anaesthesia, Rigshospitalet 2043, Copenhagen, 2300, Denmark
Study Documents: Study Protocol|Statistical Analysis Plan

NCT Number: NCT00561977
Study Title: Cancer Dietary Objectives Study
Study URL: https://beta.clinicaltrials.gov/study/NCT00561977
Acronym: CanDo
Study Status: COMPLETED
Brief Summary: We hypothesize that adding beneficial high fiber foods to the diet will result in better overall dietary quality (measured by the Alternate Healthy Eating Index), which has been shown to be associated with cancer, than either reducing saturated fat, or a

combination of high fiber and low saturated fat.
Study Results: YES
Conditions: Cancer|Heart Disease
Interventions: BEHAVIORAL: High Fiber Diet|BEHAVIORAL: low saturated fat diet|BEHAVIORAL: Combination diet
Primary Outcome Measures: Dietary Quality, Dietary quality was measured by the Alternative Healthy Eating Index (AHEI), a scale of healthy eating that goes from zero to 80 (best score)., 6 mos|Dietary Quality, Possible Score From Zero to 80 (Best Quality Diet)., The AHEI consists of 8 components (eg, vegetables,trans fat). Each contributed 0-10 points to the total score; a score of 10 indicates that the recommendations were fully met, whereas a score of 0 represents the least healthy dietary behavior. Intermediate intakes were scored proportionately between 0 and 10. All component scores were summed to obtain a total AHEI score ranging from zero(worst) to 80(best)., 3 months
Secondary Outcome Measures: Change in Weight From Baseline to 3 Months, 3 months|Change in Weight From Baseline to 6 Months, 6 months|Change in Calories From Baseline to 3 Months, kilocalories, 3 months|Change in Calories From Baseline to 6 Months, kilocalories, 6 months
Other Outcome Measures:
Sponsor: University of Massachusetts, Worcester
Collaborators: American Cancer Society, Inc.
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 36
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: IRG 93-033
Start Date: 2007-05
Primary Completion Date: 2008-05
Completion Date: 2009-02
First Posted: 2007-11-21
Results First Posted: 2010-01-18
Last Update Posted: 2011-09-02
Locations: UMass Medical School, Worcester, Massachusetts, 01655, United States
Study Documents:

NCT Number: NCT03589729
Study Title: Dexrazoxane Hydrochloride in Preventing Heart-Related Side Effects of Chemotherapy in Participants With Blood Cancers
Study URL: https://beta.clinicaltrials.gov/study/NCT03589729
Acronym:
Study Status: RECRUITING
Brief Summary: This phase II trial studies how well dexrazoxane hydrochloride works in preventing heart-related side effects of

chemotherapy in participants with blood cancers, such as acute myeloid leukemia, myelodysplastic syndrome, chronic myeloid leukemia, and myeloproliferative neoplasms. Chemoprotective drugs, such as dexrazoxane hydrochloride, may protect the heart from the side effects of drugs used in chemotherapy, such as cladribine, idarubicin, cytarabine, and gemtuzumab ozogamicin, in participants with blood cancers.
Study Results: NO
Conditions: Acute Myeloid Leukemia|Blast Phase Chronic Myelogenous Leukemia, BCR-ABL1 Positive|Blasts 10 Percent or More of Bone Marrow Nucleated Cells|High Risk Myelodysplastic Syndrome|Myeloid Sarcoma|Myeloproliferative Neoplasm|Philadelphia Chromosome Positive
Interventions: DRUG: Cladribine|DRUG: Cytarabine|DRUG: Dexrazoxane Hydrochloride|DRUG: Gemtuzumab Ozogamicin|DRUG: Idarubicin
Primary Outcome Measures: Percentage of patients experiencing a decrease in left ventricular ejection fraction (LVEF), Will assess a decrease in LVEF of 10 percent from baseline or decrease in LVEF below the normal limit of 50% during treatment with dexrazoxane hydrochloride combined with cladribine, idarubicin, cytarabine, and gemtuzumab ozogamicin., Baseline up to 6 months
Secondary Outcome Measures: Incidence of cardiac symptoms, Cardiac symptoms to be evaluated include: clinical heart failure, exertional dyspnea, orthopnea, S3 gallop, acute coronary syndrome, acute pulmonary edema and life-threatening arrhythmias, Up to 1 year|Assessment of change in troponin I and high-sensitivity troponin T, Troponin levels will be collected before and after the day 1 dose of idarubicin each month during induction, consolidation, and maintenance therapy., Up to 1 year|Incidence of adverse events, Up to 1 year|Complete remission (CR) /complete remission with incomplete blood count recovery (CRi) rates (Cohorts 1-3), Up to 1 year|Overall response (Cohorts 1-3), Up to 1 year|Overall survival (Cohorts 1-3), Up to 1 year|Event-free survival (Cohorts 1-3), Up to 1 year|Remission duration (Cohorts 1-3), Up to 1 year|Recurrence-free survival, The recurrence-free survival rate at 6 months will be a binary endpoint where the recurrence including death occurred within 6 months of treatment will be considered as "recurrence event"., Up to 6 months
Other Outcome Measures: Assessment of metal chelation effects of dexrazoxane and chemotherapy, Metal chelation effects assessed by utilizing technologies commonly used in the geochemistry., Up to 1 year|Assessment of minimal residual disease (MRD), Will explore the impact of MRD on relapse., Up to 1 year
Sponsor: M.D. Anderson Cancer Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking:

NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 2017-0937|NCI-2018-01108|2017-0937|P30CA016672
Start Date: 2018-09-19
Primary Completion Date: 2025-12-31
Completion Date: 2025-12-31
First Posted: 2018-07-18
Results First Posted:
Last Update Posted: 2023-03-16
Locations: M D Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT01560260
Study Title: Linsitinib in Treating Patients With Gastrointestinal Stromal Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT01560260
Acronym:
Study Status: COMPLETED
Brief Summary: This phase II trial studies how well linsitinib works in treating younger and adult patients with gastrointestinal stromal tumors. Linsitinib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth.
Study Results: YES
Conditions: Carney Complex|Chondrosarcoma|Gastrointestinal Stromal Tumor|Paraganglioma
Interventions: OTHER: Laboratory Biomarker Analysis|DRUG: Linsitinib|OTHER: Pharmacological Study
Primary Outcome Measures: Number of Participants With Complete Response or Partial Response Using Response Evaluation Criteria in Solid Tumors Guideline Version 1.1, Determine the response rate, Complete Response (CR) or Partial Response (PR), to treatment with linsitinib (OSI-906) in patients with advanced wild-type (WT) gastrointestional stromal tumor (GIST) as determined by RECIST 1.1., At 6 months
Secondary Outcome Measures: Clinical Benefit Rate Defined as Stable Disease (SD) >= 9 Months, Partial Response (PR) or Complete Response (CR), Prolonged non-progression is of clinical benefit (CR + PR + SD at 9 months)., Up to 2 years|Overall Survival (OS), Analyzed using Kaplan-Meier curves for the all treated and per protocol populations., Estimates at 9 months|Progression Free Survival (PFS), Analyzed using Kaplan-Meier curves for the all treated and per protocol populations., Time from date of enrollment to time of progression or death due to any cause, estimates at 9 months|Response Duration, Analyzed using Kaplan-Meier curves for the all treated and per protocol populations., Up to 37 weeks|Failure-free Survival, Analyzed using Kaplan-Meier curves for the all treated and per protocol populations, Up to 37 weeks|Tolerability and Adverse Event Profile of Linsitinib, To determine the tolerability and adverse event profile of OSI-906 in patients with advanced GIST., Up to 37 weeks|Patterns of Protein Expression in Serum and Tumor Tissues as Predictors of Response and

PFS, To explore patterns of protein expression in serum and tumor tissues as predictors of response and progression-free survival in advanced WT GIST treated with OSI-906. All Insulin Growth Factor Receptor (IGFR) and phosphorylated AKT (pAKT) evaluation was performed in a blinded manner. Distribution and intensity of positive tumor cell staining was assessed for these markers. Loss of succinate dehydrogenase complex flavoprotein subunit A (SDHA) protein expression has been correlated with the presence of a mutation in SDHA. Loss of succinate dehydrogenase complex iron sulfur subunit B (SDHB) protein expression occurs from bi-allelic inactivation of any of the succinate dehydrogenase (SDH) subunit genes. Loss of expression of one member of the complex alters the structure or production of SDH proteins such that the complex is no longer able to form. This results in elevated intracellular levels of succinate as well as loss of demethylase activity., Up to 37 weeks|Number of Participants With Metabolic Response to Linsitinib Using FDG-PET., Evaluate the number of participants with metabolic response to OSI-906 using fluorodeoxyglucose positron emission tomography (FDG-PET). Evaluation of metabolic response to linsitinib based on two criteria (EORTC and PERCIST)., Up to 37 weeks|Changes in Tumor Metabolism by FDG-PET Qualitatively and Semi-quantitatively With Standard Uptake Value (SUV), To measure changes in tumor metabolism by FDG-PET qualitatively and semi-quantitatively with SUV from baseline to first CT response evaluation and correlate the findings with size changes as defined by conventional cross-sectional imaging scans.

SUVmax determined by: SUVmax = \[VOI activity (mCi/ml) * body wt (g) \]/injected dose (mCi) SUVpeak determined by identifying the hottest cubic centimeter within a VOI centered on the lesion with the highest FDG., Baseline and 8 weeks|Correlations Between Glucose, Insulin, Tumor Tissue and Blood Biomarkers With FDG-PET Metabolic Response., To investigate correlations between glucose, insulin, tumor tissue and blood biomarkers with FDG-PET metabolic response., Up to 37 weeks
Other Outcome Measures: Time to Progression, Time to progression will be evaluated using cumulative incidence., Up to 3 years|Determine the Number of Participants With Tumor Metabolic Response Correlating With Anatomic Response and Clinical Benefit., To determine if the number of participants with tumor metabolic response correlates with anatomic response and clinical benefit., Up to 37 weeks
Sponsor: National Cancer Institute (NCI)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 20
Funder Type: NIH
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: NCI-2012-00708|NCI-2012-00708|CDR0000728619|SARC-022|SARC

022|SARC022|8945
Start Date: 2012-03
Primary Completion Date: 2015-10
Completion Date: 2015-10
First Posted: 2012-03-22
Results First Posted: 2016-11-18
Last Update Posted: 2018-09-21
Locations: Stanford Cancer Institute, Palo Alto, California, 94304, United States|University of Iowa/Holden Comprehensive Cancer Center, Iowa City, Iowa, 52242, United States|National Institutes of Health Clinical Center, Bethesda, Maryland, 20892, United States|Dana-Farber/Harvard Cancer Center, Boston, Massachusetts, 02115, United States|Sarcoma Alliance for Research Through Collaboration, Ann Arbor, Michigan, 48106, United States|University of Michigan Comprehensive Cancer Center, Ann Arbor, Michigan, 48109, United States|Oregon Health and Science University, Portland, Oregon, 97239, United States|Fox Chase Cancer Center, Philadelphia, Pennsylvania, 19111, United States
Study Documents:

NCT Number: NCT00861029
Study Title: VEG111485: A QTc Study of Pazopanib
Study URL: https://beta.clinicaltrials.gov/study/NCT00861029
Acronym:
Study Status: COMPLETED
Brief Summary: This is a Phase I, randomized, double-blind, placebo-controlled, study to estimate the effects of daily oral dosing of 800 mg pazopanib on electrocardiographic parameters (QTc interval duration) as compared with placebo in subjects with solid tumors. Moxifloxacin, will serve as a positive control.
Study Results: NO
Conditions: Carcinoma, Renal Cell
Interventions: DRUG: Pazopanib|OTHER: Placebo for pazopanib|DRUG: Moxifloxacin|OTHER: Placebo for moxifloxacin
Primary Outcome Measures: Change from baseline in QTcF interval at each time point on Study Day 9 (average of at least 3 Holter ECG replicates per time point) as compared with time-matched placebo., 11 days
Secondary Outcome Measures: ECG parameters: RR interval, QT, QTcB, heart rate, PR, QRS intervals and morphology., 11 days|Plasma pazopanib and metabolites (GSK1268992, GSK1268997 and GSK1071306) concentrations and PK parameters AUC(0-t), AUC(0-24), C24 Cmax and tmax as data permit., 11 days|Change from baseline in QTcF interval at each time point on Study Day 1 (average of at least 3 Holter ECG replicates per time point) as compared with time-matched placebo., 11 days|Plasma moxifloxacin concentrations and PK parameters AUC(0-t), AUC(0-∞), Cmax and tmax as data permit., 11 days|Safety parameters: AEs, vital signs, ECGs and clinical laboratory assessments., 11 days
Other Outcome Measures:
Sponsor: GlaxoSmithKline
Collaborators:

Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 2
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR,
OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: 111485
Start Date: 2009-03-19
Primary Completion Date: 2010-02-15
Completion Date: 2010-02-15
First Posted: 2009-03-13
Results First Posted:
Last Update Posted: 2017-11-14
Locations: GSK Investigational Site, Duarte, California, 91010, United
States|GSK Investigational Site, Santa Monica, California, 90404,
United States|GSK Investigational Site, Detroit, Michigan, 48201,
United States|GSK Investigational Site, Lebanon, New Hampshire, 03756,
United States|GSK Investigational Site, New Brunswick, New Jersey,
08901, United States|GSK Investigational Site, Greenville, South
Carolina, 29605, United States|GSK Investigational Site, Nashville,
Tennessee, 37203, United States|GSK Investigational Site, Tacoma,
Washington, 98405, United States
Study Documents:

NCT Number: NCT05750953
Study Title: Nurse-assisted Intervention "eHealth@ Hospital -2-home"
Study URL: https://beta.clinicaltrials.gov/study/NCT05750953
Acronym: Ehealth@H2H
Study Status: NOT_YET_RECRUITING
Brief Summary: A randomized controlled trial with non-communicable
disease patients from two medical hospitals in Norway will be
recruited prior to hospital discharge. The intervention group will
participate in a 42-day nurse-assisted eHealth intervention "eHealth@
Hospital-2-Home". The intervention includes monitoring the patient's
vital signs, self-reports of symptoms, health and well-being,
communication between the patients and a Nurse Navigator in the
hospital, and access to information about illness and health
resources.
Study Results: NO
Conditions: Non Communicable Diseases|Heart Failure|Colon Rectal
Cancer
Interventions: BEHAVIORAL: eHealth@Hospital-2-Home
Primary Outcome Measures: Change in patient confidence in self-
management activities., Change in the patient's confidence in self-
management of heart failure or colon-rectal cancer disease between
baseline and post-1 and 2 will be measured by the 6 items
questionnaire Self-Efficacy for Managing Chronic Disease". Values:

1-10. A higher score mean a better outcome., Baseline (at discharge), post-1 (42 days following baseline, at the end of the intervention), and post-2 (6 months after baseline)|Change in heart failure self-care behavior, Change in heart failure patients' self-care behavior between baseline and post-1 and 2 will be measured by use of the European Heart Failure Self-care Behavior Scale. Value: 1-5. Higher score mean worse outcome., Baseline (at discharge), post-1, (42 days following baseline, at the end of the intervention) and post-2 (6 months after baseline)
Secondary Outcome Measures: Change in patient experience with treatment and self-management., Change in the patient's experience with treatment and self-management of heart failure and colon-rectal cancer between baseline and post-1 and 2 will be measured by the questionnaire "Patient Experience with Treatment and Self-management" with four dimensions of Medical information (Values:1-6); Monitoring health (Values: 1-6); Medications (Values 1- 5); Medical appointments (Values: 1-5). Higher scores means a worse outcome., Baseline (at discharge), post-1(42 days following baseline, at the end of the intervention) , and post-2 (6 months after baseline)|Change in patient experience of health condition and how it affects daily life., Change in the patient's Health Related Quality of Life between baseline and post 1 and 2 will be measured with the European Quality of life 5 Dimensions -5 Levels questionnaire. Values: 1-5, were higher scores mean worse outcome, and on a visual analog scale from 0-100, were higher scores mean better outcome., Baseline (at discharge), post-1 (42 days following baseline, at the end of the intervention), and post-2 (6 months after baseline)|Change in patient experience of constructive support from healthcare personnel, Change in perceived support between baseline and post-1 and 2 will be measured using 12 items on constructive support. Values: 1-5-point. Higher score mean worse outcome., Baseline (at discharge), post-1 (42 days following baseline, at the end of the intervention), and post-2 (6 months after baseline)|Change in patient experience of shared decision-making., Change in the patient's experience of shared decision-making between baseline and post-1 and 2 will be measured using the 3 items questionnaire "CollaboRATE" Value: 0-10. Higher score mean better outcome., Baseline (at discharge), post-1 (42 days following baseline, at the end of the intervention), and post-2 (6 months after baseline)|Change in health care utilization, Change in health care utilization between baseline and post-1 and 2 will be measured using patients' self-reports of number of visits to the primary healthcare service (i.e., General Practitioner, municipal emergency department) and/or the specialist healthcare service (i.e., outpatient clinic). Fewer visits mean better outcome., Baseline (at discharge), post-1 (42 days following baseline, at the end of the intervention), and post-2 (6 months after baseline)|Days alive and out of hospital, Days alive and out of hospital will be measured by patient's self-report against data from hospital records, and calculated by subtracting number of days spent away from home due to heart failure or colon-rectal cancer related hospitalization from the day of the first reporting in the

patient application and the six months following (post 2)., Post-2 (6 months after baseline)|Number of 30 days readmission for heart failure or colon-rectal cancer related incidents, Numbers of 30-days readmission for Heart failure or Colon-rectal cancer related incidents will be collected from the electronic health care record system in the hospital., Post-1 (42 days following baseline, at the end of the intervention).|Number of 90 days readmission for heart failure or colon-rectal cancer related incidents, Numbers of 30-days readmission for heart failure or colon-rectal cancer related incidents will be collected from the electronic health care record system in the hospital., Post-2 (6 months following baseline)|Number of 12 months readmission for heart failure or colon-rectal cancer related incidents, Numbers of 12-months readmission for heart failure or colon-rectal cancer related incidents will be collected from the electronic health care record system in the hospital., Post-3 (12 months following baseline)
Other Outcome Measures: Change in medication adherence in heart failure patients, Change in medication adherence will be measures using the Medication Adherence Reasons Scale-5 (MARS -5) containing 5 items., Post-1 (42 days following baseline, at the end of the intervention), and post-2 (6 months after baseline).|Patient satisfaction with using the technology., Patient satisfaction with using the technology will be measured by the Post-Study System Usability Questionnaire. Values: 1-7. Higher score mean worse outcome., Post-1 (42 days following baseline, at the end of the intervention)
Sponsor: University of Stavanger
Collaborators: Helse Stavanger HF|St. Olavs Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 240
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: 301472
Start Date: 2023-04-01
Primary Completion Date: 2024-06-30
Completion Date: 2024-12-31
First Posted: 2023-03-02
Results First Posted:
Last Update Posted: 2023-03-17
Locations:
Study Documents:

NCT Number: NCT05444062
Study Title: Quebec Lung Cancer Screening PLUS Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT05444062

Acronym: QLC+
Study Status: NOT_YET_RECRUITING
Brief Summary: Does an educational intervention for untreated COPD and cardiovascular disease which is integrated in an existing lung cancer screening program improve guideline concordant medication adherence at 12 months
Study Results: NO
Conditions: COPD|Coronary Artery Calcification
Interventions: BEHAVIORAL: Educational material and treatment recommendations for patients, general practitioners and pharmacists
Primary Outcome Measures: Guideline concordant statin therapy 1 year following the first low dose CT scan., Among patients with moderate to severe coronary artery calcifications (CAC) not on a statin at baseline, any statin prescribed for primary prevention at least once in the 1 year following the first low dose CT scan.

(aim 1), 1 year post CT|Guideline concordant inhaler therapy 1 year following the first low dose CT scan, Among patients who have untreated or inappropriately treated COPD at baseline, any long acting muscarinic antagonist inhaler prescribed at least once in the 1 year following the first low dose CT scan (aim 2), 1 year post CT
Secondary Outcome Measures: Medication possession ratio (MPR) - Aim 1, Reflects patient adherence. Days of drug supply over 1 year with cholesterol lowering medication in the previous 1 year from pharmacy dispensation records., 1 year post CT|Medication possession ratio (MPR) - Aim 2, Reflects patient adherence. Days of drug supply over 1 year with guideline concordant inhaler therapy for COPD in the previous 1 year from pharmacy dispensation records., 1 year post CT| COPD Symptoms, COPD Assessment Test is a validated patient-reported outcome. It measures 8 symptoms of COPD on a 0-5 point scale at baseline, 6 and 12 months post intervention, Baseline, 6 months post intervention, 12 months post intervention|Quality of life using SF-36 questionnaire, SF-36 questionnaire will be filled at baseline and 12 months post intervention, Baseline, 12 months post intervention| Patient satisfaction with communication and decision making, COMRADE is a 20-item self-reported measure for use in primary care to assess risk communication and confidence in treatment decision making. It assesses patient satisfaction with information provided about risks/ benefits of treatment, perception of participation in treatment decisions, and satisfaction with that decision.

COMRADE questionnaire will be sent to patients after their first meeting with their general practitioner up to 3 months after intervention., 3 months post intervention|Health Care Utilisation, Number of unplanned clinic visits, hospitalizations for respiratory or cardiac disease, consultations with specialists (cardiology and respirology), invasive/non-invasive cardiac or respiratory investigations, 1 year post intervention|Absenteeism and presenteeism, Work productivity and activity impairment (WPAI) questionnaire, baseline|Health literacy, Health literacy will be assessed at study

entry using the Brief Health Literacy Screen., baseline
Other Outcome Measures:
Sponsor: Nicole Ezer, MD, FRCPC, MPH
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 390
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: OTHER
Other IDs: MP-37-2023-8641
Start Date: 2023-04
Primary Completion Date: 2026-04
Completion Date: 2027-04
First Posted: 2022-07-05
Results First Posted:
Last Update Posted: 2023-03-28
Locations:
Study Documents:

NCT Number: NCT00094562
Study Title: A Fish Oil Supplement to Maintain Body Weight in Patients With Disease-Related Weight Loss
Study URL: https://beta.clinicaltrials.gov/study/NCT00094562
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate the safety and effectiveness of fish oil supplements in maintaining weight in people with disease-related weight loss and/or cachexia.
Study Results: NO
Conditions: Cancer|Cancer Cachexia|Chronic Obstructive Pulmonary Disease|Chronic Heart Failure|Rheumatoid Arthritis
Interventions: DRUG: Fish oil supplement
Primary Outcome Measures: Body weight|lean body mass
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
Collaborators: National Center for Complementary and Integrative Health (NCCIH)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 25
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: DOUBLE|Primary Purpose: TREATMENT
Other IDs: J0275|03-02-10-12|P50AT000437

Start Date: 2004-06
Primary Completion Date: 2007-09
Completion Date: 2007-09
First Posted: 2004-10-21
Results First Posted:
Last Update Posted: 2019-01-18
Locations: Johns Hopkins Hospital, Baltimore, Maryland, 21287, United States
Study Documents:

NCT Number: NCT01719562
Study Title: MRI in Detecting Heart Damage in Patients With Cancer Receiving Chemotherapy With Exercise Capacity Addendum
Study URL: https://beta.clinicaltrials.gov/study/NCT01719562
Acronym:
Study Status: COMPLETED
Brief Summary: This trial studies how well magnetic resonance imaging (MRI) works in detecting heart damage in patients with cancer receiving chemotherapy. Diagnostic procedures, such as MRI, may help doctors predict whether patients will have heart damage caused by chemotherapy in patients with cancer receiving chemotherapy.

Exercise Capacity Addendum Brief Summary: This study is designed to demonstrate feasibility of performing the physical activity intervention and the primary outcome measures before, during and six months after initiating Anth-bC for treatment of non- or Hodgkin lymphoma. This study will test the potential for a novel (lifestyle) intervention designed to improve exercise capacity, health-related quality of life and cardiac and cognitive dysfunction. This data will inform the development of the R33 phase of the clinical trial to determine if the physical activity intervention can reduce exercise intolerance in this high-risk population. In addition, cardiac MRI data from individuals within this pilot will be compared to cardiac MRI data from individuals in the parent study that did not undergo either of the two interventional arms of this study.
Study Results: YES
Conditions: Cardiac Toxicity|Malignant Neoplasm|Breast Cancer
Interventions: PROCEDURE: Magnetic resonance imaging|OTHER: Physical Activity|OTHER: Healthy Living|DEVICE: Cardiopulmonary Exercise Testing (CPET)|OTHER: Questionnaire Administration
Primary Outcome Measures: Number of Participants Completing the Trial (Exercise Capacity Addendum), The number of participants who completed the intervention., 6 months after treatment initiation|Number of Participants Able to Complete Assessments (Exercise Capacity Addendum), Number of participants who completed the 6-minute walk test at 6-months., 6 months after treatment initiation
Secondary Outcome Measures: Peak Exercise Cardiac Output (Exercise Capacity Addendum), Peak exercise cardiac output refers to the amount of blood that the heart pumps out per minute. It is an important measure of how effectively the heart is working to deliver oxygen and

nutrients to the body's tissues. Peak exercise cardiac output was measured in a cardiac magnetic resonance imaging (MRI) exam., 6 months after treatment|Arteriovenous Oxygen Difference (A-V O2) (Exercise Capacity Addendum), Arteriovenous Oxygen Difference (A-V O2) is the difference in oxygen levels between arterial blood and venous blood. A-V O2 difference is important because it reflects how much oxygen is being used by the body's tissues during exercise or physical activity. A higher A-V O2 difference is generally considered better., 6 months after treatment initiation|Maximum Rate of Oxygen Consumption (VO2) (Exercise Capacity Addendum), Maximum rate of oxygen consumption (VO2) is an objective measure of cardiorespiratory fitness. VO2 was assessed with a cardiopulmonary exercise test (CPET). Higher VO2 represents greater cardiorespiratory fitness., 6 months after treatment initiation|Left Ventricular Function (Exercise Capacity Addendum), Left ventricular ejection fraction (LVEF, %) is a measure of cardiac function. LVEF was assessed with a cardiac magnetic resonance imaging (MRI) exam. The higher the LVEF, the more efficiently the heart is at pumping blood to the rest of the body with every heart beat., 6 months after treatment initiation|Cognitive Function- Controlled Oral Word Association (COWA) Test (Exercise Capacity Addendum), The COWA test was used to assess cognitive function and verbal fluency. Participants were asked to produce as many words as they can that begin with the given letter (i.e. T or L) within a 1-min time period. The COWA test total score was measured by summing the total number of acceptable words produced for three different letters. Minimum possible score for the COWA text is 0. There is no maximum possible score. Higher scores represent greater verbal fluency., 6 months after treatment initiation|Health-Related Quality of Life (Exercise Capacity Addendum), The Functional Assessment of Cancer Treatment-Lymphoma (FACT-Lym) is a 42-item scale used to assess the health-related quality of life of lymphoma survivors. The FACT-Lym questionnaire examines the four primary domains of HRQL: physical, social, emotional, and functional well-being, and patient's concerns related to lymphoma. The FACT-Lym was examined as a total score, ranging from 0 to 168 points. Higher scores reflect better health-related quality of life., 6 months after treatment initiation|6-minute Walk Distance (Exercise Capacity Addendum), The 6-minute walk test is a low cost sub-maximal exercise test that serves as an indirect measure of cardiorespiratory fitness. Participants were instructed to walk at their own pace to cover as much ground (in meters) as possible for 6 minutes., 6 months after treatment initiation|Functional Assessment of Cancer Therapy - (FACT-Fatigue) (Exercise Capacity Addendum), The FACT-fatigue is a 13-item scale that has been widely used to assess cancer-related fatigue. The FACT-fatigue questionnaire was scored by summing all 13 items with a reverse point system. This produces a range of 0 to 52, with a higher score indicating better functioning and less fatigue., 6 months after treatment initiation
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators: National Cancer Institute (NCI)

Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 28
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: IRB00020968|NCI-2012-01613|P30CA012197|CCCWFU 99112|
R01CA167821|R21CA226960
Start Date: 2013-01-01
Primary Completion Date: 2022-03-08
Completion Date: 2022-03-08
First Posted: 2012-11-01
Results First Posted: 2023-03-01
Last Update Posted: 2023-05-19
Locations: Comprehensive Cancer Center of Wake Forest University,
Winston-Salem, North Carolina, 27157, United States|Virginia
Commonwealth University Health Sciences, Richmond, Virginia, 23284,
United States
Study Documents: Study Protocol and Statistical Analysis Plan|Informed
Consent Form

NCT Number: NCT04486573
Study Title: Cardiac Effects From Radiation Therapy by MRI
Study URL: https://beta.clinicaltrials.gov/study/NCT04486573
Acronym:
Study Status: RECRUITING
Brief Summary: The investigators will identify 10 patients in the
department of radiation oncology who will receive standard of-care
radiation therapy, and the treating radiation oncologist anticipates a
mean left ventricular dose of at least 5 Gy. Patients will be
evaluated by CMRI before and within one week of the completion of RT.
We will compare the pre- and post-RT CMRI scans to identify changes
related to radiation exposure. Our primary endpoint will be changes in
myocardial strain. Secondary endpoints will include other CMRI
parameters.
Study Results: NO
Conditions: Radiation Treatment|Cancer|Cardiotoxicity
Interventions: DIAGNOSTIC_TEST: Cardiac Magnetic Resonance Imaging
Primary Outcome Measures: Change in myocardial strain, Assess for a
change in myocardial strain, as measured by CMRI scans performed
before and after RT, 2 years
Secondary Outcome Measures: T1 pre- and post-contrast values, Measured
by scans performed before and after RT, 2 years|Extracellular volume
fraction, Measured by scans performed before and after RT, 2 years|T2
values, Measured by scans performed before and after RT, 2 years|Late
gadolinium enhancement, Measured by scans performed before and after
RT, 2 years|Left ventricular ejection fraction, Measured by scans
performed before and after RT, 2 years|End diastolic volume, Measured

by scans performed before and after RT, 2 years|End systolic volume, Measured by scans performed before and after RT, 2 years|Left atrial volume, Measured by scans performed before and after RT, 2 years|Wall thickness, Measured by scans performed before and after RT, 2 years|Left ventricular mass index, Measured by scans performed before and after RT, 2 years
Other Outcome Measures:
Sponsor: University of Colorado, Denver
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 20-0537.cc|NCI-2020-06349
Start Date: 2020-07-15
Primary Completion Date: 2024-03-27
Completion Date: 2025-03
First Posted: 2020-07-24
Results First Posted:
Last Update Posted: 2023-04-25
Locations: University of Colorado Hospital, Aurora, Colorado, 80045, United States
Study Documents:

NCT Number: NCT05596760
Study Title: Promoting Goals-of-Care Discussions for Patients With Memory Problems and Their Caregivers
Study URL: https://beta.clinicaltrials.gov/study/NCT05596760
Acronym: PICSI-M
Study Status: NOT_YET_RECRUITING
Brief Summary: The goal of this clinical trial is to improve communication among clinicians, patients with memory problems, and their family members. We are testing a way to help clinicians have better conversations to address patients' goals for their healthcare. To do this, we created a simple, short guide called the "Jumpstart Guide." The goal of this research study is to show that using this kind of guide is possible and can be helpful for patients and their families. Patients' clinicians may receive a Jumpstart Guide before the patient's clinic visit. Researchers will compare patients whose clinician received a Jumpstart Guide to patients whose clinician did not receive a guide to see if more patients in the Jumpstart Guide group had conversations about the patient's goals for their healthcare. Patients and their family members will also be asked to complete surveys after the visit with their clinician.
Study Results: NO
Conditions: Dementia|Chronic Disease|Neoplasm Metastasis|Lung

Neoplasm|Pulmonary Disease, Chronic Obstructive|Heart Failure, Congestive|Liver Cirrhosis|Kidney Failure, Chronic|Lung Diseases, Interstitial|Peripheral Vascular Diseases|Diabetes With End Organ Damage|Palliative Care, Patient Care|Health Care Quality, Access, and Evaluation|Patient Care|Health Communication|Patient Care Planning|Quality of Life
Interventions: BEHAVIORAL: Jumpstart Guide
Primary Outcome Measures: EHR documentation of Goals of Care discussions, The primary outcome is the proportion of patients who have a goals-of-care discussion that has been documented in the EHR in the period by 90 days following randomization. The proportion is the number of patients with GOC documentation over the number of patients in each study arm., 90 days following randomization
Secondary Outcome Measures: Anxiety and depression (HADS), Symptoms of depression and anxiety assessed with the Hospital Anxiety and Depression Scale (HADS). The HADS is a reliable, valid 14-item, 2-domain (anxiety and depression) tool used to assess symptoms of psychological distress. Seven items evaluate anxiety and seven evaluate depression. Each item is scored on a 4-point scale (ranging from 0-3) with scores for each subscale (anxiety and depression) ranging from 0-21., 30 days following randomization.
Other Outcome Measures:
Sponsor: University of Washington
Collaborators: National Institute on Aging (NIA)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: STUDY00015800|R01AG078169
Start Date: 2023-07
Primary Completion Date: 2025-06
Completion Date: 2027-03
First Posted: 2022-10-27
Results First Posted:
Last Update Posted: 2023-05-11
Locations:
Study Documents:

NCT Number: NCT02496260
Study Title: Biomarkers and Cardiac MRI as Early Indicators of Cardiac Exposure Following Breast Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT02496260
Acronym:
Study Status: COMPLETED
Brief Summary: Radiotherapy plays an integral role in breast cancer therapy. Multiple randomized studies have demonstrated decreased

local-regional recurrence rates and decreased breast-cancer mortality. However, balanced with this survival benefit is the potential toxicity of the treatment itself. In particular, cardiac effects of radiotherapy have been a concern and an area of research for the past 20 years. From long-term follow up of patients with lymphoma, it is known that radiotherapy can lead to increased risk of myocardial infarction, valvular dysfunction, systolic and diastolic function abnormalities, and heart failure among cancer-survivors. Patients with breast cancer receive lower doses to smaller volumes of the heart, but they also have an excellent long-term survival, so it is crucial to study the effects of low dose radiotherapy. Indeed, a recent study suggests that these effects can be seen within the first 5 years after treatment, and that there is no dose threshold. This study aims to develop imaging and blood biomarkers of cardiac exposure, as a first step to identifying patients at increased risk for cardiac effects, so they can be targeted for close monitoring and early intervention, potentially with statins or ACE inhibitors. Additionally, by characterizing a time-course and radiation dose-volume relationship, potentially real-time modifications can be made to RT field design for patients sensitive to RT effects. Finally, this information can be incorporated into better designs of treatment plans for future patients.
Study Results: NO
Conditions: Breast Cancer
Interventions: PROCEDURE: Research Cardiac MRI|PROCEDURE: Biomarkers
Primary Outcome Measures: Number of patients in which cardiac MRI indicated subclinical cardiac abnormalities after radiotherapy that correlated with cardiac events, The study aims to characterize longitudinal changes in imaging characteristics of cardiac damage. Cardiac MRI endpoints will include myocardial edema, microvascular dysfunction, myocardial fibrosis, and subclinical impairment of systolic and diastolic function., One year
Secondary Outcome Measures: Number patients in which blood and serum biomarkers were identified that correlated with cardiac damage due to radiation, The study aims to characterize longitudinal changes in potential early biomarkers of cardiac damage. Biomarker endpoints derived from blood or its components include measuring levels of galectin-3, NT-Pro brain natriuretic peptide, troponin, C-reactive protein, myeloperoxidase, and growth differentiation factor 15., One year|Number of unique biomarkers identified that were associated with radiation related cardiac injury, Biomarker endpoints derived from blood or its components include measuring levels of galectin-3, NT-Pro brain natriuretic peptide, troponin, C-reactive protein, myeloperoxidase, and growth differentiation factor 15. Additional biomarkers may be included as the research in those fields progresses during the conduct of this clinical trial., One year
Other Outcome Measures:
Sponsor: Henry Ford Health System
Collaborators: University of Michigan Rogel Cancer Center
Sex: FEMALE

Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 25
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 9481
Start Date: 2015-07
Primary Completion Date: 2017-12
Completion Date: 2018-12
First Posted: 2015-07-14
Results First Posted:
Last Update Posted: 2022-03-03
Locations: Henry Ford Health System, Detroit, Michigan, 48202, United States
Study Documents:

NCT Number: NCT00420160
Study Title: Does Moderate Intensity Exercise Help Prevent Smoking Relapse Among Women?
Study URL: https://beta.clinicaltrials.gov/study/NCT00420160
Acronym:
Study Status: COMPLETED
Brief Summary: This study compares the effects of a standard smoking cessation treatment, including one-time brief counseling and provision of nicotine patch plus an 8-week moderate intensity exercise program versus the same standard smoking cessation treatment plus equivalent contact control among 60 healthy women. We hypothesize that participants in the smoking cessation plus moderate intensity exercise condition will be more likely to quit smoking than participants in the smoking cessation treament plus contact control condition.
Study Results: NO
Conditions: Lung Cancer|Heart Disease|COPD
Interventions: BEHAVIORAL: Smoking cessation treatment plus moderate intensity exercise|BEHAVIORAL: Smoking cessation treatment plus health education
Primary Outcome Measures: 7-day point prevalence smoking abstinence verified by saliva cotinine taken, post-intervention (8 weeks after baseline)
Secondary Outcome Measures: 7-day point prevalence smoking abstinence verified by saliva cotinine, taken one month post-intervention (12 weeks after baseline)
Other Outcome Measures:
Sponsor: The Miriam Hospital
Collaborators: National Cancer Institute (NCI)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 59
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 1R03CA119747
Start Date: 2007-02
Primary Completion Date: 2008-06
Completion Date: 2008-12
First Posted: 2007-01-09
Results First Posted:
Last Update Posted: 2015-04-14
Locations: The Miriam Hospital, Providence, Rhode Island, 02903, United States
Study Documents:

NCT Number: NCT04392960
Study Title: Novel Imaging Tools in Newly-diagnosed Patients With Cardiac AL Amyloidosis
Study URL: https://beta.clinicaltrials.gov/study/NCT04392960
Acronym:
Study Status: RECRUITING
Brief Summary: This will be a systematic, combined, prospective assessment of the novel echographic, CMR, and PET imaging tools in newly-diagnosed patients with cardiac AL amyloidosis at baseline and after treatment.
Study Results: NO
Conditions: AL Amyloidosis
Interventions: DRUG: [18F]Florbetaben
Primary Outcome Measures: Evaluation of the prognostic relevance of advanced imaging variables., - for CMR: T1, T2, ECV, indexed volumes, mass, ejection fraction (EF);, 12 months after diagnosis|Evaluation of the prognostic relevance of advanced imaging variables., - for echocardiography: left ventricular wall thickness (mLVW), EF, 2D-GLS, midwall fractional shortening (mFS), and stroke volume index (SVI);, 12 months after diagnosis|Evaluation of the prognostic relevance of advanced imaging variables., - for F-PET: myocardial uptake score., 12 months after diagnosis|Evaluation of advanced imaging variables in response assessment., The same variables considered at baseline will be measured 6 months after initiation of chemotherapy targeting the amyloid plasma cell clone. Changes in these variables compared to baseline will be considered., 6 months after initiation of chemotherapy targeting the amyloid plasma cell clone
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: IRCCS Policlinico S. Matteo
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 69
Funder Type: OTHER

Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: AC-015-IT
Start Date: 2020-07-22
Primary Completion Date: 2025-02-28
Completion Date: 2025-02-28
First Posted: 2020-05-19
Results First Posted:
Last Update Posted: 2023-06-06
Locations: Fondazione IRCCS Policlinico San Matteo, Pavia, 27100, Italy
Study Documents:

NCT Number: NCT01874561
Study Title: Thorough QT/QTc (Corrected QT Interval) Study to Evaluate the Effect of Custirsen on Cardiac Repolarization
Study URL: https://beta.clinicaltrials.gov/study/NCT01874561
Acronym:
Study Status: COMPLETED
Brief Summary: This is a 3-arm, parallel-group, active- and placebo-controlled, double-blind, randomized study, to compare treatment with intravenous custirsen at 640 mg (highest intended therapeutic dose) with placebo. The purpose of this study is to assess the effect of custirsen treatment on cardiac conduction and repolarization (electrical activity of the heart) in healthy subjects. The positive control employed to demonstrate assay sensitivity consists of a group receiving a single oral dose of 400 mg moxifloxacin on day 7. The moxifloxacin arm is un-blinded but the ECG readings are blinded.
Study Results: NO
Conditions: Cardiac Conduction and Repolarization
Interventions: DRUG: Custirsen|DRUG: Placebo|DRUG: Moxifloxacin
Primary Outcome Measures: Individually-corrected QT interval (QTcI), The primary ECG variable and endpoint for this study is the time-matched change from baseline in QTcI method on day 7 at each time point. Holter ECGs will be performed at baseline (day -1) and prior to the start of infusion on day 7 and 1, 2 (end of infusion), 2.5, 3, 4, 5, 6, 8, 12, 16, 20, and 23.5 hours after the start of infusion., Up to 23.5 hours after the start of study drug infusion on Day 7
Secondary Outcome Measures: Fridericia-corrected QT interval (QTcF), QTcF time-matched change from baseline on day 7 at the following time points: 1, 2 (end of infusion), 2.5, 3, 4, 5, 6, 8, 12, 16, 20, and 23.5 hours, Up to 23.5 hours after study drug infusion on Day 7|Heart rate, PR interval, QRS interval and uncorrected QT interval, Holter ECGs will be performed at baseline (day -1) and prior to the start of infusion on day 7 and 1, 2 (end of infusion), 2.5, 3, 4, 5, 6, 8, 12, 16, 20, and 23.5 hours after the start of infusion., Up to 23.5 hours after study drug infusion on Day 7|ECG morphological patterns, Holter ECGs will be performed at baseline (day -1) and prior to the start of infusion on day 7 and 1, 2 (end of infusion), 2.5, 3, 4, 5, 6, 8, 12,

16, 20, and 23.5 hours after the start of infusion., Up to 23.5 hours after study drug infusion on Day 7|QTc (QTcI and QTcF) Intervals, The relationship between the placebo-corrected QTc (QTcI and QTcF) change from baseline and plasma concentrations of custirsen (pharmacokinetic/pharmacodynamic analysis). Holter ECGs will be performed at baseline (day -1) and prior to the start of infusion on day 7 and 1, 2 (end of infusion), 2.5, 3, 4, 5, 6, 8, 12, 16, 20, and 23.5 hours after the start of infusion., Up to 23.5 hours after study drug infusion on Day 7|Assay sensitivity, A comparison between the active control, moxifloxacin (400 mg), and placebo will also be performed to demonstrate assay sensitivity as required by current regulatory guidance. Holter ECGs will be performed at baseline (day -1) and prior to the start of infusion on day 7 and 1, 2 (end of infusion), 2.5, 3, 4, 5, 6, 8, 12, 16, 20, and 23.5 hours after the start of infusion., Up to 23.5 hours after study drug infusion on Day 7|Maximum observed plasma concentration (Cmax), From Day 1 through the Follow-up Visit (approximately Day 17)|Time to maximum observed plasma concentration (Tmax), From Day 1 through the Follow-up Visit (approximately Day 17)|Area under the plasma concentration-time curve (AUC0-t), From Day 1 through the Follow-up Visit (approximately Day 17)|Area under the curve from time 0 to infinity (AUC0-∞), From Day 1 through the Follow-up Visit (approximately Day 17)|Percentage of AUC0-∞ due to extrapolation from the time of last measurable concentration to infinity, From Day 1 through the Follow-up Visit (approximately Day 17)|Area under the curve from time 0 to 24 hours (AUC0-24), From Day 1 through the Follow-up Visit (approximately Day 17)|Terminal elimination rate constant (kel), From Day 1 through the Follow-up Visit (approximately Day 17)|Apparent terminal half life ($t_{\frac{1}{2}}$), From Day 1 through the Follow-up Visit (approximately Day 17)|Apparent volume of distribution (Vz), From Day 1 through the Follow-up Visit (approximately Day 17)|Apparent total body clearance (CL), From Day 1 through the Follow-up Visit (approximately Day 17)|Occurrence of Adverse Events, From signing of the informed consent through the Follow-up Visit (approximately 17 days)
Other Outcome Measures:
Sponsor: Achieve Life Sciences
Collaborators: Teva Branded Pharmaceutical Products R&D, Inc.
Sex: MALE
Age: ADULT
Phases: PHASE1
Enrollment: 155
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: TV1011-TQT-108
Start Date: 2013-05
Primary Completion Date: 2013-12
Completion Date: 2014-01

First Posted: 2013-06-11
Results First Posted:
Last Update Posted: 2016-10-10
Locations: Teva Investigational Site 10565, Lenexa, Kansas, United States
Study Documents:

NCT Number: NCT04066153
Study Title: Patient Reported Unmet Needs for Function and Supportive Occupational- and Physiotherapy Rehabilitation Interventions
Study URL: https://beta.clinicaltrials.gov/study/NCT04066153
Acronym:
Study Status: COMPLETED
Brief Summary: Purpose: To determine unmet functional needs in patients referred to the Palliative Care Unit at Rigshospitalet, Copenhagen University Hospital will be asked to fill out self reported questionnaires regarding problem intensity, problem burden and felt needs, physical functioning, emotional functioning, fatigue, sleep, distress. Furthermore patients physical function will be evaluated.
Study Results: NO
Conditions: Cancer|Kidney Diseases|Heart Failure|Neurologic Disorder|Liver Diseases|Pulmonary Disease|Side Effect|Quality of Life|Physical Disorder
Interventions:
Primary Outcome Measures: Unmet physical functioning needs, The Three-Levels-of-Needs Questionnaire (3LNQ), At baseline
Secondary Outcome Measures: Lower body physical function, 30 seconds Sit-To-Stand test, At baseline|Hand grip strength, Maximum strength test by handgrip dynamometer, At baseline|Walking endurance, Six Minute Walking Test, At baseline|Health-related quality of life, EORTC QLQ-C30, At baseline|Overall distress, Distress thermometer, At baseline|Psychological distress, Hospital Anxiety and Depression Scale (HADS), At baseline|Sleep quality, Pittsburgh Sleep Quality Index (PSQI), At beseline|Level of fatigue, Functional Assessment of Cancer Therapy - Fatigue (FACT-F) 13 item fatigue subscale, At baseline|Patients self-perception of performance in everyday living, The Canadian Occupational Performance Measure (COPM), At baseline|Physical activity level, International Physical Activity Questionnaire (IPAQ) short form, At baseline
Other Outcome Measures:
Sponsor: Rigshospitalet, Denmark
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 43
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2018-418 6670

Start Date: 2019-08-20
Primary Completion Date: 2019-11-08
Completion Date: 2019-11-08
First Posted: 2019-08-26
Results First Posted:
Last Update Posted: 2020-04-01
Locations: Rigshospitalet, Copenhagen, Denmark
Study Documents:

NCT Number: NCT01782053
Study Title: Communicating Smoking Risks Through Graphic Warning Labels
Study URL: https://beta.clinicaltrials.gov/study/NCT01782053
Acronym:
Study Status: COMPLETED
Brief Summary: Smoking is the largest preventable health risk in the U.S. The Family Smoking Prevention and Tobacco Control Act of 2010 mandated the placement of larger pictorial warnings on cigarette packs as well as nine new statements of smoking risks. This trial tests the effectiveness of the warnings proposed by the Food and Drug Administration by providing cigarettes with the proposed labels to 320 smokers across two sites (Philadelphia, PA and Columbus, OH). In addition, the trial tests the effects of different warning label components.
Study Results: NO
Conditions: Lung Cancer|Heart Disease
Interventions: BEHAVIORAL: Picture warning|BEHAVIORAL: Control
Primary Outcome Measures: Intention to try to quit smoking in next 30 days, Assessed after 4 weeks of exposure to new labels
Secondary Outcome Measures: Affective reactions toward cigarettes and smoking cues, After 4 weeks of exposure to the new warning labels
Other Outcome Measures:
Sponsor: University of Pennsylvania
Collaborators: Ohio State University
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 245
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: FACTORIAL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 1R01CA157824-01A1
Start Date: 2013-01
Primary Completion Date: 2014-04
Completion Date: 2014-04
First Posted: 2013-02-01
Results First Posted:
Last Update Posted: 2014-12-02
Locations: Lazenby Hall, Ohio State University, Columbus, Ohio, 43210,

United States|Annenberg Public Policy Center, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT05595577
Study Title: Improving Exercise Capacity With a Tailored Physical Activity Intervention
Study URL: https://beta.clinicaltrials.gov/study/NCT05595577
Acronym: PALS
Study Status: RECRUITING
Brief Summary: The purpose of this research is to test whether participating in either a physical activity intervention or a series of educational classes will help to preserve exercise capability, heart function, brain-based activities (like memory), and quality of life.

Participants will be randomized to 1 of 2 pathways:

* First pathway consists of organized health workshops. These workshops are intended to provide information on topics such as proper nutrition, management of stress, sleep practices, and emphasis on a healthy lifestyle that may help the participants through cancer treatment. This pathway will also test whether stretching may help participants through cancer treatment.
* Second pathway participants will take part in some unsupervised and some potentially supervised moderate activity sessions each week throughout participants' cancer treatment to take place either remotely or in person, depending on availability of facilities at the time visits are scheduled.
Study Results: NO
Conditions: Non Hodgkin Lymphoma|Heart; Functional Disturbance|Hodgkin Lymphoma|Quality of Life
Interventions: OTHER: Exercise with Trainerize application|DIAGNOSTIC_TEST: Cardiopulmonary exercise testing|DIAGNOSTIC_TEST: MRI scan|BEHAVIORAL: Quality of Life Questionnaires|BEHAVIORAL: Cognitive and Brain Function Questionnaires|OTHER: Blood draws
Primary Outcome Measures: Change in Peak VO2, An analysis of covariance (ANCOVA) model will be used to assess post-intervention group differences in VO2, adjusted for baseline peak VO2., At baseline and 6 months after study intervention
Secondary Outcome Measures: Change in Peak Exercise Cardiac Output, Measured on a continuous scale and will be analyzed using a repeated measures ANCOVA (RMANCOVA) approach., At baseline and 6 months after study intervention|Change in Calculated A-V Oxygen Levels, Measured on a continuous scale and will be analyzed using a repeated measures ANCOVA (RMANCOVA) approach., At baseline and 6 months after study intervention|Changes in Measurements of Pre-exercise Left Ventricular Function, Measured on a continuous scale and will be analyzed using a repeated measures ANCOVA (RMANCOVA) approach., At baseline and 6 months after study intervention|Change in Neurocognitive Function -

Hopkins Verbal Learning Test, The Hopkins Verbal Learning Test (HVLT-R) consists of memorization of a list of words to test the ability to recall immediately after memorization (immediate recall) and after a 20-minute delay (delayed recall). This test has three parts and two alternate forms. Total scores could range from 0 to 30. Lower raw scores indicate difficulties with the task., At baseline and 6 months after study intervention|Change in Neurocognitive Function - Controlled Oral Word Association Test (COWAT), The Controlled Oral Word Association Test is a verbal fluency test in which participants are asked to say as many words as possible from a given category and in a specified timeframe (typically 60 seconds). COWAT is measured by calculating the total number of acceptable words produced for at the given letter of the alphabet. Errors and perseverations (word repetitions) are not included in this score., At baseline and 6 months after study intervention|Change in Neurocognitive Function - Digit Span-Backward Test, The digit span backward test is used to assess working memory. Participants are given a series of digits and asked to repeat them backward. The item score is the sum of the scores on the two trials for that item (range=0-2). The total raw score for backwards digit span is the sum of the item scores; maximum backwards digit span total raw score is 16 points., At baseline and 6 months after study intervention|Change in Neurocognitive Function - Trail Making Test, The Trail Making Test (TMT) asks patients to connect consecutive "targets" (numbers and/or letters) on a page arranged in a specific geometric pattern. Scoring is based on time taken to complete the test (e.g. 35 seconds yielding a score of 35) with lower scores being better., At baseline and 6 months after study intervention|Change in 6-Minute Walk Distance, Measured on a continuous scale and will be analyzed using a repeated measures ANCOVA (RMANCOVA) approach., At baseline, 3 months and 6 months after study intervention|Health-Related Quality of Life Questionnaire (FACT-Lym), 42-item questionnaire to assess the quality of life for lymphoma patients. 5-point Likert scale - 0 (not at all) to 4 (very much). Subscale domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, Functional Well-Being, Lymphoma Subscale. Some items are reverse scored. Subscales scores are added to get the total score. The higher the score, the better the quality of life. Scores can range from 0-168, At baseline, 3 months and 6 months after study intervention|Fatigue Questionnaire, Questionnaire to assess the difference in the level of fatigue participants experience will performing study interventions. 5-point Likert scale - 0 (not at all) to 4 (very much). The higher the score the higher level of fatigue participants experience. Score range 0-52., At baseline, 3 months and 6 months after study intervention|Change in Physical Activity Levels - Godin Leisure Time Exercise Questionnaire, The questionnaire is a 4-item measure used to classify participants' activity levels during a typical 7-day period based on how many times on average participants exercise more than 15 minutes during their free time of strenuous, moderate or mild exercise., At baseline, 3 months and 6 months after study intervention|Change in Physical Function - Balance Test,

Participants will be asked to maintain balance for up to 30 seconds in three positions characterized by a progressive narrowing of the base support: heel of one foot beside the big toe of the other foot (semi-tandem position), heel of one foot in front of and touching the toes of the other foot (tandem position), and single leg stand., At baseline, 3 months and 6 months after study intervention|Change in Physical Function - Chair Stand Test, The repeated chair stand test will be performed using a straight-backed chair placed with its back against a wall. Participants will be first asked to stand from a sitting position without using their arms. If they can perform the task, they will then be asked to stand up and sit down five times as quickly as possible. The time to complete the task will be recorded., At baseline, 3 months and 6 months after study intervention|Change in Physical Function - 4-Meter Walk Gait Speed Test, The gait speed test will assess the participant's ability to walk 4 meters. Participants will be instructed to start at a marked walking course with toes touching the start line and when cued to start, will begin walking at their usual speed. The time to walk from the starting line to the end of the 4-meter walk will be recorded, At baseline, 3 months and 6 months after study intervention|Change in Physical Function - Grip Strength, Grip strength will be assessed using an isometric handgrip dynamometer while the participant is seated with the head facing straight ahead. The elbow should be bent at a 90 degree angle and the wrist should be at the mid-prone position. The participant should exert maximally and quickly (about 1 second) and two trials should be made alternately with each hand, with at least 30 seconds between trials for the same hand (recorded in kilograms)., At baseline, 3 months and 6 months after study intervention
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 66
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IRB00087763|4R33CA226960-03|WFBCCC 98622
Start Date: 2023-03-01
Primary Completion Date: 2023-07
Completion Date: 2023-08
First Posted: 2022-10-27
Results First Posted:
Last Update Posted: 2023-04-21
Locations: Wake Forest Baptist Comprehensive Cancer Center, Winston-Salem, North Carolina, 27157, United States|Virginia Commonwealth University, Richmond, Virginia, 23298, United States
Study Documents:

NCT Number: NCT04670094
Study Title: Comorbidities and Risk Score in COVID-19 Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04670094
Acronym: Comorbidities
Study Status: COMPLETED
Brief Summary: Retrospective multi-center cohort study. Consecutive patients hospitalized for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) up to October 2020 will be included. Patients are followed until discharge from hospital or death.
Study Results: NO
Conditions: Covid19
Interventions:
Primary Outcome Measures: In-hospital mortality, Description of the hospital mortality caused by the COVID19 disease, Until study completion, an average of 1 year|Mortality up to 3 months from admission, Description of the mortality patients up to 3 months from admission, Until study completion, an average of 1 year
Secondary Outcome Measures: Admission to Intensive care unit (ICU), Description of the admission to ICU, Until study completion, an average of 1 year|Complications occurred during the hospital course, Description of the complications occurred during the hospital course, Until study completion, an average of 1 year|Correlation between admission to ICU and in-hospital mortality, Description of the possible correlation between the admission of ICU and in-hospital mortality of the patients, Until study completion, an average of 1 year
Other Outcome Measures:
Sponsor: University of Milano Bicocca
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 4555
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Comorbidities
Start Date: 2020-12-30
Primary Completion Date: 2021-05-29
Completion Date: 2021-05-29
First Posted: 2020-12-17
Results First Posted:
Last Update Posted: 2022-11-09
Locations: ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy|ASST Spedali Civili, Montichiari, Italy|ASST Monza-Ospedale San Gerardo, Monza, Italy|Humanitas Clinical and Research Hospital, Rozzano, Italy|Centre for Tropical and Infectious Diseases and Microbiology, IRCCS Sacro Cuore, Verona, Italy
Study Documents:

NCT Number: NCT04283994
Study Title: Project to Improve Communication About Serious Illness--Hospital Study: Comparative Effectiveness Trial (Trial 2)
Study URL: https://beta.clinicaltrials.gov/study/NCT04283994
Acronym: PICSI-H
Study Status: RECRUITING
Brief Summary: The objective of this protocol is to test the effectiveness of a Jumpstart intervention on patient-centered outcomes for patients with chronic illness by ensuring that they receive care that is concordant with their goals over time, and across settings and providers. This study is particularly interested in understanding the effect of the intervention to improve quality of palliative care for patients with Alzheimer's disease and related dementias (ADRD) but will also include other common chronic, life-limiting illnesses. The specific aims are:

1. To evaluate the efficacy of the Survey-based Patient/Clinician Jumpstart compared to the EHR based clinician Jumpstart and usual care for improving quality of care; the primary outcome is EHR documentation of a goals-of-care discussion from randomization through hospitalization or 30 days. Secondary outcomes include: a) intensity of care outcomes (e.g., ICU use, ICU and hospital length of stay, costs of care during the hospitalization, 7 and 30 day readmission); and b) patient- and family-reported outcomes assessed by surveys at 3 days and 4 weeks after randomization, including occurrence and quality of goals-of-care discussions in the hospital, goal-concordant care, psychological symptoms, and quality of life.
2. To conduct a mixed-methods evaluation of the implementation of the intervention, guided by the RE-AIM framework for implementation science, incorporating quantitative evaluation of the intervention's reach and adoption, as well as qualitative analyses of interviews with participants, to explore barriers and facilitators to future implementation and dissemination.
Study Results: NO
Conditions: Dementia|Chronic Disease|Neoplasm Metastasis|Lung Neoplasms|Pulmonary Disease, Chronic Obstructive|Heart Failure, Congestive|Liver Cirrhosis|Kidney Failure, Chronic|Lung Diseases, Interstitial|Peripheral Vascular Disease|Diabetes With End Organ Injury|Palliative Care, Patient Care|Health Care Quality, Access, and Evaluation|Patient Care|Inpatients|Health Communication|Patient Care Planning|Quality of Life
Interventions: BEHAVIORAL: Survey-based Patient/Clinician Jumpstart|BEHAVIORAL: EHR-based Clinician Jumpstart
Primary Outcome Measures: EHR documentation of Goals of Care discussions, The primary outcome is the proportion of patients who have a goals-of-care discussion that has been documented in the EHR in the period between randomization and 30 days following randomization. The proportion is the number of patients with GOC documentation over the number of patients in each study arm. Documentation of goals-of-

care discussions will be evaluated using our NLP/ML methods., Assessed for the period between randomization and 30 days following randomization
Secondary Outcome Measures: Intensity of care/ICU use: ICU admissions, Secondary outcomes include measures of intensity of care, including utilization metrics: Number of ICU admissions during the patient's (index) hospital stay will be collected from the EHR., Assessed for the period between randomization and 30 days following randomization|Intensity of care/ICU use: ICU length of stay, Secondary outcomes include measures of intensity of care, including utilization metrics: Number of days alive and out of the ICU within 30 days from randomization will be collected from the EHR. Number of ICU days from randomization to hospital discharge or death will also be collected from the EHR., Assessed for the period between randomization and 30 days following randomization|Intensity of care/Hospital use: Hospital length of stay, Secondary outcomes include measures of intensity of care, including utilization metrics: Number of days alive and out of the hospital within 30 days from randomization will be collected from the EHR. Number of hospital days from randomization to hospital discharge or death will also be collected from the EHR., Assessed for the period between randomization and 30 days following randomization|Intensity of care: Hospital Readmissions 30 days, Secondary outcomes include measures of intensity of care, including utilization metrics: Number of hospital readmissions between randomization and 30 days following randomization collected from the EHR., Assessed for the period between randomization and 30 days following randomization|Intensity of care: ICU Readmissions 30 days, Secondary outcomes include measures of intensity of care, including utilization metrics: Number of ICU readmissions between randomization and 30 days following randomization will be collected from the EHR., Assessed for the period between randomization and 30 days following randomization|Intensity of care: Healthcare costs, Costs for intervention vs. control will be reported in US dollars and identified from UW Medicine administrative financial databases. Costs will be reported for total hospital costs and disaggregated costs (direct-variable, direct fixed, indirect costs). Direct-variable costs will include supply and drug costs. Direct-fixed costs will include labor, clinical department administration, and overhead fees. Indirect costs represent services provided by cost centers not directly linked to patient care such as information technology and environmental services. Costs for ED (emergency department) days and ICU days will be similarly assessed., Between randomization and 30 days after randomization|Intensity of care: Healthcare utilization, Subjects will complete a short healthcare utilization survey at the time of the 2nd follow-up questionnaire in which they will self-report the number of visits to emergency departments, hospitals and/or outpatient clinics during the study period., Between randomization and 30 days after randomization|All-cause mortality at 1 year (safety outcome), From Washington State death certificates., 1 year after randomization|Patient or surrogate/family-reported discussion of goals, Subjects will self-report (yes or

no) if they had a discussion of goals of care ("the kind of medical care you/your loved one would want") during the index hospitalization. This outcome will be presented as a proportion: the number of subjects reporting a goals-of-care discussion over the number of patients in each study arm., 3 days and 4 weeks after randomization|Quality of Communication (QOC), Quality of goals-of-care communication is assessed with the end-of-life communication scale (QOC_eol) of the Quality of Communication (QOC) survey. The QOC_eol subscale is based on 4 to 7 items, with item scores ranging from 0 (worst) to 10 (best)., 3 days after randomization|SUPPORT questions, Concordance between the care patients want and the care they are receiving will be measured with two questions from the SUPPORT study. The first defines patients' preferences: "If you \[patient\] had to make a choice at this time, would you prefer a course of treatment focused on extending life as much as possible, even if it means having more pain and discomfort, or would you want a plan of care focused on relieving pain and discomfort as much as possible, even if that means not living as long?" The second question assesses perceptions of current treatment using the same two options. The outcome is a dichotomous variable of whether the preference matches the report of care received., 3 days and 4 weeks after randomization|Anxiety and depression (HADS), Symptoms of depression and anxiety assessed with the Hospital Anxiety and Depression Scale (HADS). The HADS is a reliable, valid 14-item, 2-domain (anxiety and depression) tool used to assess symptoms of psychological distress. Seven items evaluate anxiety and seven evaluate depression. Each item is scored on a 4-point scale (ranging from 0-3) with scores for each subscale (anxiety and depression) ranging from 0-21., 4 weeks after randomization|EuroQol 5 Dimensions 5 Level (EQ-5D-5L), The EuroQol 5 Dimension 5 Level (EQ-5D-5L) is a self-report survey that measures quality of life across 5 domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression., 4 weeks after randomization|SF1, We will use the SF1 as a measure of self-reported overall health status., 3 days and 4 weeks after randomization|CollaboRATE, The CollaboRATE is patient-reported measure of shared decision making., 3 days after randomization|Patient reported discussion of life-sustaining treatments, We are using the following question to probe patient-reported discussions of life-sustaining treatments with their doctors: "Have you ever thought about what kinds of life-sustaining treatments you would want, or not want, if you got a lot sicker? Yes/no", 3 days and 4 weeks after randomization|Goal concordance, Concordance between the care patients want and the care they are receiving will be measured by an investigator-developed question: "Do you think that your current medical care is in line with your goals?", 3 days and 4 weeks after randomization

Other Outcome Measures: Key Implementation Factors, Qualitative interviews after individual participation has concluded. Interviews will be guided by the RE-AIM and Consolidated Framework for Implementation Research (CFIR) to explore the factors associated with implementation (e.g., reach, maintenance, feasibility, inner and outer

settings, individuals, and processes of care.) Individual constructs within these domains were chosen to fit this specific intervention and context., 3 months after randomization
Sponsor: University of Washington
Collaborators: National Institute on Aging (NIA)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 600
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: STUDY00007031-B|1R01AG006244
Start Date: 2021-07-26
Primary Completion Date: 2023-09-01
Completion Date: 2025-08-01
First Posted: 2020-02-25
Results First Posted:
Last Update Posted: 2023-03-06
Locations: Harborview Medical Center, Seattle, Washington, 98104, United States|UW Medical Center - Northwest, Seattle, Washington, 98133, United States|UW Medical Center - Montlake (UWMC), Seattle, Washington, 98195, United States
Study Documents:

NCT Number: NCT04182594
Study Title: Cardiovascular Events in GnRH Agonist vs. Antagonist
Study URL: https://beta.clinicaltrials.gov/study/NCT04182594
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is to test if the use of Degarelix for 1 year associated with a lower rate of cardiovascular toxicity compared to Gonadotropin-releasing hormone (GnRH) agonists in patients with advanced prostate cancer and cardiovascular risk factors, receiving combination therapy of Androgen deprivation therapy (ADT) and second line hormonal or chemotherapy?
Study Results: NO
Conditions: Hormone Sensitive Prostate Cancer|Prostate Cancer|Cardiac Event
Interventions: DRUG: Degarelix|DRUG: GnRH agonist
Primary Outcome Measures: time to first cardiovascular event, To compare time to first cardiovascular event as estimated by the cumulated probability at the 1-year time-point of patients with advanced prostate cancer treated for one year with Degarelix vs. GnRH agonist. This will be a composite outcome composed of: Death, CVA, MI, TIA, cardiac emergency room visits, heart catheterization., 1 year
Secondary Outcome Measures: time to first MACCE event, To compare time to first MACCE event as estimated by the cumulated probability at the 1-year timepoint of patients with advanced prostate cancer treated

with Degarelix vs. GnRH agonist and combination therapy.

MACCE will be defined as:

1. Death of any cause
2. MI
3. CVA
4. Percutaneous coronary intervention, (PCI) with stent insertion, 1 year|cardiac echocardiography, To compare change in ejection fraction (EF) as measured by cardiac echocardiography of patients with advanced prostate cancer treated with Degarelix vs. GnRH agonist, at baseline, six-, nine- and twelve-months of combination treatment., 1 year|Hormonal Profile, To compare testosterone serum levels (ng/dL) of patients with advanced prostate cancer treated with Degarelix vs. GnRH agonist, at baseline, three-, six- and twelve-months of combination treatment., 1 year|NTproBNP levels, To compare levels of NTproBNP (pg/mL) in patients with advanced prostate cancer treated with Degarelix vs. GnRH agonist, at baseline, three-, six-, nine- and twelve-months of combination treatment., 1 year|Adverse events, To compare rate of other adverse events in patients with advanced prostate cancer treated with Degarelix vs GnRH agonist and combination therapy., 1 year|PSA levles, To compare PSA serum levels (ng/mL) of patients with advanced prostate cancer treated with Degarelix vs. GnRH agonist, at baseline, three-, six- nine- and twelve-months of combination treatment., 1 year|BMI, To compare changes in body mass index (BMI) in patients with advanced prostate cancer treated with Degarelix vs. GnRH agonist, at baseline, three-, six- and twelve-months of combination treatment., 1 year|Quality of life: FACT-P questionnaire, To compare the quality of life by self-reported FACT-P questionnaire, by patients with advanced prostate cancer treated with Degarelix vs. GnRH agonist, at baseline, three-, six- and twelve-months of combination treatment, 1 year|Glucose profile, To compare glucose levels (mg/dL) in patients with advanced prostate cancer treated with Degarelix vs GnRH agonist, at baseline, three-, six- and twelve-months of combination treatment., 1 year|Cholesterol levles, To compare Cholesterol serum levels (mg/dL) of patients with advanced prostate cancer treated with Degarelix vs. GnRH agonist, at baseline, three-, six- nine- and twelve-months of combination treatment., 1 year
Other Outcome Measures:
Sponsor: Rabin Medical Center
Collaborators: Ferring Pharmaceuticals
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 80
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: 0670-19-RMC

Start Date: 2020-01-17
Primary Completion Date: 2023-01-17
Completion Date: 2023-01-17
First Posted: 2019-12-02
Results First Posted:
Last Update Posted: 2019-12-02
Locations: Rabin Medical Center - Beilinson Hospital, Petah Tikva, 4941492, Israel
Study Documents:

NCT Number: NCT03879629
Study Title: TrAstuzumab Cardiomyopathy Therapeutic Intervention With Carvedilol
Study URL: https://beta.clinicaltrials.gov/study/NCT03879629
Acronym: TACTIC
Study Status: RECRUITING
Brief Summary: Breast cancer patients undergoing trastuzumab-based HER2-directed therapy are at risk of heart function decline or heart failure symptoms, but it is unknown if, when, and for how long cardiovascular protective strategies, e.g. with a beta-blocker, could help. This study randomly assigns those taking curative-intent trastuzumab-based HER2-directed therapy to the beta-blocker carvedilol-either when significant heart function decline or subtle early signs of heart injury (either by elevation of a cardiac blood biomarker, i.e. cardiac troponin, or by an abnormal heart ultrasound marker, i.e. global longitudinal strain) are noted, or preventatively before beginning trastuzumab-based HER2-directed therapy. This study will further randomly assign those patients on carvedilol to either discontinuation at the end of trastuzumab-based HER2-directed therapy or continuation for another year, providing much needed clinical trial data on what the best strategy ("tactic") for those at risk of cardiotoxicity with trastuzumab-based HER2-directed therapy is.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Carvedilol
Primary Outcome Measures: Rate of asymptomatic and symptomatic cardiac dysfunction, Incidence of heart failure or asymptomatic decline in left-ventricular ejection fraction (LVEF) by \>10% in patients whose LVEF is ≥50% or LVEF drop ≥5% in those with a decrease to \<50% (primary outcome measure), 1 year|Rate of reversible cardiac function decline, Reversible LVEF decline to within 5% of baseline (secondary primary outcome measure), 1 year
Secondary Outcome Measures: Cardiac function changes after completion of HER2-directed therapy, Delta change in LVEF from completion to one year after completion of trastuzumab-based HER2-directed therapy, 1 year|Gene variants and risk of cardiotoxicity and response to therapy, Correlation of absolute delta change in GLS and LVEF while on trastuzumab and after stopping trastuzumab with the frequency of the following SNPs: trastuzumab-related: p\<1x10-5 hits from Norton GWAS (six loci) 130 HER 2 Ile665Val, HER2 Pro1170Ala125, 126, 130,

anthracycline-related: ABCB1 rs1128503, ABCB4 rs1149222, ABCC1 rs45511401, ABCC2 res17222723, CAT rs10836235, CBR3 rs1056892, CYBA rs4673, CYP3A4*22 rs35599367, NCF4 rs1883112, RAC2 rs13058338, RARG rs2229774, SLC28A3 rs7853758, TOP2B rs10865801, and UGT 1A6*4 rs1786378374, 150-152, beta-blocker-related: β2-AR Gln27Gln, β1-AR Arg389Arg 80-82 and CYP2D6 polymorphisms (CYP2D6 alleles (*1, *2, *3, *4, *5, *6, *7, *8, *9, *10, *11, *15, *17, *19, *20, *29, *35, *36, *40 and *41), as well as 7 CYP2D6 gene duplications (*1 9 N, *2 9 N, *4 9 N, *10 9 N, *17 9 N, *35 9 N and *41 9 N) by use of the AmpliChip CYP450 GeneChip, 2 years
Other Outcome Measures:
Sponsor: Mayo Clinic
Collaborators: National Cancer Institute (NCI)|Miami Heart Research Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 450
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: MC1932|R01CA233610|NCI-2019-08427
Start Date: 2019-08-21
Primary Completion Date: 2024-12-31
Completion Date: 2025-09-30
First Posted: 2019-03-19
Results First Posted:
Last Update Posted: 2023-06-22
Locations: Mayo Clinic, Phoenix, Arizona, 85054, United States|Mayo Clinic in Florida, Jacksonville, Florida, 32224, United States|Mayo Clinic in Rochester, Rochester, Minnesota, 55905, United States|Washington University in St. Louis, Saint Louis, Missouri, 63110, United States|MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT00728429
Study Title: Aerobic Exercise in Patients Receiving Chemotherapy for Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00728429
Acronym:
Study Status: TERMINATED
Brief Summary: RATIONALE: Aerobic exercise may help prevent side effects caused by chemotherapy and help improve heart health.

PURPOSE: This randomized clinical trial is studying the side effects of aerobic exercise and to see how well it works in patients receiving chemotherapy for cancer.
Study Results: NO

Conditions: Cardiac Toxicity|Chemotherapeutic Agent Toxicity|
Unspecified Adult Solid Tumor, Protocol Specific
Interventions: BEHAVIORAL: exercise intervention
Primary Outcome Measures: Percentage of patients enrolling in the study, day 1|Percentage of patients completing the study, 24 weeks|V02 peak before and after chemotherapy, 24 weeks
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: CDR0000601334|CCCWFU-99108|CCCWFU-IRB-IRB00006209
Start Date: 2008-06
Primary Completion Date: 2009-05
Completion Date: 2009-05
First Posted: 2008-08-05
Results First Posted:
Last Update Posted: 2017-05-30
Locations: Wake Forest University Comprehensive Cancer Center, Winston-Salem, North Carolina, 27157-1096, United States
Study Documents:

NCT Number: NCT00441077
Study Title: Interventions to Educate An Underserved Population About Inherited Disease Risks
Study URL: https://beta.clinicaltrials.gov/study/NCT00441077
Acronym:
Study Status: COMPLETED
Brief Summary: This study will examine how to communicate with an underserved population about inherited disease risks. It will present information about inherited risk to a Latino population through either a lay health advisor (LHA) or through printed information. The LHA is a member of the Latino community who has received training in public speaking, group facilitation, and managing group dynamics and in family health history and genetics. Previous studies have shown that an LHA can effectively communicate health information to diverse audiences, but such interventions have not been studied in the context of inherited risk.

Spanish-speaking Latino men and women over the age of 18 in the Oakland, CA, and Washington, DC, areas who have basic Spanish reading and writing skills may be eligible for this study.

Participants are recruited to one of two groups. One group participates in group educational sessions with an LHA about inherited disease risks and family health history, and the other receives this information from a brochure.

Educational Sessions

Groups of 5 to 8 individuals complete a questionnaire and then participate in a 45-minute educational session on concepts related to genetics, family health history, lifestyle and environment. Participants engage in role-playing to practice discussing family health history with family members. The LHA teaches participants the skills needed to fill in family health history tool called My Family Health Portrait and answers questions. After the question and answer session, participants complete a second questionnaire.

Brochure-Only

Participants complete a questionnaire and then read a Spanish-language brochure produced by the U.S. Surgeon General's Office about the importance of knowing one's family history. They then complete a second questionnaire.
Study Results: NO
Conditions: Healthy Volunteers
Interventions: BEHAVIORAL: Education
Primary Outcome Measures: Intentions to seek information about family history.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Human Genome Research Institute (NHGRI)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 550
Funder Type: NIH
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: OTHER
Other IDs: 999907102|07-HG-N102
Start Date: 2007-02-19
Primary Completion Date: 2007-12-12
Completion Date: 2007-12-12
First Posted: 2007-02-28
Results First Posted:
Last Update Posted: 2017-07-02
Locations: La Raza, Oakland, California, United States|La Clinica del Pueblo, Washington, D.C., District of Columbia, 20009, United States
Study Documents:

NCT Number: NCT02939729
Study Title: Physiotherapy Prehabilitation in Patients Undergoing Cardiac or Thoracic Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT02939729
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to determine the effects of a physiotherapy prehabilitation programme (walking and deep breathing exercises) in cardiac or thoracic patients by measuring changes in lung volumes, functional capacity physiotherapy length of stay postoperatively.
Study Results: NO
Conditions: Coronary Artery Disease|Lung Cancer|Lung Tumor
Interventions: OTHER: Walking Programme|DEVICE: Incentive Spirometer|OTHER: Deep Breathing Exercises
Primary Outcome Measures: Difference between groups functional activity from baseline to point of admission for surgery as measured by the 6MWT., The 6MWT is a validated test that requires no exercise equipment or "advanced" training for the assessor. Walking is an activity carried out on a daily basis by most people. The 6MWT measures the distance that a person can walk on a flat surface over a period of 6 minutes. The majority of activities of daily living are carried out at "sub-maximal" levels similar to the level of exertion of the 6MWT as the patient sets their own intensity (American Thoracic Society 2002). A review of functional walking tests suggested that "the 6MWT is easy to administer, better tolerated, and more reflective of activities of daily living than the other walk tests" (Solway et al 2001). Other prehabilitation studies have used the 6MWT as an outcome measure of functional activity therefore is widely accepted as a reliable measure of functional activity (Sawatzky et al 2014; Carli et al 2010; Gillis et al 2014)., From date of randomisation to date of admission for surgery (up to 8 weeks)
Secondary Outcome Measures: Functional capacity as measured by 6MWT on day of discharge and at return clinic appointment (up to 8 weeks), Measure of level of physical activity measured in metres, Date of discharge from physiotherapy and at return clinic appointment (up to 8 weeks)|Tidal Volume (TV) measures with incentive spirometer., Lung volume measure in mls, At baseline, preoperative, postoperative days 1, 2 and 3 and at return clinic appointment (up to 8 weeks)|Day of discharge from Physiotherapy., Physiotherapy discharge criteria: mobilising safely and independently with or without walking aid approximately 100 metres; independently managing chest and safely completed stairs assessment (approximately post op day 3 to 5)., Once all physiotherapy criteria have been met (approximately 3 to 5 days).|Total postoperative hospital length of stay., Total post operative hospital length is days in hospital after surgery., Once all hospital discharge criteria have been met (approximately 5-7 days).|EQ-5D score., A standardized and validated measure of health status which can be used in a wide range of health conditions. It is a simple method which patients can complete at the beginning and end of

treatment. It encompasses five dimensions of health: mobility, ability to self care, ability to complete activities of daily living, pain and discomfort, and anxiety and depression (Chartered Society of Physiotherapists, 2016)., At baseline and follow up clinic appointment (up to 8 weeks).
Other Outcome Measures:
Sponsor: Golden Jubilee National Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 40
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 16/CARD/18
Start Date: 2016-09
Primary Completion Date: 2019-08
Completion Date: 2019-08
First Posted: 2016-10-20
Results First Posted:
Last Update Posted: 2019-10-29
Locations: Golden Jubilee National Hospital, Glasgow, G81 4DY, United Kingdom
Study Documents:

NCT Number: NCT01672294
Study Title: Caregiver Outlook: An Intervention to Improve Caregiving in Serious Illness
Study URL: https://beta.clinicaltrials.gov/study/NCT01672294
Acronym:
Study Status: COMPLETED
Brief Summary: Informal caregivers provide a majority of care for patients during serious illness. Lack of preparation and completion may leave caregivers less capable of caring for a loved one or making crucial decisions influencing care.

This study will examine whether a preparation and completion intervention reduces caregiver anxiety, depression, anticipatory grief, and burden and improves patient quality of life and health care use.
Study Results: YES
Conditions: Heart Failure|Pulmonary Disease|Cancer
Interventions: OTHER: Preparation and life completion|OTHER: Attention Control
Primary Outcome Measures: Caregiver Anxiety, Profile of Moods States (POMS) anxiety sub-scale The anxiety sub-scale from the modified Brief Profile of Mood States (POMS),7110 a six-item measure of psychological distress. Individual items used a 5 point Likert scale (0-4). The sub-

scale minimum score was 0 and maximum was 24 (more anxious)., Measured at baseline, 5 weeks, and 8 weeks
Secondary Outcome Measures: Spirituality, Functional Assessment of Chronic Illness Therapy - Spiritual Well-Being (FACIT-SP) subscale. The 12-item measure assess spiritual well-being: faith, meaning, and purpose. Individual items use a 5 point likert scale (0-4). The scale minimum score is 0 (negative well being) and maximum is 48 (positive well being)., Measured at baseline, 5 weeks, and 8 weeks|Depression, Centers for Epidemiologic Study of Depression short form (CES-D) is a 10-item measure of depression. Items are rated on a 4 point Likert scale (0-3) with total scores ranging from 0 to 30. Higher scores indicate greater depressive symptoms, Measured at baseline, 5 weeks, and 8 weeks|Patient Days of VA Hospital Use, The number of days that a patient used either the VA emergency department (ED) or was an inpatient at a VA hospital in the 6 months following randomization. Inclusion of non-VA utilization was made unpractical due to the long delay in filing for non VA reimbursement (up to 2 years). The original variable was Day AT home, defined to be 180 days minus the days in ED or inpatient hospital. This was changed to days of use due to distribution/modeling considerations., In the 6 months after randomization|Caregiver Burden, Caregiver Reaction Assessment (CRA). The Caregiver Reaction Assessment is a 24-item multidimensional instrument designed to measure a caregiver's reactions to caregiving for family members with a variety of chronic illnesses. The esteem subscale has 7 items with a 5 level Likert scale: 1=Strongly Disagree to 5=Strongly Agree. The score is the average of the 7 items ranging from a low score of 1 associated with negative reactions and high score of 5 with positive reactions., Measured at baseline, 5 weeks, and 8 weeks|Caregiver Completion, Quality of life at the End of Life (Family Edition) is a 17-item measure of quality of life at the end of life assessing five domains: life completion, relationship with health care providers, preparation for death, physical symptoms and affective social support. The 3-item Life Completion subscale uses a 5 point (0-4) Likert scale. The subscale ranges from 0 (poor) to 4 (better outcome)., Measured at baseline, 5 weeks, and 8 weeks|Prolonged Grief - Number of Participants With Anticipatory Grief, The Prolong Grief Disorder scale is a clinically-based diagnosis determination scale modified for this study. The components/requirements that were dropped were a) diagnosis should not be made until at least 6 months since death, and b) the disturbance is not better accounted for major depressive disorder, generalized anxiety disorder or post traumatic stress disorder. The outcome was a dichotomized variable with 1 indicating symptoms of prolonged grief are present and 0 indicating insufficient symptoms., Measured at baseline, 5 weeks, and 8 weeks|Caregiver Preparation, Quality of life at the End of Life (Family Edition) is a 17-item measure of quality of life at the end of life assessing five domains: life completion, relationship with health care providers, preparation for death, physical symptoms and affective social support. The 5-item preparation subscale uses a 5 point (0-4) Likert scale. The subscale ranges from 0 (poor) to 4 (better

outcome)., Measured at baseline, 5 weeks, and 8 weeks
Other Outcome Measures:
Sponsor: VA Office of Research and Development
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 286
Funder Type: FED
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IIR 11-347
Start Date: 2013-06
Primary Completion Date: 2015-12
Completion Date: 2016-04
First Posted: 2012-08-24
Results First Posted: 2017-01-06
Last Update Posted: 2017-04-17
Locations: Durham VA Medical Center, Durham, NC, Durham, North Carolina, 27705, United States
Study Documents:

NCT Number: NCT04036032
Study Title: Role of Aerobic Exercise to Modulate Cardiotoxicity in Long Term Cancer Survivors Exposed to Anthracycline Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04036032
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Over 50% of the more than 270,000 childhood cancer survivors in the U.S. have been treated with anthracyclines and thus are at risk of developing cardiotoxicity. The impact of exercise training on LV structure has been extensively studied. Left ventricular hypertrophy and cardiac chamber enlargement with the accompanying ability to generate a large stroke volume are direct results of exercise training. Aerobic exercise therapy offers a non-pharmacological mechanism to modulate multiple gene expression pathways that may promote cardiac remodeling. No prior studies have investigated the efficacy of aerobic exercise in the prevention or treatment of anthracycline-induced cardiotoxicity. We hypothesize that exercise intervention leads to a reverse in adverse cardiac remodeling with improvement of global and regional myocardial function in patients exposed to anthracycline.
Study Results: NO
Conditions: Cancer|Cardiotoxicity
Interventions: OTHER: Exercise program
Primary Outcome Measures: Small increase in the left and right ventricular volume, Small increase in the left and right ventricular volume, Baseline to Week 12|Small increase in left and right ventricular mass, Small increase in left and right ventricular mass,

Baseline to Week 12
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Connecticut Children's Medical Center
Collaborators: Nationwide Children's Hospital
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 65
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 14-110
Start Date: 2015-06-19
Primary Completion Date: 2023-09-27
Completion Date: 2023-09-27
First Posted: 2019-07-29
Results First Posted:
Last Update Posted: 2023-02-06
Locations: CT Children's Medical Center, Hartford, Connecticut, 06106, United States|Nationwide Children's Hospital, Columbus, Ohio, 43205, United States
Study Documents:

NCT Number: NCT05478018
Study Title: Type 1 Interferon Induced Changes to Exercise Adaptations in Systemic Lupus Erythematosus Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05478018
Acronym: LUPEX
Study Status: RECRUITING
Brief Summary: Investigating the physiological effects of the interferons type 1 and 2 (IFNs), and the cytokines Interleukin 6 (IL-6) and tumor necrosis factor (TNF) on the adaptive changes to exercise in patients with systemic lupus erythematosus (SLE).

The investigators hypothesize that the pathogenic blockage of IL-6 signalling that occurs in SLE, will decrease the cardiac and metabolic adaptations to aerobic exercise, and this decrease can be related to the IFN signature.

60 patients will be included in a 12-week investigator blinded 1:1 randomised high intensity aerobic exercise intervention study.
Study Results: NO
Conditions: Systemic Lupus Erythematosus|Interferon Deficiency
Interventions: BEHAVIORAL: High Intensity Interval Training
Primary Outcome Measures: Changes in maximal aerobic capacity (VO2max), Measured by VO2max test, 12 weeks|Patient reported Fatigue, measured by Fatigue Severity Scale Questionnaire (FSS), 12 weeks
Secondary Outcome Measures: Left ventricular mass, measured by echocardiography, 12 weeks|stroke volume, measured by

echocardiography, 12 weeks|left ventricular and atrial end-diastolic volume, measured by echocardiography, 12 weeks|global longitudinal strain, measured by echocardiography, 12 weeks|left ventricular ejection fraction, measured by echocardiography, 12 weeks|coronary perfusion reserve, measured by echocardiography (\& 82Rb-PET-CT), 12 weeks|Waist-To-Height Ratio, measured with tape measure, 12 weeks|Y2K updated SLE disease activity (SLEDAI-2K) with the SELENA modifications, Physician evaluated changes in measures of SLE, 12 weeks|Systemic Lupus Erythematosus Disease Activity Index 2000 Responder Index-50 (SRI-50), Itemized Physician evaluated changes in measures of SLE on a scale from 0-22 that account for partial improvements in condition, 12 weeks|Visual Analog Scale (VAS) of global disease by Physician, Physician evaluated changes in measures of SLE (0-100% of line), higher scores equal higher activity, 12 weeks|VAS fatigue (0-100), Patient reported outcome measures (PROMs), higher scores equal higher fatigue, 12 weeks|VAS pain (0-100), Patient reported outcome measures (PROMs), higher scores equal more pain, 12 weeks|Short Form (SF)-36 Health Survey (0-100), Patient reported outcome measures (PROMs), Possible scores range from 0 to 100, with higher scores representing better health status, 12 weeks|SLAQ - (range 0 -33), Patient reported outcome measures (PROMs), Possible scores range from 0 to 33, with higher scores representing more active SLE, 12 weeks|SLE activity Visual Analog Scale - (1-10), Patient reported outcome measures (PROMs), Possible scores range from 1 to 10, with higher scores representing more active SLE, 12 weeks|Dynamic Spirometry - Forced Expiratory Volume at 1 second (FEV1) volume, Pulmonary function testing, FEV1 volume, 12 weeks|Dynamic Spirometry - Forced Expiratory Volume at 1 second (FEV1) Percent of expected, Pulmonary function testing, FEV1%, 12 weeks|Dynamic Spirometry - Forced Vital Capacity Volume, Pulmonary function testing, FVC Volume, 12 weeks|Dynamic Spirometry - Forced Vital Capacity - Percent of Expected, Pulmonary function testing FVC%, 12 weeks|Dynamic Spirometry Forced Expiratory Volume at 1 second (FEV1) by Forced Vital Capacity - Ratio, Pulmonary function testing, FEV1/FVC ratio, 12 weeks|Dynamic Spirometry Forced Expiratory Volume at 1 second (FEV1) by Forced Vital Capacity - Ratio - Percentage of expected, Pulmonary function testing, FEV1/FVC ratio %, 12 weeks|Dynamic Spirometry - Total Lung Capacity - Volume, Pulmonary function testing, TLC Volume, 12 weeks|Dynamic Spirometry - Total Lung Capacity - Percentage of expected, Pulmonary function testing, TLC%, 12 weeks|Dynamic Spirometry - Residual Volume - Volume, Pulmonary function testing, RV-Volume, 12 weeks|Dynamic Spirometry - Residual Volume - Percentage of Expected, Pulmonary function testing, RV%, 12 weeks|Dynamic Spirometry - Alveolar Volume - Volume, Pulmonary function testing, AV-Volume, 12 weeks|Dynamic Spirometry - Alveolar Volume - Percentage of expected, Pulmonary function testing, AV-%, 12 weeks|Dynamic Spirometry - Diffusing capacity for Carbon Monoxide - Volume, Pulmonary function testing, DLCOc-Volume, 12 weeks|Dynamic Spirometry - Diffusing capacity for Carbon Monoxide - Percentage, Pulmonary function testing, DLCOc-%, 12 weeks|Dynamic Spirometry - Carbon monoxide transfer coefficient -

diffusing capacity per liter of lung volume, Pulmonary function testing, KCO-Volume, 12 weeks|Dynamic Spirometry - Carbon monoxide transfer coefficient - diffusing capacity per liter of lung volume - percentage of expected, Pulmonary function testing, KCO-%, 12 weeks|Body composition - Total adipose tissue - Weight, Measured by DXA Scan - fat(g), 12 weeks|Body composition - Total adipose tissue - Percentage, Measured by DXA Scan - fat(%), 12 weeks|Body composition - Android adipose tissue - Weight, Measured by DXA Scan - android fat(g), 12 weeks|Body composition - Android adipose tissue - Percentage, Measured by DXA Scan - android fat(%), 12 weeks|Body composition - Gyneoid adipose tissue - Weight, Measured by DXA Scan - Gyneoid fat(g), 12 weeks|Body composition - Gyneoid adipose tissue - Percentage, Measured by DXA Scan - Gyneoid fat(%), 12 weeks|Body composition - Total Lean Mass - Weight, Measured by DXA Scan - Muscle Mass(g), 12 weeks|Body composition - Bone Mass Density - Weight/ square-centimeter, Measured by DXA Scan - BMD(g/cm\^2), 12 weeks|Oral glucose tolerance test, 75g of glucose taken while fasting, 12 weeks|Axial accelerometer-based physical activity monitors, Free-living physical activity is measured using axial accelerometer-based physical activity monitors (AX3; Axivity, Newcastle upon Tyne, UK) for a 3 to 5 day period, 12 weeks|Change in fasting total cholesterol, low-density lipoprotein (LDL)-cholesterol and high-density lipoprotein (HDL)-cholesterol (mmol/L). Following an overnight fast (10 hours), blood samples are collected and processed by a trained laboratory technician and analysed according to standard procedures.monitors (AX3; Axivity, Newcastle upon Tyne, UK) for a 3 to 5 day period, 12 weeks|Change in triglycerides (mmol/L). Following an overnight fast (10 hours), blood samples are collected and processed by a trained laboratory technician and analysed according to standard procedures.monitors (AX3; Axivity, Newcastle upon Tyne, UK) for a 3 to 5 day period, 12 weeks|Change in Epigenetic Expression related to IFN alpha, Measured by mRNA analysis on PBMCs, 12 weeks|Change in Epigenetic Expression related to IFN Beta, Measured by mRNA analysis on PBMCs, 12 weeks|Change in Epigenetic Expression related to IFN Gamma, Measured by mRNA analysis on PBMCs, 12 weeks|Change in Epigenetic Expression related to TNF, Measured by mRNA analysis on PBMCs, 12 weeks|Change in Epigenetic Expression related to IL-6, Measured by mRNA analysis on PBMCs, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for Il-1, Analyzed for Il-1, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for Il-6, Analyzed for Il-6, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for sIL-6r, Analyzed for soluble Il-6-receptor, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for Il-10, Analyzed for Il-10, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for IFNα, Analyzed for IFNα, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for IFNγ, Analyzed for IFNγ, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for hgb, Analyzed for hemoglobin, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout -

Analyzed for plates, Analyzed for thrombocytes, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for Na,K,Cl, Analyzed for electrolytes, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for hct, Analyzed for hematocrit., 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for High Sensitvity C-Reactive Protein, Analyzed for HS-CRP, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for Ferritin, Analyzed for ferritin, 12 weeks|Change in peripheral blood Adaptation to Acute Exercise Bout - Analyzed for leucocyte differential, Analyzed for Leukocyte Differential, 12 weeks|Peripheral Capillary Changes - Capillary Density, Measured by Nailfold Capillaroscopy by trained physician (score of 1-4, higher scores equal fewer capillaries), 12 weeks|Peripheral Capillary Changes - Average Capillary Width (micrometers), Measured by Nailfold Capillaroscopy by trained physician - Width Measured in µm, 12 weeks|Peripheral Capillary Changes - Average Capillary Length(micrometers), Measured by Nailfold Capillaroscopy by trained physician - Length Measured in µm, 12 weeks|Peripheral Capillary Changes - Count of avascular areas, Measured by Nailfold Capillaroscopy by trained physician - Avascular Areas (1-4 higher scores indicate more avascular areas), 12 weeks|Peripheral Capillary Changes - Capillary Disorganization, Measured by Nailfold Capillaroscopy by trained physician - Capillary Disorganization (1-4 higher scores indicate more avascular areas), 12 weeks|Peripheral Capillary Changes - Microhemorrhages (average per finger), Measured by Nailfold Capillaroscopy by trained physician - Microhemorrhages (avg per finger), 12 weeks|Peripheral Capillary Changes - Bushy Capillaries (average per millimeter), Measured by Nailfold Capillaroscopy by trained physician - Bushy Capillaries (average per millimeter), 12 weeks|Peripheral Capillary Changes - Megacapillaries (average per millimeter), Measured by Nailfold Capillaroscopy by trained physician - Megacapillaries (average per millimeter), 12 weeks|Peripheral Capillary Changes - Meandering capillaries (average per millimeter), Measured by Nailfold Capillaroscopy by trained physician - Meandering capillaries (average per millimeter), 12 weeks|Peripheral Capillary Changes - Tortous capillaries (average per millimeter), Measured by Nailfold Capillaroscopy by trained physician - Tortous capillaries (average per millimeter), 12 weeks|Peripheral Capillary Changes - Other Findings, Measured by Nailfold Capillaroscopy by trained physician - Physicians comment, 12 weeks|Dietary Changes, Patient Reported by Questionnaire, 12 weeks|Proteinuria, Measured by Dipstick, 12 weeks|Myocardial blood flow, Measured by 82Rb-Pet-CT, on a subset of 40 participants, 12 weeks
Other Outcome Measures: Muscle Biopsy for epigenetic markers of physical activity, Optional for Participants: NF-κB p65 DNA binding activity (ELISA), phosphorylated and total JNK, phosphorylated AMPK (p-AMPK) total AMPK (Western blotting), , as well as NF-κB binding activity (Western blotting)., 12 weeks|Muscle Biopsy for epigenetic markers of inflammation and myokine signalling, Optional for Participants: mRNA expression of genes related to TNF, IL-6, IFN

alpha, beta and Gamma signalling, 12 weeks
Sponsor: Rigshospitalet, Denmark
Collaborators: Copenhagen Lupus and Vasculitis Clinic, Center for Rheumatology and Spine Diseases, Rigshospitalet
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: BASIC_SCIENCE
Other IDs: H-21039032
Start Date: 2022-04-01
Primary Completion Date: 2024-03-01
Completion Date: 2024-09-01
First Posted: 2022-07-28
Results First Posted:
Last Update Posted: 2022-07-28
Locations: Center for Physical Activity Research, Copenhagen, 2200, Denmark
Study Documents:

NCT Number: NCT03089502
Study Title: Efficacy of Cardio-Oncology Rehabilitation Exercise for Women With Breast Cancer and Treatment Related Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT03089502
Acronym: CORE
Study Status: TERMINATED
Brief Summary: Breast cancer is the leading cause of cancer among Canadian women with nearly 26,000 new cases diagnosed each year. Fortunately, advancements in diagnostic tools and curative treatments have significantly improved overall survival. However, the development of cardiac toxicity (including asymptomatic and symptomatic heart failure) associated with use of anthracycline containing chemotherapy and targeted therapies including trastuzumab limits improvements in survival for women with breast cancer. Cardiac toxicity is a life threatening complication that leads to reduced physical functioning and quality of life. The increased risk is associated with shared risk factors among cancer and heart failure and the direct influence of cancer therapy on the cardiovascular system. Cardiac rehabilitation (CR) (including exercise training and education/counselling) has been shown to improve health outcomes, reduce heart failure related hospitalizations and modestly improve mortality among individuals with non-treatment related heart failure and may benefit women with breast cancer and treatment related cardiac toxicity (BC-CT). Therefore, this single centre, randomized control trial aims to determine if participation in an exercise based CR program can improve cardiorespiratory fitness, cardiovascular function/structure and

health, and quality of life among women with BC-CT.
Study Results: NO
Conditions: Breast Cancer|Left Ventricular Dysfunction|Heart Failure, Systolic
Interventions: OTHER: Exercise Rehabilitation
Primary Outcome Measures: Cardiopulmonary Fitness, A cardiopulmonary exercise test will be completed following the Bruce or modified Bruce protocol. Breath-by-breath gas samples will be collected and averaged over a 20-second period using a calibrated metabolic cart (Vmax Encore, SensorMedics, Yoba Linda, CA)., Baseline and 12 weeks
Secondary Outcome Measures: Cardiovascular Risk Profile, This will be assessed using a standard blood requisition blood form including measurement of lipids, cholesterol, and triglyceride levels. Anthropometrics including body mass index, waist circumference, body fat percent and hemodynamic profiles including heart rate, systolic and diastolic blood pressure values (resting and during exercise) will also be collected., Baseline and 12 weeks|Cardiac Function and Structure at Rest, 2D Echocardiography will be used for the measurement of left ventricular volumes, cardiac output, stroke volume, left ventricular ejection fraction, diastolic function, left ventricular wall thickness and left ventricular cavity size. Strain and Strain Rate via 2D-Speckle tracking imaging will also be collected at rest to assess cardiac function., Baseline and 12 weeks.|Cardiac Function During Stress (Exercise), Exercise will be performed following a standardized stress echocardiography protocol. 2D-echocardiography assessments will be conducted at rest, during exercise and within 30 seconds of exercise completion., Baseline and 12 weeks|Endothelial Function, Endothelial dependant flow mediated dilation of the brachial artery will be assessed using a portable ultrasound unit (Vivid 9E GE Healthcare), and a 8-14-MHz transducer (GE Medical Systems Wauwatosa, WI USA)., Baseline and 12 weeks|Arterial Stiffness, Arterial Stiffness will be measured by pulse-wave velocity (Sphygmocor® system)., Baseline and 12 weeks|Autonomic Function, Baroreceptor sensitivity will be collected as a measure of autonomic function. Each participant will be secured with a three-lead ECG and finger plethysmography worn on the middle finger, while measures of a beat-by-beat blood pressure are recorded (Finapres; Ohmeda Inc, Englewood, CO)., Baseline and 12 weeks|Quality of Life, The Kansas City Cardiomyopathy Questionnaire will be used to assess health related quality of life for heart failure.

The FACT-B questionnaire will be used as a measurement of health related quality of life for individuals with breast cancer., Baseline and 12 weeks
Other Outcome Measures: Exercise Adherence, Adherence will be assessed using an attendance sheet for each the supervised sessions. If participants do not complete their target exercise prescription, the reasons will be recorded. The participants will also complete weekly exercise diaries at home each week and will be asked to record reasons for missed sessions or if they were unable to meet their exercise

prescription. A step counter (PiezoRx®) that monitors the participants' moderate/vigorous activity time (\>100 steps per minute) as well as bouts per week (greater than 10 minutes of moderate/ vigorous activity) will also be recorded. These measurements will be used to confirm the reported exercise sessions to be completed at home each week., Throughout the exercise training program (up to 12 weeks)
Sponsor: University Health Network, Toronto
Collaborators: MSH-UHN AMO Innovation Fund|Canadian Institutes of Health Research (CIHR)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 2
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: CORE
Start Date: 2018-04-01
Primary Completion Date: 2018-05-01
Completion Date: 2018-05-01
First Posted: 2017-03-24
Results First Posted:
Last Update Posted: 2018-10-12
Locations: Toronto Rehabilitation Institute, Toronto, Ontario, Canada
Study Documents:

NCT Number: NCT03516994
Study Title: Reducing Disparities in the Quality of Advance Care Planning for Older Adults
Study URL: https://beta.clinicaltrials.gov/study/NCT03516994
Acronym: EQUALACP
Study Status: ENROLLING_BY_INVITATION
Brief Summary: This study compares the effectiveness of two different approaches to advance care planning among older African Americans and older Whites living in the community. The two approaches are a structured approach with an advance care planning conversation led by a trained person using Respecting Choices (First Steps) and a patient-driven approach which includes a Five Wishes advance care planning form written in plain language. The study will determine which approach is more effective at increasing advance care planning within each racial group and reducing differences between the two groups in advance care planning.
Study Results: NO
Conditions: Metastatic Cancer|Congestive Heart Failure|Chronic Obstructive Pulmonary Disease|Parkinson Disease|Interstitial Lung Disease|Amyotrophic Lateral Sclerosis|End Stage Liver Disease|End Stage Renal Disease|Diabetes Complications
Interventions: BEHAVIORAL: Respecting Choices First Steps|BEHAVIORAL: Five Wishes Form

Primary Outcome Measures: Proportion of African Americans who complete advance care planning, completion of an advance care planning document (living will, healthcare proxy, medical orders, Five Wishes, other); discussion with clinician documented in chart, patient report of advance care planning discussion (designated decision-maker, discussed values, goals, preferences) with family, friends, or others, 12 months|Proportion of Whites who complete advance care planning, completion of an advance care planning document (living will, healthcare proxy, medical orders, Five Wishes, other); discussion with clinician documented in chart, patient report of advance care planning discussion (designated decision-maker, discussed values, goals, preferences) with family, friends, or others, 12 months
Secondary Outcome Measures: Difference in Proportion of Whites versus African Americans who complete advance care planning, Difference of proportion in whites versus African Americans who complete formal or informal advance care planning, 12 months|Patient Readiness to Engage in Advance Care Planning, Measure assessing patient's readiness to name decision-maker, discuss care preferences, complete legal advance directive, 3 months|Patient Quality of Life, Measure (Promis 29) assessing quality of life, including domains of physical functional, emotional, and social well-being, 3 months, 6 months, one year
Other Outcome Measures:
Sponsor: Duke University
Collaborators:
Sex: ALL
Age: OLDER_ADULT
Phases: NA
Enrollment: 800
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: OTHER
Other IDs: Pro00091633|OLC-1609-36381
Start Date: 2018-08-01
Primary Completion Date: 2024-04-01
Completion Date: 2024-05-01
First Posted: 2018-05-07
Results First Posted:
Last Update Posted: 2023-01-06
Locations: University of Alabama at Birmingham, Birmingham, Alabama, 35294, United States|Emory University, Atlanta, Georgia, 30322, United States|University of South Carolina, Columbia, South Carolina, 29208, United States|University of Texas Southwestern, Dallas, Texas, 75235, United States
Study Documents:

NCT Number: NCT02404818
Study Title: Early Markers of Radiation-Induced Cardiac Injury in Hodgkin Lymphoma Treated With Radiation Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT02404818

Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate if radiation and chemotherapy treatment cause cardiac abnormalities among survivors of Hodgkin's lymphoma.
Study Results: NO
Conditions: Hodgkin's Lymphoma
Interventions: PROCEDURE: Cardiac Magnetic Resonance Imaging| PROCEDURE: Echocardiogram
Primary Outcome Measures: Cardiac Abnormalities As Measured By Cardiac MRI, Day 1|Cardiac Abnormalities As Measured By Echocardiogram, Day 1
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Florida
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 5
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UFPTI-1431-HL02|IRB201703302
Start Date: 2015-04
Primary Completion Date: 2021-04-14
Completion Date: 2021-04-14
First Posted: 2015-04-01
Results First Posted:
Last Update Posted: 2022-06-10
Locations: University of Florida Health Proton Therapy Institute, Jacksonville, Florida, 32206, United States
Study Documents:

NCT Number: NCT01948232
Study Title: Pilot Study of Perindopril in Childhood Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT01948232
Acronym:
Study Status: WITHDRAWN
Brief Summary: The purpose of this study is to evaluate the feasibility of conducting a medical intervention trial in childhood cancer survivors with early echocardiographic evidence of cardiac remodeling.
Study Results: NO
Conditions: Childhood Cancer Survivors
Interventions: DRUG: Perindopril
Primary Outcome Measures: Proportion of patients consenting to study, The number of eligible patients approached to join the study, the proportion consenting to the study, the proportion refusing the study (with reasons for refusal) and the proportion remaining on study at 18-months., 18-month

Secondary Outcome Measures: LV wall thinning, Rate of change of the end-diastolic left ventricular posterior wall z-score and of the thickness to dimension ratio z-score, 18 months
Other Outcome Measures:
Sponsor: The Hospital for Sick Children
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE2
Enrollment: 0
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 1000035483
Start Date: 2013-09
Primary Completion Date: 2015-07
Completion Date: 2015-07
First Posted: 2013-09-23
Results First Posted:
Last Update Posted: 2015-10-06
Locations: The Hospital for Sick Children, Toronto, Ontario, M5G1E2, Canada
Study Documents:

NCT Number: NCT04183218
Study Title: Characterizing Chemo-Radiotherapy Treatment-Related Cardiac Changes in Non-metastatic, Non-recurrent Lung and Esophageal Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04183218
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This trial studies cardiac changes after radiation or chemo-radiation for the treatment of lung or esophageal cancer that has not spread to other places in the body (non-metastatic) or has not come back (non-recurrent). Continuous cardiac monitoring with an implanted device may help to identify cardiac changes that would remain unnoticed, and facilitate the treatment of these early cardiac changes as part of standard care.
Study Results: NO
Conditions: Clinical Stage 0 Esophageal Adenocarcinoma AJCC v8|Clinical Stage 0 Esophageal Squamous Cell Carcinoma AJCC v8|Clinical Stage I Esophageal Adenocarcinoma AJCC v8|Clinical Stage I Esophageal Squamous Cell Carcinoma AJCC v8|Clinical Stage II Esophageal Adenocarcinoma AJCC v8|Clinical Stage II Esophageal Squamous Cell Carcinoma AJCC v8|Clinical Stage IIA Esophageal Adenocarcinoma AJCC v8|Clinical Stage IIB Esophageal Adenocarcinoma AJCC v8|Clinical Stage III Esophageal Adenocarcinoma AJCC v8|Clinical Stage III Esophageal Squamous Cell Carcinoma AJCC v8|Localized Esophageal Carcinoma|Localized Lung Carcinoma|Pathologic Stage 0 Esophageal Adenocarcinoma

AJCC v8|Pathologic Stage 0 Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage I Esophageal Adenocarcinoma AJCC v8|Pathologic Stage I Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage IA Esophageal Adenocarcinoma AJCC v8|Pathologic Stage IA Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage IB Esophageal Adenocarcinoma AJCC v8|Pathologic Stage IB Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage IC Esophageal Adenocarcinoma AJCC v8|Pathologic Stage II Esophageal Adenocarcinoma AJCC v8|Pathologic Stage II Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage IIA Esophageal Adenocarcinoma AJCC v8|Pathologic Stage IIA Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage IIB Esophageal Adenocarcinoma AJCC v8|Pathologic Stage IIB Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage III Esophageal Adenocarcinoma AJCC v8|Pathologic Stage III Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage IIIA Esophageal Adenocarcinoma AJCC v8|Pathologic Stage IIIA Esophageal Squamous Cell Carcinoma AJCC v8|Pathologic Stage IIIB Esophageal Adenocarcinoma AJCC v8|Pathologic Stage IIIB Esophageal Squamous Cell Carcinoma AJCC v8|Postneoadjuvant Therapy Stage I Esophageal Adenocarcinoma AJCC v8|Postneoadjuvant Therapy Stage I Esophageal Squamous Cell Carcinoma AJCC v8|Postneoadjuvant Therapy Stage II Esophageal Adenocarcinoma AJCC v8|Postneoadjuvant Therapy Stage II Esophageal Squamous Cell Carcinoma AJCC v8|Postneoadjuvant Therapy Stage III Esophageal Adenocarcinoma AJCC v8|Postneoadjuvant Therapy Stage III Esophageal Squamous Cell Carcinoma AJCC v8|Postneoadjuvant Therapy Stage IIIA Esophageal Adenocarcinoma AJCC v8|Postneoadjuvant Therapy Stage IIIA Esophageal Squamous Cell Carcinoma AJCC v8|Postneoadjuvant Therapy Stage IIIB Esophageal Adenocarcinoma AJCC v8|Postneoadjuvant Therapy Stage IIIB Esophageal Squamous Cell Carcinoma AJCC v8|Stage 0 Lung Cancer AJCC v8|Stage I Lung Cancer AJCC v8|Stage IA1 Lung Cancer AJCC v8|Stage IA2 Lung Cancer AJCC v8|Stage IA3 Lung Cancer AJCC v8|Stage IB Lung Cancer AJCC v8|Stage II Lung Cancer AJCC v8|Stage IIA Lung Cancer AJCC v8|Stage IIB Lung Cancer AJCC v8|Stage III Lung Cancer AJCC v8|Stage IIIA Lung Cancer AJCC v8|Stage IIIB Lung Cancer AJCC v8|Stage IIIC Lung Cancer AJCC v8

Interventions: PROCEDURE: Biospecimen Collection|DEVICE: Cardiac Event Monitor|OTHER: Chemoradiotherapy|RADIATION: Radiation Therapy

Primary Outcome Measures: Cardiac event rate at 12 months, The proportion of failures (cardiac event) will be estimated by the number of cardiac events divided by the total number of evaluable patients. Confidence intervals for the true success proportion will be calculated according to the approach of Duffy and Santner (1987)., Up to 12 months

Secondary Outcome Measures: Incidence of acute adverse events (AE), Descriptive statistics of frequency (percentage) will be used to summarize AE incidence and severity as measured by the Common Terminology Criteria for Adverse Events (CTCAE) 5.0. 95% confidence intervals will be constructed around point estimates., Within the first 6 months from the date of enrollment|Incidence of late adverse events, Descriptive statistics of frequency (percentage) will be used

to summarize AE incidence and severity as measured by the CTCAE 5.0. 95% confidence intervals will be constructed around point estimates., After the first 6 months from the date of enrollment|Loco-regional recurrence, Analyses will be descriptive in nature. Statistical tests on endpoints (t-test for continuous data; Wilcoxon rank-sum test, Fisher's exact test, or Chi-square test for ordinal data) will be utilized to determine differences at any particular time point. Graphical displays will be produced, such as mean profile plots or bar charts., Up to 12 months|Distant recurrence, Analyses will be descriptive in nature. Statistical tests on endpoints (t-test for continuous data; Wilcoxon rank-sum test, Fisher's exact test, or Chi-square test for ordinal data) will be utilized to determine differences at any particular time point. Graphical displays will be produced, such as mean profile plots or bar charts., Up to 12 months|Disease-free survival, Analyses will be descriptive in nature. Statistical tests on endpoints (t-test for continuous data; Wilcoxon rank-sum test, Fisher's exact test, or Chi-square test for ordinal data) will be utilized to determine differences at any particular time point. Graphical displays will be produced, such as mean profile plots or bar charts., From study registration any local, regional, distant failure, or death, assessed up to 12 months|Cause specific survival, Analyses will be descriptive in nature. Statistical tests on endpoints (t-test for continuous data; Wilcoxon rank-sum test, Fisher's exact test, or Chi-square test for ordinal data) will be utilized to determine differences at any particular time point. Graphical displays will be produced, such as mean profile plots or bar charts., From registration to death due to cancer, assessed up to 12 months|Cardiac event free survival, Analyses will be descriptive in nature. Statistical tests on endpoints (t-test for continuous data; Wilcoxon rank-sum test, Fisher's exact test, or Chi-square test for ordinal data) will be utilized to determine differences at any particular time point. Graphical displays will be produced, such as mean profile plots or bar charts., From registration to cardiac event or death, assessed up to 12 months|Cardiac death, Cardiac death would include documented congestive heart failure, myocardial infarction, arrhythmia, heart block, or any other cardiac cause documented in the medical records, death certificate, or autopsy as one of the major contributing causes of death. Analyses will be descriptive in nature. Statistical tests on endpoints (t-test for continuous data; Wilcoxon rank-sum test, Fisher's exact test, or Chi-square test for ordinal data) will be utilized to determine differences at any particular time point. Graphical displays will be produced, such as mean profile plots or bar charts., From registration to death due to cardiac reasons, assessed up to 12 months|Overall survival, Analyses will be descriptive in nature. Statistical tests on endpoints (t-test for continuous data; Wilcoxon rank-sum test, Fisher's exact test, or Chi-square test for ordinal data) will be utilized to determine differences at any particular time point. Graphical displays will be produced, such as mean profile plots or bar charts., From registration to death due to any cause, assessed up to 12 months

Other Outcome Measures: Imaging changes, Imaging changes in the heart substructures associated with occurrence of cardiac events will be an exploratory component of this trial. Changes will be described at each time point using frequency distributions., Baseline up to 12 months
Sponsor: Mayo Clinic
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 24
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: MC1723|NCI-2019-07938|MC1723
Start Date: 2019-09-23
Primary Completion Date: 2023-09-23
Completion Date: 2024-09-23
First Posted: 2019-12-03
Results First Posted:
Last Update Posted: 2023-05-17
Locations: Mayo Clinic in Arizona, Scottsdale, Arizona, 85259, United States
Study Documents:

NCT Number: NCT02921802
Study Title: A Study of Special Use Results Surveillance of Revlimid 5mg Capsules
Study URL: https://beta.clinicaltrials.gov/study/NCT02921802
Acronym:
Study Status: COMPLETED
Brief Summary: To understand the safety and efficacy of Revlimid® 5 mg Capsules (hereinafter referred to as Revlimid) in all patients who are treated with it under the actual condition of use pursuant to the conditions of approval.

1. Planned registration period This period started on the date of initial marketing of Revlimid and will end at the time when the planned number of patients to be enrolled is reached.
2. Planned surveillance period This period started on the date of initial marketing of Revlimid and will end on the day when the approval condition related to all-case surveillance is terminated.
Study Results: NO
Conditions: Multiple Myeloma|Myelodysplastic Syndromes
Interventions:
Primary Outcome Measures: Adverse Events (AEs), Number of participants with adverse events for 6 month treatment, Up to 6 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Celgene
Collaborators:

Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 4626
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NIS-Celgene-JP-PMS-001a
Start Date: 2010-07-20
Primary Completion Date: 2013-03-29
Completion Date: 2013-03-29
First Posted: 2016-10-03
Results First Posted:
Last Update Posted: 2022-06-14
Locations: Shinko Hospital, Kobe, Hyogo, 651-0072, Japan
Study Documents:

NCT Number: NCT04510532
Study Title: Early Detection of CMP in Patients With Breast Cancer Using Cardiac Magnetic Resonance
Study URL: https://beta.clinicaltrials.gov/study/NCT04510532
Acronym:
Study Status: RECRUITING
Brief Summary: Breast cancer is the most common cancers among women worldwide.Although chemotherapy and surgery have greatly improved the survival rate, most types of chemotherapy have been reported to have varying degrees of cardiotoxicity. The investigators will focus on the cardiotoxicity of pyrotinib and apatinib which belong to the new tyrosine kinase inhibitors in respective chemotherapy among more subjects.
Study Results: NO
Conditions: Breast Cancer|Chemotherapy Induced Systolic Dysfunction
Interventions: DIAGNOSTIC_TEST: CMR examination
Primary Outcome Measures: Composite endpoint of cardiac condition, Compose of ejection fraction (%), change between 1 and 6 months after treatment|Composite endpoint of quantitative fibrosis assessment, Compose of percentage of extracellular volume (%) and positive rate of late gadolinium enhancement (%)., change between 1 and 6 months after treatment|Exercise tolerance, 6 minutes walking test, change between 1 and 6 months after treatment
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: RenJi Hospital
Collaborators: Ruijin Hospital|Shanghai Fifth People's Hospital
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 300
Funder Type: OTHER
Study Type: OBSERVATIONAL

Study Design: Observational Model: |Time Perspective: p
Other IDs: 2020-08-06R
Start Date: 2020-10-30
Primary Completion Date: 2023-09
Completion Date: 2023-09
First Posted: 2020-08-12
Results First Posted:
Last Update Posted: 2023-06-01
Locations: Renji Hospital, Shanghai, Shanghai, 200127, China
Study Documents:

NCT Number: NCT00688532
Study Title: Study of Coronary Heart Disease (CHD) & Heart Failure (HF) Risk in Prostate Cancer Patients, Taking Casodex or Not
Study URL: https://beta.clinicaltrials.gov/study/NCT00688532
Acronym:
Study Status: COMPLETED
Brief Summary: A retrospective cohort study performed in the GPRD,UK. All patients with incident prostate cancer identified between 1 Jan 1999 and 31 Dec 2005 and a frequency-matched cohort of the general population will be followed- up for two outcomes; CHD including acute myocardial infarction or death from coronary heart disease and HF until Dec 31, 2006. Outcomes will be validated through requests to primary care physicians. Incidence rate´ratios of CHD and HF in the two cohorts will be calculated. In the cohort of prostate cancer the relative risk of CHD and HF associated with the use of bicalutamide compared to non-use will be estimated.
Study Results: NO
Conditions: Prostate Cancer
Interventions:
Primary Outcome Measures: Coronary heart disease including acute myocardial infarction and death from CHD, From study start 1 Jan 1999 through 31December 2006|Heart Failure, From study start 1 Jan 1999 through 31December 2006
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: AstraZeneca
Collaborators:
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 5103
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: D6874C00008
Start Date: 2007-12
Primary Completion Date: 2009-06
Completion Date: 2009-06
First Posted: 2008-06-03

Results First Posted:
Last Update Posted: 2013-01-31
Locations:
Study Documents:

NCT Number: NCT05930418
Study Title: Cardiovascular Magnetic Resonance Prognosticators in Pediatric Oncology Patients With Sepsis
Study URL: https://beta.clinicaltrials.gov/study/NCT05930418
Acronym:
Study Status: RECRUITING
Brief Summary: The overall purpose of this protocol is to identify subacute sepsis-associated cardiac disease in pediatric patients with cancer by CMR and evaluate the CMR findings during their follow-up. This will help inform heart failure management decision making. Evidence of dysfunction or elevated T2 values may inform adjustment of afterload reduction and beta blocker administration, and elevated ECV findings will suggest the need for increased surveillance for diastolic dysfunction.

Primary Objectives:

(Feasibility Phase) To determine the feasibility of cardiac MRI without anesthesia in the immediate post-sepsis period in children with cancer.

CMR scanning will be completed within 10 days of presentation - this will allow us to ensure that possible hemodynamic or respiratory instability and renal dysfunction has resolved prior to transport to the MRI scanner during the most acute phase of illness.

(Completion Phase) To estimate the frequency of subacute sepsis-associated cardiac disease, including myocardial inflammation and dysfunction, in the post-acute phase (within 10 days of presentation) of severe sepsis in children with cancer
Study Results: NO
Conditions: Acute Respiratory Distress Syndrome|Sepsis|Cardiovascular Shock
Interventions: DIAGNOSTIC_TEST: Cardiac MRI
Primary Outcome Measures: Feasibility of cardiac MRI in pediatric oncology patients with sepsis, The proportion of enrolled participants who have evaluable cMRI data within 10 days after onset of sepsis, within 10 days after onset of sepsis|Frequency of subacute sepsis-associated cardiac disease, To estimate the frequency of subacute sepsis-associated cardiac disease, including myocardial inflammation and dysfunction, in the post-acute phase (within 10 days of presentation) of severe sepsis in children with cancer, Within 10 days of presentation
Secondary Outcome Measures:
Other Outcome Measures:

Sponsor: St. Jude Children's Research Hospital
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: CRIMSON2
Start Date: 2023-04-14
Primary Completion Date: 2023-12-31
Completion Date: 2024-06-30
First Posted: 2023-07-05
Results First Posted:
Last Update Posted: 2023-07-05
Locations: St. Jude Children's Research Hospital, Memphis, Tennessee, 38105, United States
Study Documents:

NCT Number: NCT00705094
Study Title: Cardiac Function and Cardiovascular Risk Profile in Testicular Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT00705094
Acronym:
Study Status: COMPLETED
Brief Summary: For many years, researchers and doctors have studied different kinds of treatments to improve the survival of men with testicular cancer. However, recent research has shown that many years later, men who had testicular cancer appear to be at higher risk for developing heart disease (heart attack or heart failure), especially if they received chemotherapy. Since these studies were done many years after men received treatment, there was no way to know if other factors contributed to the health problems they experienced. This study is being done because it would be helpful to study heart function and cardiovascular disease risk factors of men who have been diagnosed with testicular cancer, before and after they receive chemotherapy treatment compared to men who receive treatment with surgery alone.
Study Results: NO
Conditions: Testicular Cancer|Seminoma|Non-seminomatous
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: AHS Cancer Control Alberta
Collaborators:
Sex: MALE
Age: ADULT, OLDER_ADULT

Phases:
Enrollment: 30
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: GU-24167
Start Date: 2008-09
Primary Completion Date: 2011-05
Completion Date: 2012-07
First Posted: 2008-06-25
Results First Posted:
Last Update Posted: 2014-10-01
Locations: Cross Cancer Institute, Edmonton, Alberta, T6G 1Z2, Canada
Study Documents:

NCT Number: NCT03559894
Study Title: Severe and Transient Hypoxemia During Selective Intra-arterial Chemotherapy for Retinoblastoma in Children: Evaluation of the Right-sided Heart Function.
Study URL: https://beta.clinicaltrials.gov/study/NCT03559894
Acronym:
Study Status: UNKNOWN
Brief Summary: Children having selective ophthalmic artery chemotherapy for retinoblastoma under general anaesthesia may experience troubles during the procedure. The troubles are transient, may be severe and include hypoxemia, hypotension and bradycardia. All children having such trouble always fully recovered without any sequelae or prolonged length of stay. The investigators suspect that these phenomenons are caused by transient pulmonary hypertension.The objective is to see whether transient pulmonary hypertension and right-sided heart failure is present during theses phenomenon by trans-thoracic echocardiography.
Study Results: NO
Conditions: Retinoblastoma
Interventions: DIAGNOSTIC_TEST: Trans-thoracic echocardiography
Primary Outcome Measures: Identification of pulmonary hypertension and/or right-sided heart failure (systolic arterial pulmonary pressure and visual function of the right ventricle is measured), Perioperative.
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Christian Kern
Collaborators:
Sex: ALL
Age: CHILD
Phases:
Enrollment: 50
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p

Other IDs: 2017-01539
Start Date: 2018-01-01
Primary Completion Date: 2019-05-31
Completion Date: 2019-05-31
First Posted: 2018-06-18
Results First Posted:
Last Update Posted: 2018-06-18
Locations: CHUV, Lausanne, Vaud, 1011, Switzerland
Study Documents:

NCT Number: NCT00735618
Study Title: Relaxation and Heart Rate Variability
Study URL: https://beta.clinicaltrials.gov/study/NCT00735618
Acronym:
Study Status: COMPLETED
Brief Summary: Primary:

* To characterize the physiologic changes of the autonomic nervous system, demonstrated by heart rate variability (HRV) high frequency (HF) spectral analysis, before and after a 15 minute, one-time, guided relaxation program for cancer patients.

Secondary:

* To assess whether change of HRV correlates with subjective feeling for anxiety, based on visual analog scale scores.
Study Results: YES
Conditions: Cancer
Interventions: OTHER: Guided Relaxation
Primary Outcome Measures: Differences Between Pre/Post ESAS Score, Total symptom burden as measured by Edmonton Symptom Assessment Scale (ESAS) in which there are eight visual analog scales (VAS) of 0 to 10, with 10 being most severe. The differences from ESAS baseline (before) to post (after) a 15 minute, one-time, guided relaxation program for each participant assessed, with the average difference in ESAS scores for all participants reported., Baseline and following completion of HRV recordings and relaxation program (45 - 60 minutes elapsed time)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 2008-0028

Start Date: 2008-06
Primary Completion Date: 2008-09
Completion Date: 2008-09
First Posted: 2008-08-15
Results First Posted: 2009-03-03
Last Update Posted: 2011-12-19
Locations: UT MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT00627029
Study Title: Evaluation of Programs of Coordinated Care and Disease Management
Study URL: https://beta.clinicaltrials.gov/study/NCT00627029
Acronym: Coca
Study Status: UNKNOWN
Brief Summary: This is a Congressionally mandated study. In the original study, 16 demonstration programs provided care coordination services to beneficiaries with chronic illness in Medicare's fee-for-service program. A five-year CMS-funded study tested whether the programs can improve patients' use of medical services, improve patients' outcomes and satisfaction with care, and reduce Medicare costs. The study also assessed physicians' satisfaction with the programs.

In 2008 Congress extended the project for two of the original programs--Mercy Medical Center - North Iowa and Health Quality Partners in Pennsylvania--and they will enroll Medicare beneficiaries and provide care coordination services into the spring of 2010.
Study Results: NO
Conditions: Congestive Heart Failure|Diabetes|Coronary Artery Disease|Chronic Obstructive Pulmonary Disease|Cancer|Cerebrovascular Disease|Alzheimer's Disease|Psychotic Disorder|Major Depression
Interventions: BEHAVIORAL: Care Coordination
Primary Outcome Measures: Medicare program expenditures, Eight years
Secondary Outcome Measures: Claims-based and patient-reported quality of care, Eight years
Other Outcome Measures:
Sponsor: Mathematica Policy Research, Inc.
Collaborators: Centers for Medicare and Medicaid Services
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 18277
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: MPR 8756|CMS 500-95-0047(09
Start Date: 2000-09

Primary Completion Date: 2015-08
Completion Date: 2016-12
First Posted: 2008-02-29
Results First Posted:
Last Update Posted: 2015-10-01
Locations: Hospice of the Valley MediCaring Project, Phoenix, Arizona, 85016, United States|Georgetown University Medical Center-Mind My Heart Program, Washington, District of Columbia, 20036, United States|Quality Oncology/Matria Healthcare, Sunrise, Florida, 33323, United States|CorSolutions/Matria Healthcare, Rosemont, Illinois, 60018, United States|Carle Foundation and Hospital, Urbana, Illinois, 61801, United States|Mercy Medical Center - North Iowa, Mason City, Iowa, 50401, United States|Medical Care Development, Augusta, Maine, 04330, United States|University of Maryland Medical Center, Baltimore, Maryland, 21201, United States|Charlestown/Erickson Retirement Communities, Catonsville, Maryland, 21228, United States|Washington University-St.Louis School of Medicine/Barnes-Jewish Hospital, St. Louis, Missouri, 63110, United States|QMed, Inc., Eatontown, New Jersey, 07724, United States|Lovelace Health Systems, Albuquerque, New Mexico, 87102, United States|Jewish Home Lifecare, New York, New York, 10025, United States|Avera McKennan Hospital and University Health Center, Sioux Falls, South Dakota, 57117, United States|CenVaNet, Richmond, Virginia, 23220, United States
Study Documents:

NCT Number: NCT00620529
Study Title: The Effects of Fish Oils on Blood Pressure, Heart Rate Variability and Liver Fat in the Polycystic Ovary Syndrome
Study URL: https://beta.clinicaltrials.gov/study/NCT00620529
Acronym: fops
Study Status: COMPLETED
Brief Summary: We hypothesise that fish oils will have a beneficial effect on cardiometabolic parameters in women with PCOS. The purpose of this study therefore is to examine the effects of fish oils on blood pressure, heart rate variability and liver fat content in obese women with the polycystic ovary syndrome.
Study Results: NO
Conditions: Polycystic Ovary Syndrome
Interventions: DIETARY_SUPPLEMENT: Ocean Nutrition 2050|DIETARY_SUPPLEMENT: Olive oil capsules
Primary Outcome Measures: 24 hour ambulatory systolic blood pressure, week 8 and week 24
Secondary Outcome Measures: 24 hour heart rate variability, week 8 and week 24|liver fat content (MRI), week 8 and week 24
Other Outcome Measures:
Sponsor: Keogh Institute for Medical Research
Collaborators: Royal Perth Hospital
Sex: FEMALE
Age: ADULT
Phases: PHASE4

Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|
Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR,
OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: EC 2008/049
Start Date: 2008-02
Primary Completion Date: 2008-12
Completion Date: 2009-02
First Posted: 2008-02-21
Results First Posted:
Last Update Posted: 2010-02-02
Locations: School of Medicine and Pharmacology, Royal Perth Hospital,
Perth, Western Australia, 6000, Australia
Study Documents:

NCT Number: NCT04822077
Study Title: Study on Proton Radiotherapy of Thymic Malignancies
Study URL: https://beta.clinicaltrials.gov/study/NCT04822077
Acronym: PROTHYM
Study Status: RECRUITING
Brief Summary: This is a multicentre non-randomized phase II study of
proton beam radiotherapy in patients with thymic epithelial tumours
(i.e. thymoma and thymic carcinoma) in the post-operative setting or
in inoperable patients with localized disease.

Patients not willing or for any reason unsuitable to undergo proton
treatment will be asked to participate in a follow-up assessment after
the regular photon treatment in the same manner as the included
patients.

Primary endpoints are:Toxicity (e.g. cardiac and pulmonary toxicity)
and Local control at 5 year Secondary endpoints: PFS, Overall
survival, Quality of life, measured by EORTC QLQ 30 + LC 13 and
relapse pattern
Study Results: NO
Conditions: Cardiotoxicity|Pulmonary Toxicity|Thymus Neoplasms
Interventions: RADIATION: Proton radiation
Primary Outcome Measures: Cardiotoxicity and pulmonary toxicity of
therapy, Proportion of patients with cardiac and pulmonary toxicity
measured by CTCAE 4.0 \> Grade 2, At 60 months from treatment|Local
tumor control, Freedom from tumor progression (CR,PR or SD) mesured by
CT-scan, At 60 months from treatment
Secondary Outcome Measures: Quality of life questionnaire EORTC QLQ 30
(European Organisation for Research and Treatment of Cancer), Scale
from 1-100 for 30 items, higher score indicates a better situation.,
At 60 months from treatment|Quality of life questionnaire LC13 (Lung
cancer specific module of EORTC), Scale from 1-100 for 13 items and
higher score indicates worse symptoms., At 60 months from treatment|

Survival, Overall survival, From treatment and for 5 years
Other Outcome Measures:
Sponsor: Ass. Prof. Jan Nyman
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 40
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: PROTHYM 2.2
Start Date: 2018-04-18
Primary Completion Date: 2026-04-01
Completion Date: 2029-04-01
First Posted: 2021-03-30
Results First Posted:
Last Update Posted: 2021-03-30
Locations: Department of Oncology, Norrlands Universitetssjukhus, Umeå, Norrland, 901 85, Sweden|Department of Oncology, Karolinska University Hospital, Stockholm, Stockholm County, 171 76, Sweden|Department of Oncology, Sahlgrenska University Hospital, Gothenburg, Västra Götaland, 413 45, Sweden
Study Documents: Study Protocol

NCT Number: NCT02626377
Study Title: Multicenter Prospective Cohort of Informal Caregivers in Burgundy and Franche-Comté
Study URL: https://beta.clinicaltrials.gov/study/NCT02626377
Acronym: ICE
Study Status: TERMINATED
Brief Summary: Medical progress and modification of lifestyles have prolonged life expectancy, despite the development of chronic diseases. The support and care are often provided by a network of informal caregivers composed of family, friends, and neighbors. They became essential to help maintening the elderly persons to live at home. It has been demonstrated that the importance and the diversity of informal tasks may jeopardize their own physical, mental and social well-being.

The aim of the Informal Carers of Elderly Cohort is to define, through a longitudinal study of their life course, the profiles of caregivers of patients with a diagnosis of one of the following diseases: cancer (breast, prostate, colon-rectum), neuro-degenerative diseases (Parkinson's disease, Alzheimer's and similar diseases), neuro-vascular diseases (Cerebrovascular Accident (CVA)), Age-related Macular Degeneration(AMD) and heart disease (heart failure), aged ≥ 60 years old and living in Burgundy or Franche-Comte. By following the different phases of the caregiving relationship from the announcement

of the diagnosis, it will be possible to assess the quality of life of caregivers and evaluate the implementation of a pragmatic social action to help informal caregivers through a randomized intervention trial nested in the cohort.

Thanks to an analytical and longitudinal definition of the profiles of informal caregivers, this study could gather precise information on their life courses and their health trajectory by identifying the consequences associated with the concept of their role of aid in care. In addition, the randomized intervention trial will explore the efficacy, in terms of quality of life, and efficiency of a social action to support the caregivers. These data will allow to identify strategies that could be used to improve the existing sources of aid and to propose new approaches to help caregivers. This study will provide the opportunity to identify the most relevant means of support and to give an impulse for new healthcare policies.
Study Results: NO
Conditions: Breast Cancer|Colorectal Cancer|Prostate Cancer|Alzheimer Disease|Age-related Macular Degeneration|Parkinson Disease|Cardiac Disease|Ischemic Stroke|Hemorrhagic Stroke
Interventions: BEHAVIORAL: Support provided by social worker|OTHER: Information booklet receipt
Primary Outcome Measures: (Interventional Study) Comparison of caregivers' HRQoL according to the allocated intervention by randomization based on summaries score the MOS SF36, The main objective of the randomized study is to compare the Health Related Quality of Life based on summaries score the MOS SF36 one year after randomization according to the allocated intervention., One year after randomization|(Observational study) Changes in HRQoL of patients' caregivers using the MOS SF36 questionnaire, The main objective of the observational study is to define the longitudinal profiles of patient's caregivers according to the evaluation of their HRQoL using the MOS SF36 questionnaire, At 1, 3, 6, 9, 12, 15,18, 21, 24, 30, 36, 42, 48, 54 and 60 months post-randomization|(Observational study) Changes in HRQoL of cancer patients' caregivers using the CarGoQoL questionnaire, the aim of the observational study is to define the longitudinal profiles of cancer patient's caregivers according to the evaluation of their HRQoL using the CarGoQoL questionnaire, At 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48,54 and 60 months post-randomization|(Observational study) Changes in the coping strategies of patients' caregivers using the Borteyrou, Rascle and Truchot Questionnaire, The aim of the observational study is to define the longitudinal profiles of patient's caregivers according to the evaluation of their coping strategies using the Borteyrou, Rascle and Truchot Questionnaire., At 1, 6, 12, 24, 36, 48 and 60 months post-randomization|(Observational study) Changes in feelings of anxiety and depression of patients' caregivers according to the HADs questionnaire, The aim of the observational study is to define the longitudinal profiles of patient's caregivers according to the evaluation of their anxiety and depression according to the HADs questionnaire., At 1, 3, 6, 9, 12,

18, 24, 30, 36, 42, 48,54 and 60 months post-randomization|(Observational study) Changes in social support of patients' caregivers using the SSQ6 questionnaire, The aim of the observational study is to define the longitudinal profiles of patient's caregivers according to the evaluation of their social support using the SSQ6 questionnaire., At 1, 6, 12, 24, 36, 48 and 60 months post-randomization|(Observational study) Changes in burden of patients' caregivers using the Zarit burden inventory, The aim of the observational study is to define the longitudinal profiles of patient's caregivers according to the evaluation burden using the Zarit burden inventory, At 1, 6, 12, 24, 36, 48 and 60 months post-randomization

Secondary Outcome Measures: (Interventional Study) Comparison of caregivers' HRQoL according to the intervention allocated by randomization based on summaries score the MOS SF36, To compare the Health Related Quality of Life based on summaries score the MOS SF36 two years after randomization according to the allocated intervention., Two years after randomization|(Interventional Study) Changes in HRQoL of patients' caregivers according to the allocated intervention using the MOS SF36 questionnaire, To compare longitudinally all dimensions of HRQoL using the MOS SF36 questionnaire according to the allocated intervention., At 1, 3, 6, 9, 12, 15,18, 21, 24, 30, 36, 42, 48, 54 and 60 months post-randomization|(Interventional Study) Changes in HRQoL of cancer patients' caregivers according to the allocated intervention using the CarGoQol questionnaire, To compare longitudinally the HRQoL of cancer patients' caregivers, according to the allocated intervention, using the CarGoQol questionnaire., At 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48,54 and 60 months post-randomization|(Interventionnal Study) Changes in the coping strategies of patients' caregivers according to the allocated intervention using the Borteyrou, Rascle and Truchot Questionnaire, To compare longitudinally the coping strategies of patients' caregivers, according to the allocated intervention, using the Borteyrou, Rascle and Truchot Questionnaire., At 1, 6, 12, 24, 36, 48 and 60 months post-randomization|(Interventional Study) Changes in feelings of anxiety and depression of patients' caregivers according to the allocated intervention using the HADs Questionnaire, To compare longitudinally the feelings of anxiety and depression of patients' caregivers, according to the allocated intervention, using the HADs Questionnaire., At 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48,54 and 60 months post-randomization|(Interventional Study) Changes in social supports of patients' caregivers according to the allocated intervention using the SSQ6 questionnaire, To compare longitudinally the social support of patients' caregivers, according to the allocated intervention, using the SSQ6 questionnaire., At 1, 6, 12, 24, 36, 48 and 60 months post-randomization|(Interventional Study) Changes in burden of patients' caregivers according to the allocated intervention using the Zarit burden inventory, To compare longitudinally the burden of patients' caregivers, according to the allocated intervention, using the Zarit burden inventory., At 1, 6, 12, 24, 36, 48 and 60

months post-randomization|(Interventional study) Efficiency of the intervention of a social worker for caregivers using a cost-utility analysis, The efficiency of the intervention of a social worker for caregivers will be assessed using a cost-utility analysis, aiming at comparing in terms of costs and utility the intervention versus the absence of intervention of a social worker, At 1, 3, 6,9,12,15,18 and 24 months post-randomization|(Observational study) Changes in the caregivers/patients' relationship using a qualitative approach (semi-structure interview), to evaluate the caregivers/patients' relationship and the changes of the relationship using a qualitative approach (semi-structure interview), to describe the specificity of the care and of the help from people carrying diseases with behavioral disorders (Alzheimer-type dementia in particular), At 1,6,12,18,24,30,36,42,48,54 and 60 months post randomization|(Observational study) Changes in the role of caregiver due to a situation generating a rupture (entry into an institution or death, disease remission) using a qualitative approach (semi-structure interview), to study the situations generating a rupture in their role of caregiver (entry into an institution or death, disease remission) using a qualitative approach (semi-structure interview), At 1,6,12,18,24,30,36,42,48,54 and 60 months post randomization
Other Outcome Measures:
Sponsor: Centre Hospitalier Universitaire de Besancon
Collaborators: Methodological and quality of life unit in oncology (CHRU de Besançon)|University of Franche-Comté|University of Burgundy|Pôle de Gérontologie Interrégional Bourgogne et Franche-Comté|CARSAT Bourgogne et Franche-Comté|CCAS of Dijon|CCAS of Besançon|CCAS of Montbéliard|Burgundy Regional Council|Franche-Comté Regional Council|The Municipality of Besançon|The Municipality of Dijon|General Council of the Doubs|General Council of the Territoire de Belfort|Collectif Inter Associatif Sur la Sante Bourgogne|Union Régionale Interfédérale des Œuvres et Organismes Privés Sanitaires Bourgogne|Association Gérontopôle Pierre Pfitzenmeyer|Pôle de compétitivité Vitagora Goût-Nutrition-Santé|National Old Age Insurance Fund for Employees (CNAVTS)|Sheerbrooke Gérontopôle|France Alzheimer|Institut Régional de Vieillissement (IRV)|Novartis Pharmaceuticals|Roche Foundation|Ligue contre le cancer, France|National Cancer Institute, France|Quality of life and cancer clinical research platform|National Research Agency, France
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 186
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: OTHER
Other IDs: P/2014/231
Start Date: 2015-10
Primary Completion Date: 2019-05

Completion Date: 2019-05
First Posted: 2015-12-10
Results First Posted:
Last Update Posted: 2022-07-22
Locations: CHRU de Besançon, Besançon, 25030, France
Study Documents:

NCT Number: NCT01719094
Study Title: RITHM - Resonance Imaging Trial for Heart Biomarkers in Adolescent/Young (AYA) Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT01719094
Acronym:
Study Status: COMPLETED
Brief Summary: Cardiovascular events are the leading non-cancer cause of mortality after childhood cancer, occurring at a significantly younger age than in the general population. The increased incidence of cardiovascular events adversely impacts the functional capacity, morbidity, and mortality of otherwise relatively healthy 20 to 40 year old individuals. Moreover, understanding of the mechanisms by which cancer treatment could influence the occurrence of latent cardiovascular events is unavailable. Our group and others have established independent, noninvasive magnetic resonance imaging (MRI) measures of cardiovascular risk in middle aged and elderly individuals. Cardiovascular risk include, acute coronary syndromes, cardiac death, and congestive heart failure. The goal of this application is to show that childhood cancer survivors at risk for impaired cardiovascular and cerebrovascular health have increased aortic stiffness, when compared to healthy adolescent and young adult age mate. Studies are designed to determine if MRI measures of cardiovascular function differ between adolescent/adult childhood cancer survivors (n=60), age matched controls (n=30), and adolescents/ young adults with planned treatment with chemo- and radiation therapy (n=25). The investigators propose that MRI markers responsible for cardiovascular events represent new clinical indicators that could be targeted to treat asymptomatic cardiovascular diseases.
Study Results: NO
Conditions: if Aortic Stiffness|Myocardial Wall Strain
Interventions:
Primary Outcome Measures: To determine if aortic stiffness or myocardial wall strain is increased in childhood cancer survivors who received anthracycline chemotherapy, Day 1
Secondary Outcome Measures: To determine if aortic stiffness changes during treatment with anthracycline chemotherapy in childhood cancer patients, n=25, approximately 6 months
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:

Enrollment: 101
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: IRB00014375|CCCWFU 99312
Start Date: 2012-08
Primary Completion Date: 2015-02
Completion Date: 2015-02
First Posted: 2012-11-01
Results First Posted:
Last Update Posted: 2018-07-05
Locations: Emory University School of Medicine, Atlanta, Georgia, 30322, United States|Wake Forset University Health Sciences, Winston-Salem, North Carolina, 27157, United States
Study Documents:

NCT Number: NCT01050829
Study Title: Gadobutrol Magnevist-controlled Body Study
Study URL: https://beta.clinicaltrials.gov/study/NCT01050829
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of the study is to look at the safety (what are the side effects) and efficacy (how well does it work) of gadobutrol when used for taking MR images of the body/extremities regions. The results of the MRI with gadobutrol injection will be compared to the results of MR images taken without contrast and with the results of the MR images taken with Magnevist.
Study Results: NO
Conditions: Magnetic Resonance Imaging
Interventions: DRUG: Gadobutrol (Gadovist, BAY86-4875)|DRUG: Gadopentetate Dimeglumine (Magnevist, BAY86-4882)
Primary Outcome Measures: The total score of the following 3 visualization parameters is used for primary variable: Degree of contrast enhancement; Border delineation; Internal morphology., At Day 0
Secondary Outcome Measures: Sensitivity and specificity for the detection of malignant lesions, At Day 0|Exact match of the MR diagnosis with the final clinical diagnosis based on medical records up until 3 months after the scan, At Day 0|Confidence in diagnosis, At Day 0
Other Outcome Measures:
Sponsor: Bayer
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 370
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|

Masking: SINGLE (PARTICIPANT)|Primary Purpose: DIAGNOSTIC
Other IDs: 13297
Start Date: 2010-01
Primary Completion Date: 2011-04
Completion Date: 2011-04
First Posted: 2010-01-15
Results First Posted:
Last Update Posted: 2014-12-30
Locations: Nanjing, Jiangsu, 210009, China|Suzhou, Jiangsu, 215006, China|Xi'an, Shanxi, 710032, China|Beijing, 100853, China|Shanghai, 200032, China|Shanghai, 200233, China|Kamogawa, Chiba, 296-0041, Japan|Matsuyama, Ehime, 791-0280, Japan|Chikushino, Fukuoka, 818-8516, Japan|Kobe, Hyogo, 650-0047, Japan|Sunto, Shizuoka, 411-8777, Japan|Bunkyo-ku, Tokyo, 113-8431, Japan|Fukuoka, 812-0033, Japan|Seoul, 150-713, Korea, Republic of|Seoul, 158-710, Korea, Republic of
Study Documents:

NCT Number: NCT02077218
Study Title: Computed Tomography and Biomarker Analysis in Diagnosing Coronary Artery Disease in Asymptomatic Patients Who Have Undergone Stem Cell Transplant
Study URL: https://beta.clinicaltrials.gov/study/NCT02077218
Acronym:
Study Status: COMPLETED
Brief Summary: This pilot clinical trial studies computed tomography (CT) scans and biomarker analysis in diagnosing coronary artery disease (CAD) in patients who have undergone a stem cell transplant but have no symptoms of CAD. CAD is a disease in which there is a narrowing or blockage of the coronary arteries (blood vessels that carry blood and oxygen to the heart) and patients who have undergone a stem cell transplant are at an especially high risk for CAD. A CT scan involves a series of detailed pictures of areas inside the body taken from different angles. The pictures are created by a computer linked to an x-ray machine. Studying samples of blood from patients who have undergone a stem cell transplant in the laboratory may help doctors identify and learn more about biomarkers related to CAD. Using a CT scan in combination with biomarker analysis may be a better and less-invasive way to diagnose CAD.
Study Results: NO
Conditions: Cancer Survivor|Diabetes Mellitus|Hypertension
Interventions: PROCEDURE: computed tomography|OTHER: cytology specimen collection procedure|OTHER: laboratory biomarker analysis|OTHER: questionnaire administration
Primary Outcome Measures: Feasibility, defined by the percentage of patients that enroll onto the study, successful completion of all study measurements, ability of studies to be interpreted, and achievement of the recruitment goal, The current protocol will be considered feasible if: 1) \>= 30% of eligible patients that are approached for participation enroll onto the study, 2) \>= 75% enrolled participants successfully complete all study measurements

(history/physical examination, blood draw, completion of study questionnaires, CT-imaging), 3) \>= 90% of CT-based studies can be interpreted and 4) =\< 100 individuals are approached to achieve recruitment goal of 20 participants., Up to 9 weeks
Secondary Outcome Measures:
Other Outcome Measures: Prevalence of asymptomatic CAD, as measured by CT angiography, Asymptomatic CAD will be defined as having either an abnormal coronary artery calcium (CAC) (\>= 100 Au) or more than minimal coronary luminal stenosis (\>= 30%) in any of the arteries. Descriptive statistics will be generated to characterize the extent of luminal stenosis in the study populations., Up to 9 weeks|Severity of asymptomatic CAD, as measured by CT angiography, Asymptomatic CAD will be defined as having either an abnormal coronary artery calcium (CAC) (\>= 100 Au) or more than minimal coronary luminal stenosis (\>= 30%) in any of the arteries. Descriptive statistics will be generated to characterize the extent of luminal stenosis in the study populations., Up to 9 weeks|Patient demographics (age, sex, race/ethnicity), Will be evaluated using descriptive statistics., Up to 9 weeks|Pre-HCT chest radiation, Will be evaluated using descriptive statistics., Up to 9 weeks|HCT-related exposures (TBI, conditioning chemotherapy), Will be evaluated using descriptive statistics., Up to 9 weeks|Management of GvHD, Will be evaluated using descriptive statistics., Up to 9 weeks|CVRF-specific characteristics, Will be evaluated using descriptive statistics., Up to 9 weeks|Expression of hs-CRP, Standard descriptive statistics will be utilized to derive the median, mean, standard deviation, and range of individual blood biomarkers in survivors with and without CAD., Up to 9 weeks|Expression of Lp-PLA2, Standard descriptive statistics will be utilized to derive the median, mean, standard deviation, and range of individual blood biomarkers in survivors with and without CAD., Up to 9 weeks
Sponsor: City of Hope Medical Center
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 13385|NCI-2014-00419|13385
Start Date: 2014-02
Primary Completion Date: 2015-04
Completion Date: 2015-04
First Posted: 2014-03-04
Results First Posted:
Last Update Posted: 2015-04-21
Locations: City of Hope Medical Center, Duarte, California, 91010, United States
Study Documents:

NCT Number: NCT00005418
Study Title: Epidemiology of Cardiotoxicity in Children With Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00005418
Acronym:
Study Status: COMPLETED
Brief Summary: To provide a comprehensive analysis of risk factors for the development of clinical cardiotoxicities in over 6,000 children with cancer who had been treated on standardized protocols involving the use of anthracyclines alone or in combination with other potentially cardiotoxic therapies or with no use of anthracycline therapy.
Study Results: NO
Conditions: Cardiovascular Diseases|Heart Diseases|Heart Failure, Congestive|Death, Sudden, Cardiac|Heart Failure
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
Collaborators:
Sex: MALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment:
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 4336|R03HL048020
Start Date: 1992-04
Primary Completion Date:
Completion Date: 1994-03
First Posted: 2000-05-26
Results First Posted:
Last Update Posted: 2016-03-16
Locations:
Study Documents:

NCT Number: NCT05539794
Study Title: Exercise and Lifestyle in Adolescent Cancer (HEALTHYADOL)
Study URL: https://beta.clinicaltrials.gov/study/NCT05539794
Acronym: HEALTHYADOL
Study Status: RECRUITING
Brief Summary: The investigators will study the effects of an inhospital exercise intervention combined with lifestyle--including diet--counselling along the duration of treatment (neoadjuvant \[solid tumours\]/intense chemotherapy \[leukemias\], expected median duration 5-6 months) on several health-related variables. Participants will be recruited from 3 hospitals in Madrid (Spain). Inclusion criteria: male/female aged 12-19 years, newly diagnosed with a malignant

extracranial tumour; not having received any type of therapy--except surgery--at the time of diagnosis; adequate health status (Karnofsky/Eastern Cooperative Oncology Group scale score ≥50/2); to understand Spanish language and to provide written informed consent. The investigators will recruit ≥136 participants and conduct a randomised controlled trial. In addition to usual care, the control group will be informed of the benefits of a healthy lifestyle. The intervention group will follow a physical exercise and lifestyle counselling program. The exercise intervention will be performed in the hospital gymnasium, except for neutropenic phases--during which time sessions will be performed in the patients' ward--and will also include inspiratory muscle training). Health counselling will include a psychological intervention based on motivational interviewing techniques, guidance by a nutritionist, and support sessions with survivors who will share their experiences with the study participants. The following outcomes will be assessed at baseline (diagnosis), end of treatment, and at 3-month follow-up in all participants: echocardiography-determined left ventricular function (primary outcome); and blood pressure, blood lipids, body composition, physical activity levels, energy intake, cardiorespiratory fitness, muscle strength, functional mobility, health-related quality of life, cancer-related fatigue, stress coping, anxiety, depression, clinical variables, and potential biological underpinnings of exercise multisystemic benefits (metabolic and inflammatory \[cytokine panel\] markers, plasma proteome, gut microbiome, and immune function).
Study Results: NO
Conditions: Adolescent Cancer
Interventions: BEHAVIORAL: lifestyle and physical exercise
Primary Outcome Measures: Change in left-ventricular (LV) function.(LV ejection fraction) from baseline to end of treatment, Echocardiography-determined LV ejection fraction (unit = %), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in left-ventricular (LV) function (LV ejection fraction) from baseline to follow-up, Echocardiography-determined LV ejection fraction (unit = %), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in left-ventricular (LV) function (LV fractional shortening) from baseline to follow-up, Echocardiography-determined LV fractional shortening (unit = %), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)]|Change in left-ventricular (LV) function (LV fractional shortening) from baseline to follow-up, Echocardiography-determined LV fractional shortening (unit = %), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)]
Secondary Outcome Measures: Change in resting 'clinic' arterial blood pressure from baseline to end of treatment, Arterial blood pressure (BP) (ausculatory method) (units = mmHg), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis|Change in resting 'clinic' arterial blood pressure from baseline to

follow-up, Arterial blood pressure (BP) (ausculatory method) (units = mmHg), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in serum lipid profile (cholesterol) from baseline to end of treatment, Total/HDL/LDL-cholesterol will be quantified with an automated chemistry analyser (units = mg/dL)., Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis)]|Change in serum lipid profile (cholesterol) from baseline to follow-up, Total/HDL/LDL-cholesterol will be quantified with an automated chemistry analyser (units = mg/dL)., Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)]|Change in serum lipid profile (triglycerides) from baseline to end of treatment, Tiglycerides will be quantified with an automated chemistry analyser (units = mg/dL)., Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis)]|Change in serum lipid profile (triglycerides) from baseline to follow-up, Tiglycerides will be quantified with an automated chemistry analyser (units = mg/dL)., Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)]|Change in adiposity index from baseline to end of treatment, Waist-to-hip ratio (no units), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in adiposity index from baseline to follow-up, Waist-to-hip ratio (no units), Assessed at two time points: (1) at baseline (diagnosis); (2) 3 months after the end of treatment (follow-up)|Change in DXA measures of lean mass from baseline to end of treatment, DXA-determined total lean mass (grams), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in DXA measures of lean mass from baseline to follow-up, DXA-determined total lean and fat mass (grams), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in DXA measures of fat mass from baseline to end of tratment, DXA-determined total fat mass (grams), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in DXA measures of fat mass from baseline to follow-up, DXA-determined total fat mass (grams), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in DXA measure of bone health from baseline to end of treatment, DXA-determined bone mineral density (unit = g/m2), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in DXA measure of bone health from baseline to follow-up, DXA-determined bone mineral density (unit = g/m2), Assessed at two time points: (1) at baseline (diagnosis); and 3 months after the end of treatment (follow-up)|Change in physical activity (PA) from baseline to end of treatment, PA levels (moderate/vigorous PA) determined using triaxial accelerometry (units =minutes/week), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in

physical activity (PA) from baseline to follow-up, PA levels (moderate/vigorous PA) determined using triaxial accelerometry (units = minutes/week), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in total energy intake from baseline to end of treatment., 3-day 24 h-dietary recalls to record the participants' energy intake by either themselves or parents/caregivers.

3-day, 24 h-dietary recalls will be used to record the participants' energy intake by either themselves or parents/caregivers. The investigators will provide participants with instructions on how to obtain a correct food record. Dietary recall data will be analysed using Dietsource 3.0 (Novartis) to determine total energy intake (kcal), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in total energy intake from baseline to follow-up, 3-day 24 h-dietary recalls to record the participants' energy intake by either themselves or parents/caregivers.

3-day, 24 h-dietary recalls will be used to record the participants' energy intake by either themselves or parents/caregivers. The investigators will provide participants with instructions on how to obtain a correct food record. Dietary recall data will be analysed using Dietsource 3.0 (Novartis) to determine total energy intake (kcal), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in energy intake by sustrate from baseline to end of treatment, 3-day 24 h-dietary recalls to record the participants' energy intake by either themselves or parents/caregivers.

3-day, 24 h-dietary recalls will be used to record the participants' energy intake by either themselves or parents/caregivers. The participants will provide participants with instructions on how to obtain a correct food record. Dietary recall data will be analysed using Dietsource 3.0 (Novartis) to determine protein, fat, carbohydrate, and fiber intake (g/day), Assessed at two time points: (1) at baseline (diagnosis); and (2) (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in energy intake by sustrate from baseline to follow-up, 3-day 24 h-dietary recalls to record the participants' energy intake by either themselves or parents/caregivers.

3-day, 24 h-dietary recalls will be used to record the participants' energy intake by either themselves or parents/caregivers. The participants will provide participants with instructions on how to obtain a correct food record. Dietary recall data will be analysed using Dietsource 3.0 (Novartis) to determine protein, fat, carbohydrate, and fiber intake (g/day), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in cardiorespiratory fitness (VO2peak)

from baseline to end of treatment, VO2peak will be determined with 'breath-by breath' analysis of expired gases on a metabolic cart using a ramp-like treadmill--or arm-crank ergometer--test (units = mL/kg/min), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in cardiorespiratory fitness (VO2peak) from baseline to follow-up, VO2peak will be determined with 'breath-by breath' analysis of expired gases on a metabolic cart using a ramp-like treadmill--or arm-crank ergometer--test (units = mL/kg/min), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in muscle strength from baseline to end of treatment, The 5-repetition maximum (commonly abbreviated as 5RM), which is the maximum strength capacity to perform 5 repetitions until momentary muscular exhaustion, will be measured for leg press and bench press (units = kg)., Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in muscle strength from baseline to follow-up, The 5-repetition maximum (commonly abbreviated as 5RM), which is the maximum strength capacity to perform 5 repetitions until momentary muscular exhaustion, will be measured for leg press and bench press (units = kg)., Assessed at two time points: (1) at baseline (diagnosis);and (2) 3 months after the end of treatment (follow-up)|Change in inspiratory muscle strength (PImax) from baseline to end of treatment, PImax (units = cmH20) will be determined using a mouth pressure meter with the best result from 3 attempts (interspersed with rest periods of ≥1 min-duration) taken., Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in inspiratory muscle strength (PImax) from baseline to follow-up, PImax (units = cmH20) will be determined using a mouth pressure meter with the best result from 3 attempts (interspersed with rest periods of ≥1 min-duration) taken., Assessed at three time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in psychological status (quality of life) from baseline to end of treatment, Health-related QoL (HRQoL) (Paediatric Quality of Life Inventory \[PedsQL\] 3.0 Cancer Module, designed to measure paediatric/adolescent cancer specific HRQoL) (0 to 100 scale, with higher scores indicating better HRQoL), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in psychological status (quality of life) from baseline to follow-up, Health-related QoL (HRQoL) (Paediatric Quality of Life Inventory \[abbreviated as PedsQL\] 3.0 Cancer Module, designed to measure paediatric/adolescent cancer specific HRQoL) (0 to 100 scale, with higher scores indicating better HRQoL), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in psychological status (fatigue) from baseline to end of treatment, Cancer-related fatigue (Paediatric Quality of Life (PedsQL) Multidimensional Fatigue Scale) (0 to 100 score, higher scores meaning higher fatigue), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after

diagnosis (i.e., end of treatment)|Change in psychological status (fatigue) from baseline to follow-up, Cancer-related fatigue (Paediatric Quality of Life (PedsQL) Multidimensional Fatigue Scale) (0 to 100 score, higher scores meaning higher fatigue, Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in psychological status (stress) from baseline to end of treatment, Stress coping (General form of the Adolescent Coping Scale) (0 to 20 scale, with higher scores indicating higher resilience to stress), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in psychological status (stress) from baseline to follow-ip, Stress coping (General form of the Adolescent Coping Scale) (0 to 20 scale, with higher scores indicating higher resilience to stress), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in psychological status (anxiety) from baseline to end of treatment, Anxiety (six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory \[abbbreviated as STAI\]) (0 to 100 score, with higher scores reflecting higher anxiety levels), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in psychological status (anxiety) from baseline to follow-up, Anxiety (six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory \[abbreviated as STAI\]) (0 to 100 score, with higher scores reflecting higher anxiety levels), Assessed at two time points: (1) at baseline (diagnosis); (2) 14 to 28 weeks after diagnosis (i.e., end of treatment); and (3) 3 months after the end of treatment (follow-up)|Change in psychological status (depression) from baseline to end of treatment, Depression (Child Depression Scale) (0 to 52 scale, with higher scores reflecting more depression), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis|Change in psychological status (depression) from baseline to follow-up, Depression (Child Depression Scale) (0 to 52 scale, with higher scores reflecting more depression), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in clinical variables (survival) from baseline to end of treatment, Survival (numebr of days from diagnosis to the end of the study or death), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis|Change in clinical variables (survival) from baseline to follow-up, Survival (number of days from diagnosis to the end of the study or death), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Changes in clinical variables (treatment tolerability) from baseline to end of treatment, Treatment tolerability (number of days of treatment interruption/delay, Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Changes in clinical variables (treatment tolerability) from baseline to follow-up, Treatment tolerability (number of days of treatment interruption/delay, Assessed at two time

points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in clinical variables (days of hospitalization) from baseline to end of treatment, Total hospitalisation length (number of days), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis|Change in clinical variables (days of hospitalization) from baseline to follow-up, Total hospitalisation length (number of days), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in clinical variables (global score of Common Toxicity Criteria for Adverse Events [CTCAE]) from baseline to end of treatment, Common Toxicity Criteria for Adverse Events \[CTCAE, global score, 1 (low toxicity) to 5 (highest\]), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis|Change in clinical variables (global score of Common Toxicity Criteria for Adverse Events [CTCAE]) from baseline to follow-up, Common Toxicity Criteria for Adverse Events \[CTCAE, global score, 1 (low toxicity) to 5 (highest\]), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in metabolic markers (glucose) from baseline to end of treatment, Serum fasting glycaemia (mg/dL), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis|Change in metabolic markers (glucose) from baseline to follow-up, Serum fasting glycaemia (mg/dL), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Metabolic markers (insulin) from baseline to end of treatment, Serum fasting insulinaemia (pmol/L), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Metabolic markers (insulin) from baseline to follow-up, Serum fasting insulinaemia (pmol/L), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in metabolic markers (HOMA-IR) from baseline to end of treatment, Homeostasis model assessment-insulin resistance index (HOMA-IR) (molar units), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in metabolic markers (HOMA-IR) from baseline to follow-up, Homeostasis model assessment-insulin resistance index (HOMA-IR) (molar units), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in inflammation (C-reactive protein) from baseline to end of treatment, C-reactive protein (mg/L), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in metabolic markers (C-reactive protein) from baseline to follow-up, C-reactive protein (mg/L), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in inflammatory markers (cytokines/chemokines) from baseline to end of treatment, Panel of 21 cytokines/chemokines measured in serum using Luminex® (all assessed in the same units, micrograms/dL), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after

diagnosis (i.e., end of treatment)|Change in inflammatory markers (cytokines/chemokines) from baseline to follow-up, Panel of 21 cytokines/chemokines measured in serum using Luminex® (all assessed in the same units, micrograms/dL), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (i.e., follow-up)|Change in plasma proteome from baseline to end of treatment, The investigators will use liquid chromatography coupled to tandem-mass spectrometry (LC-MS/MS) to measure levels in blood of thousands of proteins, Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in plasma proteome from baseline to follow-up, The investigators will use liquid chromatography coupled to tandem-mass spectrometry (LC-MS/MS) to measure levels in blood of thousands of proteins, Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in gut microbiome (alpha-diversity) from baseline to end of treatment, α-diversity, Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in gut microbiome (alpha-diversity) from baseline to follow-up, α-diversity, Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in gut microbiome (beta-diversity) from baseline to end of treatment, beta-diversity, Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in gut microbiome (beta-diversity) from baseline to follow-up, Beta-diversity, Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in gut microbiome (specific bacteria) from baseline to end of treatment, Changes in bacteria abundance, Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in gut microbiome (specific bacteria) from baseline to follow-up, Changes in bacteria abundance, Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in Immune phenotype (lymphocyte subpopulations) from baseline to end of treatment, Lymphocyte subpopulations (%), Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis|Change in Immune phenotype (lymphocyte subpopulations) from baseline to follow-up, Lymphocyte subpopulations (%), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in Immune phenotype (natural killer (NK) cells) from baseline to end of treatment, NK cell subsets (%), Assessed at two time points: (1) at baseline (diagnosis); (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in Immune phenotype (NK cells) from baseline to follow-up, NK cell subsets (%), Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)|Change in Immune function from baseline to end of treatment, NK cell receptors, Assessed at two time points: (1) at baseline (diagnosis); and (2) 14 to 28 weeks after diagnosis (i.e., end of treatment)|Change in immune function from

baseline to follow-up, NK cell receptors, Assessed at two time points: (1) at baseline (diagnosis); and (2) 3 months after the end of treatment (follow-up)
Other Outcome Measures:
Sponsor: Universidad Europea de Madrid
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: NA
Enrollment: 136
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: Universidad Europea de Madrid
Start Date: 2022-09-15
Primary Completion Date: 2025-12-31
Completion Date: 2026-03-31
First Posted: 2022-09-14
Results First Posted:
Last Update Posted: 2022-11-03
Locations: UEM, Madrid, Spain|Universidad Europea de Madrid, Villaviciosa de Odón, 28670, Spain
Study Documents:

NCT Number: NCT05728632
Study Title: Cardioprotective Effects of Nebivolol Versus Placebo in Patients Undergoing Chemotherapy With Anthracyclines
Study URL: https://beta.clinicaltrials.gov/study/NCT05728632
Acronym: CONTROL
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: As the cancer-related prognosis improves thanks to recent advances in cancer-targeted therapies, the prognostic burden of chemotherapy-related complications - including cardiotoxicity - is increasingly recognised. So far, the evidence supporting pharmacological preventive strategies in cardio-oncology has been inconsistent and conflicting, and there is a clear need for well-designed trials with novel interventions. In this study, by using cardiac magnetic resonance, the investigators want to assess if a commonly used beta-blocker with a unique pharmacological profile, i.e. nebivolol, can prevent cardiac dysfunction in patients with breast cancer or diffuse large B-cell lymphoma undergoing chemotherapy with anthracyclines.
Study Results: NO
Conditions: Breast Cancer|Lymphoma, Large B-Cell, Diffuse|Cardiotoxicity|Left Ventricular Dysfunction|Chemotherapy Effect
Interventions: DRUG: Nebivolol|DRUG: Placebo
Primary Outcome Measures: Left Ventricular Ejection Fraction reduction assessed by Cardiac Magnetic Resonance, The primary endpoint is defined as Left Ventricular Ejection Fraction (LVEF) reduction (unit

of measurement: %) assessed by Cardiac Magnetic Resonance at 12 months of follow-up.

LVEF reduction is defined as the difference between LVEF at baseline and LVEF at 12 months follow-up (LVEF reduction = Baseline LVEF - 12 months LVEF)., from baseline to 12 months
Secondary Outcome Measures: Left ventricular ejection fraction assessed by Cardiac Magnetic Resonance, Left ventricular ejection fraction (unit of measurement: %) assessed by Cardiac Magnetic Resonance at 12-month follow-up., at 12-month follow-up|Myocardial fibrosis assessed by Cardiac Magnetic Resonance, Myocardial fibrosis assessed by Cardiac Magnetic Resonance with T1-mapping sequences and with Late Gadolinium Enhancement images., at 12-month follow-up|Myocardial edema assessed by Cardiac Magnetic Resonance, Myocardial edema assessed by Cardiac Magnetic Resonance with T2 sequences., at 12-month follow-up|Right ventricular ejection fraction assessed by Cardiac Magnetic Resonance, Right ventricular ejection fraction (unit of measurement: %) assessed by Cardiac Magnetic Resonance, at 12-month follow-up|Left ventricular end-diastolic volume assessed by Cardiac Magnetic Resonance, Left ventricular end-diastolic volume (unit of measurement: ml) assessed by Cardiac Magnetic Resonance, at different timepoints (1-month, 6-month, 12-months)|Left ventricular end-systolic volume assessed by Cardiac Magnetic Resonance, Left ventricular end-systolic volume (unit of measurement: ml) assessed by Cardiac Magnetic Resonance, at different timepoints (1-month, 6-month, 12-months)|Left ventricular mass assessed by Cardiac Magnetic Resonance, Left ventricular mass (unit of measurement: g/m^2) assessed by Cardiac Magnetic Resonance, at different timepoints (1-month, 6-month, 12-months)|Left ventricular ejection fraction assessed by Echocardiography, Left ventricular ejection fraction (unit of measurement: %) assessed by Echocardiography, at different timepoints (1-month, 6-month, 12-months)|Left ventricular diastolic function assessed by Echocardiography, Left ventricular diastolic function assessed by Echocardiography according to Guidelines of European Association of Cardiovascular Imaging / American Society of Echocardiography, at different timepoints (1-month, 6-month, 12-months)|Right ventricular systolic function assessed by Echocardiography, Right ventricular systolic function assessed by Echocardiography according to Guidelines of European Association of Cardiovascular Imaging / American Society of Echocardiography, at different timepoints (1-month, 6-month, 12-months)|Left ventricular end-diastolic volume assessed by Echocardiography, Left ventricular end-diastolic volume (unit of measurement: ml) assessed by Echocardiography, at different timepoints (1-month, 6-month, 12-months)|Left ventricular end-systolic volume assessed by Echocardiography, Left ventricular end-systolic volume (unit of measurement: ml) assessed by Echocardiography, at different timepoints (1-month, 6-month, 12-months)|Serum troponin, Serum high-sensitivity cardiac troponin I levels (unit of measurement: ng/L), at different timepoints (1-month, 6-month, 12-months)|Serum B-type natriuretic

peptide (BNP), Serum B-type natriuretic peptide (BNP) (unit of measurement: pg/mL), at different timepoints (1-month, 6-month, 12-months)|Serum N-terminal-pro hormone B-type natriuretic peptide (NT-proBNP), Serum N-terminal-pro hormone B-type natriuretic peptide (NT-proBNP) levels (unit of measurement: pg/mL), at different timepoints (1-month, 6-month, 12-months)|All-cause mortality, All-cause mortality, at 12-month follow-up|Cardiovascular mortality, Cardiovascular mortality or death will be defined as any death due to immediate cardiovascular cause (e.g. myocardial infarction, low-output failure, arrhythmia). Unwitnessed death and death of unknown cause will be classified as cardiac death., at 12-month follow-up|Myocardial infarction, Myocardial infarction will be defined according to the 3rd Universal Definition., at 12-month follow-up|Cerebrovascular events, Cerebrovascular events will be defined as follows:

* Transient ischemic attack: rapidly developed clinical signs of global disturbance of cerebral function lasting fewer \<24 hours, regardless of the presence of an acute clinically relevant brain lesion in imaging.
* Ischemic stroke: rapidly developed clinical signs of focal or global disturbance of cerebral function lasting \>24 hours with imaging of an acute clinically relevant brain lesion.
* Intracerebral haemorrhage: diagnosis must be confirmed by cerebral imaging., at 12-month follow-up|Hospitalization for heart failure, Hospitalization for heart failure will be defined as any unplanned hospital readmission due to signs and symptoms of heart failure., at 12-month follow-up
Other Outcome Measures:
Sponsor: Giulio Stefanini
Collaborators: Agenzia Italiana del Farmaco
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 80
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 012018CONTROL
Start Date: 2019-01-01
Primary Completion Date: 2023-02-28
Completion Date: 2023-02-28
First Posted: 2023-02-15
Results First Posted:
Last Update Posted: 2023-02-23
Locations: IRCCS Humanitas Research Hospital, Rozzano, Milan, 20089, Italy
Study Documents:

NCT Number: NCT05796518
Study Title: Feasibility of a Patient Directed Tool to Assess Heart Health Among Endometrial Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT05796518
Acronym:
Study Status: RECRUITING
Brief Summary: Investigators are conducting this study to find out more about what heart health means to participants and how healthcare providers can best help to manage heart health. Participants will be asked to view an electronic tool designed to promote heart health awareness and help to manage heart health outside of the clinic. This study will provide important information to help investigators develop future programs that improve cancer patient's heart health after they complete their treatment.
Study Results: NO
Conditions: Endometrial Cancer|Survivorship
Interventions: OTHER: PREVENT Cardiovascular Health Assessment Tool|OTHER: Survey|OTHER: Interview Regarding Heart Health
Primary Outcome Measures: Number of Participants to Complete Heart Health Assessment - Feasibility, Feasibility will be defined from the number of participants who complete the web-based assessment using exact 95% binomial confidence intervals., 6 months
Secondary Outcome Measures: Number of Participants Stating Satisfaction with PREVENT Tool, Patient satisfaction will be identified through post-visit survey with a 5-point Likert scale (strongly agree to strongly disagree) regarding liking the tool, helpfulness, ease of understanding and desire to use this tool with their oncologist. One-sample t-tests will be used to test whether the average response to each question is greater than 3.5 (with three denoting a neutral response). Wilcoxon signed rank tests will be used to compare cancer survivors' knowledge regarding their cardiovascular health risk factors and perceived importance of cancer and heart disease before and after using the cardiovascular risk visualization tool., 6 months|Number of Participants to Report Initiating Discussions Regarding Cardiovascular Health with Health Care Providers, The initiation of discussions with participants' health care providers will largely be descriptive (using means as a measurement) to analyze this measure, 6 months
Other Outcome Measures:
Sponsor: Wake Forest University Health Sciences
Collaborators: National Cancer Institute (NCI)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 42
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: IRB00095005|WFBCCC 99123|P30CA012197

Start Date: 2023-08
Primary Completion Date: 2024-01
Completion Date: 2024-02
First Posted: 2023-04-03
Results First Posted:
Last Update Posted: 2023-07-05
Locations: Wake Forest Baptist Comprehensive Cancer Center, Winston-Salem, North Carolina, 27157, United States
Study Documents:

NCT Number: NCT03660618
Study Title: LSFG-SKIN, Laser Speckle Flowgraphy
Study URL: https://beta.clinicaltrials.gov/study/NCT03660618
Acronym:
Study Status: TERMINATED
Brief Summary: The purpose of this project is to quantify normal and abnormal skin blood flow regionally in different areas of the body(face, extremities, over burns and wounds) at baseline and over time in response to treatment or environmental changes, such as temperature, light and pressure.
Study Results: YES
Conditions: Hypertension|Heart Failure|Vascular Ischemia|Burns|Chemotherapy Effect|Radiation Injuries|Uveitis|Scleritis|Multiple Sclerosis|Autonomic Neuropathy|Stroke|Intracranial Hemorrhages|TIA|Migraine|Headache|Pain
Interventions: DEVICE: laser speckle flowgraphy
Primary Outcome Measures: Imaging Blood Flow, Imaging blood flow in the tissue is of major importance in the clinical environment, One visit
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Randy Kardon
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 201702725
Start Date: 2017-05-23
Primary Completion Date: 2019-03-02
Completion Date: 2019-03-02
First Posted: 2018-09-06
Results First Posted: 2019-05-07
Last Update Posted: 2023-05-10
Locations: University of Iowa Department of Ophthalmology, Iowa City, Iowa, 52242, United States

Study Documents: Study Protocol

NCT Number: NCT02044718
Study Title: Medical Record Study on Adverse Events Requiring a Higher Level of Care in Flemish Hospitals
Study URL: https://beta.clinicaltrials.gov/study/NCT02044718
Acronym:
Study Status: COMPLETED
Brief Summary: An adverse event (AE) is defined as unintended injury or complication, which results in disability, death or prolongation of hospital stay, and is caused by healthcare management (including omissions) rather than the patient's disease. Retrospective record reviews in several countries have shown that 2,9% to 16,6% of patients in acute hospitals experience one or more AEs. A patient with an AE may require a higher level of care. Although all AEs are important, preventable AEs that result in an upgraded level of patient care are of particular concern. In this study it's defined as an unplanned admission to intensive care unit (ICU) or a Mobile Emergency Team (MET) intervention. The objectives of this study are to determine the incidence of (preventable) adverse events requiring ICU admission or MET intervention and to assess the level of harm of each AE.
Study Results: NO
Conditions: Sepsis, Cancer, Heart Attack, Heart Failure, Abdominal Surgery, Trauma, Diabetes, Lung Disease, Gynaecology, Fertility, Cardiac Surgery,
Interventions:
Primary Outcome Measures: Incidence of adverse events requiring a higher level of care, An adverse event is an unintended injury or complication, which results in disability at discharge, death or prolongation of hospital stay, and is caused by healthcare management (including omissions) rather than the patient's disease. (Wilson, 1995), 6 months|The number of participants with preventable adverse events, Assess the preventability of these adverse events using six point scale with a range of not preventable until totally preventable, 6 months
Secondary Outcome Measures: Type adverse events, Divide the adverse events into categories, like diagnosis, therapy, medication, surgery, non-surgery, etc., 6 months|Clinical impact of adverse events in terms of outcome, Assess the impact of the adverse events in terms of disability, mortality, readmission., 6 months|Quality of the chart review, The patient chart will be judge on the completeness and adequacy, 6 months
Other Outcome Measures:
Sponsor: Hasselt University
Collaborators: Jessa Hospital|Algemeen Ziekenhuis Vesalius|Sint-Franciscus Ziekenhuis|Regionaal Ziekenhuis Sint-Trudo|Ziekenhuis Maas en Kempen|Ziekenhuis Oost-Limburg
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:

Enrollment: 878
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 11.50/intens11.01
Start Date: 2011-11
Primary Completion Date: 2013-06
Completion Date: 2013-06
First Posted: 2014-01-24
Results First Posted:
Last Update Posted: 2014-01-24
Locations: Hasselt University, Hasselt, Limburg, 3500, Belgium
Study Documents:

NCT Number: NCT05587023
Study Title: Effect of Ultrasound-guided Left Stellate Ganglion Block on Rapid Recovery of Patients Undergoing Cardiac Valve Replacement and Its Mechanism
Study URL: https://beta.clinicaltrials.gov/study/NCT05587023
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: In this study, Valve replacement patients undergoing cardiopulmonary bypass were randomly divided into control group and experimental group (SGB Group) , main outcome measures: postoperative complications (pulmonary infection, oxygenation injury, arrhythmia, hemorrhage, enteroparalysis, incision infection, renal insufficiency, cognitive impairment, etc.) and 30-day mortality. Secondary outcome measures: Hemodynamics, postoperative extubation time, length of stay and total cost of hospitalization. To investigate the effect of SGB on the rapid recovery of patients with Valve replacement heart disease after cardiopulmonary bypass.
Study Results: NO
Conditions: Left Stellate Ganglion Block Can Quickly Restore the Left Stellate Ganglion|Possible Molecular Mechanism of Left Stellate Ganglion Block
Interventions: PROCEDURE: stellate ganglion block
Primary Outcome Measures: Postoperative complications, Pulmonary infection, oxygenation injury, malignant arrhythmia, hemorrhage, enteroparalysis, incision infection, renal insufficiency, cognitive dysfunction and so on, within 1 week after operation
Secondary Outcome Measures: Mortality, Mortality, Within 30 days after surgery
Other Outcome Measures: The concentration of blood factors in plasma, Plasma levels of IL-6, IL-10 and TNF-α were measured by enzyme-linked immunosorbent assay (Elisa) at 1,3,6,24 and 72 h after operation., Within 3 days after surgery
Sponsor: Zhonghua Chen,MD
Collaborators: Shaoxing Hospital of Zhejiang University
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: NA
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR,
OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 2021-K-Y-294-01
Start Date: 2021-01-01
Primary Completion Date: 2022-12-01
Completion Date: 2023-12-01
First Posted: 2022-10-19
Results First Posted:
Last Update Posted: 2022-10-19
Locations: Zhonghua Chen,MD, Shaoxing, Zhejiang, China
Study Documents:

NCT Number: NCT04916223
Study Title: Study to Determine Therapeutic Massage Dosing to Improve Quality of Life in Hospitalized Patients Receiving Palliative Care
Study URL: https://beta.clinicaltrials.gov/study/NCT04916223
Acronym:
Study Status: COMPLETED
Brief Summary: Therapeutic massage is the most common non-traditional treatment option offered to improve quality of life, provide comfort and decrease pain in hospice and palliative care settings outside the hospital. Three systematic reviews of data in general pain, surgical and cancer populations found massage to be effective for treating pain versus active comparators.

Given the remarkable negative impact on QOL experienced by patients hospitalized with a serious progressive illness, a nationwide opioid crisis in the setting of public concern for untreated pain, and patient demand for integrative therapies, we wish to investigate non-traditional methods of supporting patients in pain and providing clinicians with viable alternatives. Unfortunately, very little is known about optimal delivery of massage interventions in the hospital setting, including dosing parameters such as time and frequency

We conducted a single center comparative effectiveness study to evaluate therapeutic massage "dosing" to improve self-reported quality-of-life in hospitalized patients receiving palliative care consultation.
Study Results: NO
Conditions: Cancer|Heart Failure|COPD|Sepsis|HIV Infections|ESRD|
Trauma|Stroke
Interventions: OTHER: Therapeutic massage
Primary Outcome Measures: Change from baseline to post-intervention in McGill Quality of Life Questionnaire Single Item, The McGill QOL Questionnaire is a validated reliable tool to evaluate self-reported

QOL. One item in the Questionnaire has been shown to effectively assess subject's self-reported QOL., Baseline and one day post intervention
Secondary Outcome Measures: Change from baseline to post-intervention in Edmonton Symptom Assessment Scale, The Edmonton Symptom Assessment Scale is a validated, reliable instrument developed to measure 9 different common symptoms in advanced illness, Baseline and one day post intervention|Change from baseline to post-intervention in National Comprehensive Cancer Network Distress Thermometer, The NCCN Distress Thermometer is an 11-point Likert scale tool to self-report general distress between 0 (no distress) and 10 (extreme distress), Baseline and one day post intervention|Change from baseline to post-intervention in Peace Questionnaire, We adapted a single-item probe of spiritual concerns ("are you at peace?") to a 5-point Likert scale to self-report experience of being at peace, where 0=experiencing no peace and 5=experiencing total peace., Baseline and one day post intervention|Satisfaction with assigned intervention, We developed a post-intervention Patient Satisfaction Survey that included pain-related questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, modified to reference the current hospitalization, One day post intervention
Other Outcome Measures:
Sponsor: Medstar Health Research Institute
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 405
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: 2017-260
Start Date: 2017-11-01
Primary Completion Date: 2019-03-26
Completion Date: 2019-03-26
First Posted: 2021-06-07
Results First Posted:
Last Update Posted: 2022-12-13
Locations: MedStar Washington Hospital Center, Washington, District of Columbia, 20010, United States
Study Documents:

NCT Number: NCT02897778
Study Title: Cardiac Safety Study of Entinostat in Men and Women With Advanced Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT02897778
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate the effect of

entinostat on heart rate and other electrocardiogram (ECG) parameters. This study will also evaluate the safety and tolerability of entinostat, as well as pharmacokinetic and pharmacodynamic parameters.
Study Results: NO
Conditions: Neoplasms|Neoplasms, Glandular and Epithelial|Neoplasms by Histologic Type|Bronchial Neoplasms|Lung Neoplasms|Respiratory Tract Neoplasms|Thoracic Neoplasms|Digestive System Neoplasms|Endocrine Gland Neoplasms|Carcinoma, Non-Small-Cell Lung|Lung Diseases|Breast Neoplasms|Breast Diseases|Renal Neoplasm|Solid Tumors
Interventions: DRUG: Entinostat|DRUG: Placebo
Primary Outcome Measures: Change from Baseline in Heart Rate (HR), Heart rate measured in beats per minute (bpm)., Baseline (pre-dose) through 24 hours post-dose|Change from Baseline in Electrocardiogram Procedures, Change from baseline in QT interval corrected for heart rate (Qtc), PR interval (PR) and QRS complex (QRS)., Baseline (pre-dose) through 24 hours post-dose|Change from Baseline in T-Cell Morphology, Baseline (pre-dose) through 24 hours post-dose
Secondary Outcome Measures: Number of Participants with Treatment-emergent Adverse Events (TEAES) and Serious Adverse Events (SAEs), An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. A TEAE is an AE that occurs after the first dose of study drug. A SAE is defined as any AE that at any dose results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage., First dose through 30 days post-dose or through resolution of acute toxicities (Up to 31 days)|Number of Participants with Clinically Significant Abnormalities in Laboratory Values Reported as a TEAE, Standard safety laboratory tests included Chemistry, Hematology. Any hematologic or clinical chemistry abnormality considered by the investigator to be clinically significant was reported as a TEAE., Baseline (pre-dose) through 14 days post-dose or 30 day safety follow-up visit (if applicable)|Change from Baseline in Vital Signs, Vital signs included temperature, pulse, blood pressure, and respiration rate, Baseline (pre-dose) through 14 days post-dose or 30 day safety follow-up visit (if applicable)|Change from Baseline in ECG Values, A 12-lead continuous ECG recording (via a Holter) was recorded on Day 1 for 25 hours. Safety ECGs were read and interpreted by the Investigator on-site for the purpose of safety monitoring and were transmitted electronically to the central ECG laboratory for clinical interpretation by a cardiologist, Baseline ()pre-dose through 14 days post-dose or 30 day safety follow-up visit (if applicable)|Change from Baseline in QTc, Pre-dose through 24 hours post-dose|Cmax (Maximum Plasma Concentration) of Entinostat when given as a Single Supratherapeutic Dose, Pre-dose and multiple time-points through 24 hours post-dose and 14 days post-dose|Tmax (Time of Maximum Plasma Concentration) of Entinostat when given as a Single Supratherapeutic

Dose, Pre-dose and multiple time-points through 24 hours post-dose and 14 days post-dose|AUC0-24 (Area under the Plasma Concentration-time Curve from Time Zero to 24 hours) of Entinostat when given as a Single Supratherapeutic Dose, Pre-dose and multiple time-points through 24 hours post-dose and 14 days post-dose|AUC0-t (Area under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration) of Entinostat when given as a Single Supratherapeutic Dose, Pre-dose and multiple time-points through 24 hours post-dose and 14 days post-dose|AUC0-inf (Area under the Plasma Concentration-time Curve from 0-time Extrapolated to Infinity) of Entinostat when given as a Single Supratherapeutic Dose, Pre-dose and multiple time-points through 24 hours post-dose and 14 days post-dose|t1/2 (Elimination Half-life and Apparent Plasma Terminal Phase Elimination Rate Constant) of Entinostat when given as a Single Supratherapeutic Dose, Pre-dose and multiple time-points through 24 hours post-dose and 14 days post-dose|λz (Terminal Elimination Rate Constant) of Entinostat when given as a Single Supratherapeutic Dose, Pre-dose and multiple time-points through 24 hours post-dose and 14 days post-dose
Other Outcome Measures: Changes in Immune Regulatory Cells after a Single Dose of Entinostat, when given at a Supratherapeutic Dose, Relative to Placebo Control, Pre-dose through 14 days post-dose|Variability and Changes in Protein Lysine Acetylation in Peripheral Blood Cells after a Single Dose of Entinostat, when given at a Supratherapeutic Dose and Examine the Underlying Biological Variation, Pre-dose through 14 days post-dose
Sponsor: Syndax Pharmaceuticals
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 30
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: SNDX-275-0140
Start Date: 2016-08-24
Primary Completion Date: 2017-03-13
Completion Date: 2017-03-13
First Posted: 2016-09-13
Results First Posted:
Last Update Posted: 2022-04-28
Locations: The START Center for Cancer Care, San Antonio, Texas, 78229, United States
Study Documents:

NCT Number: NCT01105923
Study Title: Study of an Intervention to Improve Problem List Accuracy and Use

Study URL: https://beta.clinicaltrials.gov/study/NCT01105923
Acronym: MAPLE
Study Status: UNKNOWN
Brief Summary: The aim of this study is to identify patients with problem list gaps and intervene to correct these gaps by creating clinical decision support interventions that alert providers to likely problem list gaps and offer clinicians the opportunity to correct them. The investigators will randomize the clinics that will receive the intervention and formally evaluate the study after a period of 6 months for improved problem list completeness to determine the effectiveness of our intervention.
Study Results: NO
Conditions: Attention Deficit Disorder With Hyperactivity|Asthma|COPD|Breast Cancer|Coronary Artery Disease|Congestive Heart Failure|Diabetes|Glaucoma|Hemophilia|Hypertension|Hyperthyroidism|Hypothyroidism|Myasthenia Gravis|Osteoporosis|Osteopenia|Renal Failure|Renal Insufficiency|Sickle Cell Disease|Stroke
Interventions: OTHER: MAPLE
Primary Outcome Measures: Intervention acceptance, Of those providers who were shown (or who would have been shown, for the control group) the intervention, the number that added a problem across control and intervention groups., 6 months (May 2010–Nov2010)
Secondary Outcome Measures: Problem list prevalence, Number of patients with selected problems on their problem list pre and post intervention across intervention and control groups., pre and post intervention|Problem list incidence, For the conditions of interest, the percent of patients that had the problem added during the study period, pre and post intervention|Quality improvement based on problem list accuracy/completion, For those with problems added due to the intervention, the number of new triggered reminders or other clinical actions., post intervention
Other Outcome Measures:
Sponsor: Brigham and Women's Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 140
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 2009P001846
Start Date: 2010-05
Primary Completion Date: 2010-11
Completion Date: 2017-11
First Posted: 2010-04-19
Results First Posted:
Last Update Posted: 2015-02-02
Locations: Brigham and Women's Hospital, Boston, Massachusetts, 02115,

United States
Study Documents:

NCT Number: NCT03904732
Study Title: Study to Develop a Prediction Model to Understand the Effect of Low-dose Aspirin on Cancer That Develops in the Colon and/or the Rectum, Diseases That Affects the Heart or Blood Vessels and Safety Outcomes in European Countries. The Study is Also Called PEACOS Model EU
Study URL: https://beta.clinicaltrials.gov/study/NCT03904732
Acronym: PEACOCS
Study Status: COMPLETED
Brief Summary: In this study researchers want to learn more about the effect of low-dose Aspirin on cancer that develops in the colon (the longest part of the large intestine) and/or the rectum (the last several inches of the large intestine before the anus), diseases that affects the heart or blood vessels and safety outcomes. Study will focus on two groups of adults aged 50-59 and 60-69 years having an increased risk of heart and/or blood vessel disease who are taking either low-dose aspirin or no low-dose aspirin for heart and/or blood vessel disease prevention. The model will be based on information publicly available either on government organization websites or in scientific journals. Based on these data researchers will focus in a first step to build a model of 2 million adults (1 million for each age group) for the UK population and in a second step, the model will be modified for use with other European countries, to reflect the epidemiology and guidelines for aspirin use in these countries.
Study Results: NO
Conditions: Colorectal Cancer|Cardiovascular Disease|Bleeding
Interventions: DRUG: Acetylsalicylic Acid (Aspirin, BAYE4465)
Primary Outcome Measures: Number of myocardial infarction and ischaemic stroke, Calculated results using a mimicked population, Up to 20 years|Number of death due to myocardial infarction or due to ischaemic stroke, Calculated results using a mimicked population, Up to 20 years|Number of colorectal cancer (CRC), Calculated results using a mimicked population, Up to 20 years|Number of death due to CRC, Calculated results using a mimicked population, Up to 20 years|Number of severe gastrointestinal (GI) bleeding requiring hospitalization, Calculated results using a mimicked population, Up to 20 years|Number of intracranial hemorrhage (ICH), Calculated results using a mimicked population, Up to 20 years|Number of symptomatic peptic ulcers requiring hospitalization, Calculated results using a mimicked population, Up to 20 years|Number of deaths due to any other cause, Calculated results using a mimicked population, Up to 20 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Bayer
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases:
Enrollment: 2000000
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 20751
Start Date: 2019-04-15
Primary Completion Date: 2020-01-31
Completion Date: 2020-01-31
First Posted: 2019-04-05
Results First Posted:
Last Update Posted: 2021-02-01
Locations: Mimicked Population, Mimicked Population, United Kingdom
Study Documents:

NCT Number: NCT01009918
Study Title: Lisinopril or Coreg CR® in Reducing Side Effects in Women With Breast Cancer Receiving Trastuzumab
Study URL: https://beta.clinicaltrials.gov/study/NCT01009918
Acronym:
Study Status: COMPLETED
Brief Summary: RATIONALE: Lisinopril or Coreg CR®, may help reduce side effects caused by trastuzumab. It is not yet known whether lisinopril or Coreg CR® are more effective than a placebo in reducing side effects caused by trastuzumab.

PURPOSE: This phase II trial is studying lisinopril and Coreg CR® to see how well they work compared with a placebo in reducing side effects in patients with HER2-positive breast cancer receiving trastuzumab.
Study Results: YES
Conditions: Breast Cancer|Cardiac Toxicity
Interventions: DRUG: Coreg CR®|DRUG: lisinopril|OTHER: placebo
Primary Outcome Measures: Number of Participants With Trastuzumab-Induced Cardiotoxicity After 52 Weeks of Treatment, Reduction in incidence of trastuzumab-induced cardiotoxicity after 52 weeks of treatment as measured by preservation of Left Ventricular Ejection Fraction (LVEF). Number of Patients who experienced a cardiotoxicity., 2 years|Number of Participants With LVEF Decrease to <50%, Number of Participants with Left Ventricular Ejection Fraction (LVEF) drop to \<50%, 2 years
Secondary Outcome Measures: Number of Patients With Trastuzumab Course Interruption, Measure indicates the number of patients who had an interruption of trastuzumab for any reason, 2 years|Quality-of-life Changes Between Baseline and 52-weeks, Quality-of-life changes as assessed by North European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ-C30), which measures the quality of life of cancer patients. Higher score indicates higher quality of life. Score range is 0-100. The questionnaire was administered at baseline and at 52 weeks., 52 weeks|Number of

Participants With Cardiotoxicity-free Survival at 750 Days From Baseline, Number of Participants with cardiotoxicity-free survival at 750 days from baseline, 2 years
Other Outcome Measures:
Sponsor: University of South Florida
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 468
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: SCUSF 0806|SCUSF-0806|5U10CA081920-11
Start Date: 2010-03
Primary Completion Date: 2017-08
Completion Date: 2018-11
First Posted: 2009-11-09
Results First Posted: 2021-01-12
Last Update Posted: 2021-03-30
Locations: Todd Cancer Institute at Long Beach Memorial Medical Center, Long Beach, California, 90806, United States|Olive View - UCLA Medical Center Foundation, Sylmar, California, 91342, United States|Aurora Presbyterian Hospital, Aurora, Colorado, 80012, United States|Boulder Community Hospital, Boulder, Colorado, 80301-9019, United States|Penrose Cancer Center at Penrose Hospital, Colorado Springs, Colorado, 80933, United States|St. Anthony Central Hospital, Denver, Colorado, 80204, United States|Porter Adventist Hospital, Denver, Colorado, 80210, United States|Presbyterian - St. Luke's Medical Center, Denver, Colorado, 80218, United States|St. Joseph Hospital, Denver, Colorado, 80218, United States|Rose Medical Center, Denver, Colorado, 80220, United States|CCOP - Colorado Cancer Research Program, Denver, Colorado, 80222, United States|Swedish Medical Center, Englewood, Colorado, 80110, United States|North Colorado Medical Center, Greeley, Colorado, 80631, United States|Littleton Adventist Hospital, Littleton, Colorado, 80122, United States|Sky Ridge Medical Center, Lone Tree, Colorado, 80124, United States|Hope Cancer Care Center at Longmont United Hospital, Longmont, Colorado, 80501, United States|McKee Medical Center, Loveland, Colorado, 80539, United States|Parker Adventist Hospital, Parker, Colorado, 80138, United States|St. Mary - Corwin Regional Medical Center, Pueblo, Colorado, 81004, United States|Exempla Lutheran Medical Center, Wheat Ridge, Colorado, 80033, United States|Ella Milbank Foshay Cancer Center at Jupiter Medical Center, Jupiter, Florida, 33458, United States|Lakeland Regional Cancer Center at Lakeland Regional Medical Center, Lakeland, Florida, 33805, United States|CCOP - Mount Sinai Medical Center, Miami Beach, Florida, 33140, United States|MBCCOP - Medical College of Georgia Cancer Center, Augusta, Georgia, 30912,

United States|Nancy N. and J. C. Lewis Cancer and Research Pavilion at St. Joseph's/Candler, Savannah, Georgia, 31405, United States|Illinois CancerCare – Bloomington, Bloomington, Illinois, 61701, United States|Illinois CancerCare – Canton, Canton, Illinois, 61520, United States|Illinois CancerCare – Carthage, Carthage, Illinois, 62321, United States|Resurrection Medical Center, Chicago, Illinois, 60631, United States|Louis A. Weiss Memorial Hospital, Chicago, Illinois, 60640, United States|Decatur Memorial Hospital Cancer Care Institute, Decatur, Illinois, 62526, United States|Illinois CancerCare – Eureka, Eureka, Illinois, 61530, United States|Galesburg Clinic, PC, Galesburg, Illinois, 61401, United States|Illinois CancerCare – Havana, Havana, Illinois, 62644, United States|Illinois CancerCare – Kewanee Clinic, Kewanee, Illinois, 61443, United States|La Grange Memorial Hospital, La Grange, Illinois, 60525, United States|Illinois CancerCare – Macomb, Macomb, Illinois, 61455, United States|Illinois CancerCare – Monmouth, Monmouth, Illinois, 61462, United States|Good Samaritan Regional Health Center, Mount Vernon, Illinois, 62864, United States|Illinois CancerCare – Community Cancer Center, Normal, Illinois, 61761, United States|Advocate Christ Medical Center, Oak Lawn, Illinois, 60453-2699, United States|Oncology Hematology Associates of Central Illinois, PC – Ottawa, Ottawa, Illinois, 61350, United States|Illinois CancerCare – Pekin, Pekin, Illinois, 61603, United States|CCOP – Illinois Oncology Research Association, Peoria, Illinois, 61615, United States|Illinois CancerCare – Peru, Peru, Illinois, 61354, United States|Illinois CancerCare – Princeton, Princeton, Illinois, 61356, United States|West Suburban Center for Cancer Care, River Forest, Illinois, 60305, United States|Regional Cancer Center at Memorial Medical Center, Springfield, Illinois, 62781-0001, United States|Bloomington Hospital Regional Cancer Institute, Bloomington, Indiana, 47403, United States|Elkhart Clinic, LLC, Elkhart, Indiana, 46514-2098, United States|Michiana Hematology-Oncology, PC – Elkhart, Elkhart, Indiana, 46514, United States|Elkhart General Hospital, Elkhart, Indiana, 46515, United States|St. Francis Hospital Cancer Care Services, Indianapolis, Indiana, 46237, United States|Howard Community Hospital, Kokomo, Indiana, 46904, United States|Center for Cancer Therapy at LaPorte Hospital and Health Services, La Porte, Indiana, 46350, United States|Michiana Hematology-Oncology, PC – South Bend, Mishawaka, Indiana, 46545-1470, United States|Saint Joseph Regional Medical Center, Mishawaka, Indiana, 46545-1470, United States|Michiana Hematology Oncology PC – Plymouth, Plymouth, Indiana, 46563, United States|Reid Hospital & Health Care Services, Richmond, Indiana, 47374, United States|CCOP – Northern Indiana CR Consortium, South Bend, Indiana, 46601, United States|Memorial Hospital of South Bend, South Bend, Indiana, 46601, United States|Michiana Hematology Oncology PC – La Porte, Westville, Indiana, 46391, United States|Cedar Rapids Oncology Associates, Cedar Rapids, Iowa, 52403, United States|Medical Oncology and Hematology Associates – West Des Moines, Clive, Iowa, 50325, United States|CCOP – Iowa Oncology Research Association, Des Moines, Iowa, 50309, United States|Medical Oncology and Hematology Associates at John Stoddard Cancer

Center, Des Moines, Iowa, 50309, United States|Medical Oncology and Hematology Associates at Mercy Cancer Center, Des Moines, Iowa, 50314, United States|Covenant Cancer Treatment Center, Waterloo, Iowa, 50702, United States|Lucille P. Markey Cancer Center at University of Kentucky, Lexington, Kentucky, 40536-0093, United States|MBCCOP - LSU Health Sciences Center, New Orleans, Louisiana, 70112, United States|Mercy Hospital, Portland, Maine, 04101, United States|Mercy Medical Center, Baltimore, Maryland, 21202, United States|Alvin and Lois Lapidus Cancer Institute at Sinai Hospital, Baltimore, Maryland, 21215, United States|Suburban Hospital, Bethesda, Maryland, 20814, United States|Jordan Hospital Club Cancer Center, Plymouth, Massachusetts, 02360, United States|Battle Creek Health System Cancer Care Center, Battle Creek, Michigan, 49017, United States|Bay Regional Medical Center, Bay City, Michigan, 48708, United States|Mecosta County Medical Center, Big Rapids, Michigan, 49307, United States|Barbara Ann Karmanos Cancer Institute, Detroit, Michigan, 48201-1379, United States|Singh and Arora Hematology Oncology, PC, Flint, Michigan, 48532, United States|Butterworth Hospital at Spectrum Health, Grand Rapids, Michigan, 49503, United States|Lacks Cancer Center at Saint Mary's Health Care, Grand Rapids, Michigan, 49503, United States|West Michigan Cancer Center, Kalamazoo, Michigan, 49007-3731, United States|Great Lakes Cancer Institute - Lapeer Campus, Lapeer, Michigan, 48446, United States|Clemens Regional Medical Center, Mount Clemens, Michigan, 48043, United States|Mercy General Health Partners, Muskegon, Michigan, 49444, United States|Northern Michigan Hospital, Petoskey, Michigan, 49770, United States|Lakeland Regional Cancer Care Center - St. Joseph, Saint Joseph, Michigan, 49085, United States|Lakeside Cancer Specialists, PLLC, Saint Joseph, Michigan, 49085, United States|Providence Cancer Institute at Providence Hospital - Southfield Campus, Southfield, Michigan, 48075, United States|Munson Medical Center, Traverse City, Michigan, 49684, United States|Fairview Ridges Hospital, Burnsville, Minnesota, 55337, United States|Mercy and Unity Cancer Center at Mercy Hospital, Coon Rapids, Minnesota, 55433, United States|Fairview Southdale Hospital, Edina, Minnesota, 55435, United States|Mercy and Unity Cancer Center at Unity Hospital, Fridley, Minnesota, 55432, United States|Hutchinson Area Health Care, Hutchinson, Minnesota, 55350, United States|HealthEast Cancer Care at St. John's Hospital, Maplewood, Minnesota, 55109, United States|Virginia Piper Cancer Institute at Abbott - Northwestern Hospital, Minneapolis, Minnesota, 55407, United States|Hennepin County Medical Center - Minneapolis, Minneapolis, Minnesota, 55415, United States|Humphrey Cancer Center at North Memorial Outpatient Center, Robbinsdale, Minnesota, 55422-2900, United States|CCOP - Metro-Minnesota, Saint Louis Park, Minnesota, 55416, United States|Park Nicollet Cancer Center, Saint Louis Park, Minnesota, 55416, United States|Regions Hospital Cancer Care Center, Saint Paul, Minnesota, 55101, United States|United Hospital, Saint Paul, Minnesota, 55102, United States|St. Francis Cancer Center at St. Francis Medical Center, Shakopee, Minnesota, 55379, United States|Lakeview Hospital, Stillwater, Minnesota, 55082, United States|

Ridgeview Medical Center, Waconia, Minnesota, 55387, United States| Willmar Cancer Center at Rice Memorial Hospital, Willmar, Minnesota, 56201, United States|Minnesota Oncology - Woodbury, Woodbury, Minnesota, 55125, United States|Central Care Cancer Center, Bolivar, Missouri, 65613, United States|Southeast Cancer Center, Cape Girardeau, Missouri, 63703, United States|Saint Luke's Hospital, Chesterfield, Missouri, 63017, United States|Goldschmidt Cancer Center, Jefferson City, Missouri, 65109, United States|Freeman Cancer Institute, Joplin, Missouri, 64804, United States|Missouri Baptist Cancer Center, Saint Louis, Missouri, 63131, United States|Mercy Hospital St. Louis, Saint Louis, Missouri, 63141, United States|CCOP - Montana Cancer Consortium, Billings, Montana, 59101, United States| Hematology-Oncology Centers of the Northern Rockies - Billings, Billings, Montana, 59102, United States|Billings Clinic - Downtown, Billings, Montana, 59107-7000, United States|Bozeman Deaconess Cancer Center, Bozeman, Montana, 59715, United States|Big Sky Oncology, Great Falls, Montana, 59405-5309, United States|Sletten Cancer Institute at Benefis Healthcare, Great Falls, Montana, 59405, United States| Kalispell Regional Medical Center, Kalispell, Montana, 59901, United States|Montana Cancer Specialists at Montana Cancer Center, Missoula, Montana, 59807-7877, United States|Good Samaritan Cancer Center at Good Samaritan Hospital, Kearney, Nebraska, 68848-1990, United States| Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, 03756-0002, United States|Foundation Medical Partners, Nashua, New Hampshire, 03060, United States|Oncology Center at St. Joseph Hospital, Nashua, New Hampshire, 03060, United States| Dizzy Gillespie Cancer Institute at Englewood Hospital and Medical Center, Englewood, New Jersey, 07631, United States|Monmouth Medical Center, Long Branch, New Jersey, 07740-6395, United States|UMDNJ University Hospital, Newark, New Jersey, 07103, United States|Franklin & Edith Scarpa Regional Cancer Center at South Jersey Healthcare, Vineland, New Jersey, 08360, United States|Lovelace Medical Center - Downtown, Albuquerque, New Mexico, 87102, United States|Presbyterian Cancer Treatment Center at Presbyterian Kaseman Hospital, Albuquerque, New Mexico, 87110, United States|University of New Mexico Cancer Center, Albuquerque, New Mexico, 87131-5636, United States|Bassett Healthcare Regional Cancer Program at Mary Imogene Bassett Hospital, Cooperstown, New York, 13326, United States|Charles R. Wood Cancer Center at Glens Falls Hospital, Glens Falls, New York, 12801, United States|Nalitt Cancer Institute at Staten Island University Hospital, Staten Island, New York, 10305, United States|Park Ridge Health, Henderson, North Carolina, 28792, United States|McDowell Cancer Center at Akron General Medical Center, Akron, Ohio, 44307, United States| Summa Center for Cancer Care at Akron City Hospital, Akron, Ohio, 44309-2090, United States|Aultman Cancer Center at Aultman Hospital, Canton, Ohio, 44710-1799, United States|David L. Rike Cancer Center at Miami Valley Hospital, Dayton, Ohio, 45409, United States|Samaritan North Cancer Care Center, Dayton, Ohio, 45415, United States|CCOP - Dayton, Dayton, Ohio, 45420, United States|Blanchard Valley Medical Associates, Findlay, Ohio, 45840, United States|Middletown Regional

Hospital, Franklin, Ohio, 45005-1066, United States|Wayne Hospital, Greenville, Ohio, 45331, United States|Charles F. Kettering Memorial Hospital, Kettering, Ohio, 45429, United States|UVMC Cancer Care Center at Upper Valley Medical Center, Troy, Ohio, 45373-1300, United States|United States Air Force Medical Center - Wright-Patterson, Wright-Patterson Air Force Base, Ohio, 45433-5529, United States|Ruth G. McMillan Cancer Center at Greene Memorial Hospital, Xenia, Ohio, 45385, United States|Cancer Care Associates - Norman, Norman, Oklahoma, 73071, United States|Cancer Care Associates - Mercy Campus, Oklahoma City, Oklahoma, 73120, United States|Natalie Warren Bryant Cancer Center at St. Francis Hospital, Tulsa, Oklahoma, 74136, United States|Geisinger Cancer Institute at Geisinger Health, Danville, Pennsylvania, 17822-0001, United States|Geisinger Hazleton Cancer Center, Hazleton, Pennsylvania, 18201, United States|Joan Karnell Cancer Center at Pennsylvania Hospital, Philadelphia, Pennsylvania, 19107, United States|Cancer Center at Phoenixville Hospital, Phoenixville, Pennsylvania, 19460, United States|Guthrie Cancer Center at Guthrie Clinic Sayre, Sayre, Pennsylvania, 18840, United States|Geisinger Medical Group - Scenery Park, State College, Pennsylvania, 16801, United States|Frank M. and Dorothea Henry Cancer Center at Geisinger Wyoming Valley Medical Center, Wilkes-Barre, Pennsylvania, 18711, United States|Keyserling Cancer Center at Beaufort Memorial Hospital, Beaufort, South Carolina, 29902, United States|St. Francis Hospital, Greenville, South Carolina, 29601, United States|Gibbs Cancer Center - Pelham, Greer, South Carolina, 29651, United States|Rapid City Regional Hospital, Rapid City, South Dakota, 57701, United States|Martha Jefferson Hospital Cancer Care Center, Charlottesville, Virginia, 22901, United States|Green Bay Oncology, Limited at St. Vincent Hospital Regional Cancer Center, Green Bay, Wisconsin, 54301-3526, United States|Green Bay Oncology, Limited at St. Mary's Hospital, Green Bay, Wisconsin, 54303, United States|Mercy Regional Cancer Center, Janesville, Wisconsin, 53547, United States|Gundersen Lutheran Center for Cancer and Blood, La Crosse, Wisconsin, 54601, United States|D.N. Greenwald Center, Mukwonago, Wisconsin, 53149, United States|Regional Cancer Center at Oconomowoc Memorial Hospital, Oconomowoc, Wisconsin, 53066, United States|Waukesha Memorial Hospital Regional Cancer Center, Waukesha, Wisconsin, 53188, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT01225978
Study Title: Refining Information Technology Support for Genetics in Medicine
Study URL: https://beta.clinicaltrials.gov/study/NCT01225978
Acronym: RISGIM
Study Status: UNKNOWN
Brief Summary: The clinical use of genetic testing is expanding and, as a result, the number of variants identified in patients is growing. Knowledge of the clinical impact of these variants improves over time. However, the combination of more testing and the rapid evolution of genetic knowledge make it impossible for clinicians to fully account

for the latest implications of their patients' genetic profiles as patient care decisions are made. This proposed study plans to enhance and evaluate IT infrastructure developed to provide timely genetic variant updates and patient search functionality to clinicians to assist in optimizing patient care.
Study Results: NO
Conditions: Hypertrophic Cardiomyopathy|Hearing Loss|Cancer
Interventions: DEVICE: GeneInsight Clinic (GIC)
Primary Outcome Measures: Efficiency of Obtaining Updated Genetic Variant Information, Phone and email logging procedures will be implemented before study onset to establish a solid baseline. Laboratory staff will log each time they receive a phone call or email requesting updated information on a genetic variant. These logs will be maintained throughout the study period even once the GIC tool becomes available.

System auditing processes will capture data on when genetic variants are updated, when alerts are sent, and clinician accesses to online screens.

Centralized system data will be evaluated to track usage of the GIC patient search functions, using a flagging approach., Continuous across 21 months
Secondary Outcome Measures: Perception of Impact of Variant Update Significance Level Alerting on Clinician Workload, Surveys will be constructed that ask treating clinicians about their experience with using the GIC and its perceived impact on workload. The surveys will be distributed both pre and post implementation of the GIC system to provide comparative data. Interviews will also be conducted, transcribed, coded for themes, and open-ended comments will be classified to reflect issues relating to clinician experience with the GIC. Call logs and centralized system audit information which can track time spent using the tool will be used to determine time and effort required to get updated information., Continuous Across 21 months|Perception of Impact of Variant Update Significance Level Alerting on Clinician Satisfaction, Surveys will be constructed that ask treating clinicians about their satisfaction with using the GIC. The surveys will be distributed both pre and post implementation of the GIC system to provide comparative data. Interviews will also be conducted, transcribed, coded for themes, and open-ended comments will be classified to reflect issues relating to clinician experience with the GIC. Call logs and centralized system audit information which can track time spent using the tool will be used to determine time and effort required to get updated information., Continuous Across 21 months|Perception of Impact of Variant Update Significance Level Alerting on Clinical Care, Surveys will be constructed that ask treating clinicians about their experiences with using the GIC and its perceived impact on clinical care. The surveys will be distributed Both pre and post implementation of the GIC system to provide comparative data. Interviews will also be conducted, and those along

with open-ended comments will be classified to reflect issues relating to clinician experience with the GIC. Call logs and centralized system audit information which can track time spent using the tool will be used to determine time and effort required to get updated information., Continuous Across 21 months
Other Outcome Measures:
Sponsor: Brigham and Women's Hospital
Collaborators: National Institutes of Health (NIH)|National Library of Medicine (NLM)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 40
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2009P002147|1RC1LM010526
Start Date: 2009-09
Primary Completion Date: 2012-12
Completion Date: 2014-12
First Posted: 2010-10-21
Results First Posted:
Last Update Posted: 2014-01-24
Locations: Brigham and Women's Hospital Cardiovascular Genetics Center, Boston, Massachusetts, 02115, United States|Children's Hospital Boston's Cardiovascular Genetics Clinic, Boston, Massachusetts, 02115, United States|Children's Hospital Boston's Ear, Nose, and Throat Clinic, Boston, Massachusetts, 02115, United States|Massachusetts General Hospital Division of Pulmonary Oncology, Boston, Massachusetts, 02115, United States|Massachusetts General Hospital's Diagnostic Molecular Pathology Laboratory, Boston, Massachusetts, 02115, United States|Massachusetts General Hospital's Hypertrophic Cardiomyopathy Clinic, Boston, Massachusetts, 02115, United States|Massachusetts General Hospital's Medical Genetics Clinic, Boston, Massachusetts, 02115, United States|University of Michigan Cardiovascular Center, Ann Arbor, Michigan, 48109, United States|Fred A. Litwin Centre for Clinical Genetics and Genomic Medicine, Toronto, Ontario, M5G 2C4, Canada
Study Documents:

NCT Number: NCT01370278
Study Title: Clearance Of Mucus In Stents (COMIS)
Study URL: https://beta.clinicaltrials.gov/study/NCT01370278
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The goal of this clinical research study is to compare the effects of sodium bicarbonate to normal saline when used for clearing mucus blockage in patients with airway stents.
Study Results: NO
Conditions: Lung Neoplasms|Respiratory Failure|Pneumonia|Acute

Coronary Syndromes|Unstable Angina|Myocardial Infarction|Cardiac Arrhythmia|Thromboembolic Disease
Interventions: OTHER: Normal Saline|OTHER: Sodium Bicarbonate
Primary Outcome Measures: Percentage of obstruction resolution as Good or Excellent, Response/efficacy of sodium bicarbonate versus normal saline in airway stents graded using scale. Percentage of obstruction resolution (relative to initial stent lumen obstruction by mucus): Good response 51-75% clearance; and Excellent 76 - 100% clearance. The Mantel-Haenszel chi-square test stratified by degree of lumen obstruction at study enrollment used to compare response (good or excellent obstruction resolution) rates between treatment arms., Baseline to 7 days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 43
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: DIAGNOSTIC
Other IDs: 2010-0990|NCI-2011-01119
Start Date: 2011-06-16
Primary Completion Date: 2023-06-30
Completion Date: 2023-06-30
First Posted: 2011-06-09
Results First Posted:
Last Update Posted: 2023-04-11
Locations: University of Texas MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents:

NCT Number: NCT05200078
Study Title: Deep Inspiration Breath-hold Radiotherapy for Left-sided Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05200078
Acronym:
Study Status: RECRUITING
Brief Summary: Postoperative breast radiotherapy (RT) has been associated with increased risk of heart toxicity. However, there is a lack of knowledge for radiation-induced early cardiovascular injury, especially for hypofractionated RT. This study aims to prospectively detect and predict early clinical or subclinical cardiac events in women undergoing adjuvant RT for breast cancer.
Study Results: NO
Conditions: Breast Cancer|Cardiac Event

Interventions: DEVICE: Deep inspiration breath-hold technique
Primary Outcome Measures: Incidence of clinical or subclinical cardiac injury, predefined cardiac events, two years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Shu lian Wang
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 166
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2020-2-4023
Start Date: 2021-09-01
Primary Completion Date: 2022-06-30
Completion Date: 2023-06-30
First Posted: 2022-01-20
Results First Posted:
Last Update Posted: 2022-01-20
Locations: Cancer Hospital, Chinese Academy of Medical Sciences, Beijing, 100021, China
Study Documents:

NCT Number: NCT03474458
Study Title: A Trial of Doxycycline vs. Standard Supportive Therapy in Newly-diagnosed Cardiac AL Amyloidosis Patients Undergoing Bortezomib-based Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT03474458
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Systemic amyloidoses are rare diseases affecting approximately 1 in 100,000 persons each year.

In systemic amyloidoses abnormal proteins deposit in bodily organs and severely impair their function, causing death if not treated effectively. Light chain (AL) amyloidosis is caused by a usually small population of plasma cells (the cells that produce antibodies). These cells produce part of antibodies, the light chains (LC) that form amyloid deposits. Almost every organ, with the exception of the brain, can be affected by AL amyloidosis. The heart is involved in three fourths of patients and is responsible for almost all the deaths occurring in the first 6 months after diagnosis. Current therapy of AL amyloidosis is based on drugs targeting the plasma cells producing the amyloid-forming LC. At present, most patients receive a powerful anti-plasma cell drug, bortezomib, as part of their initial treatment. However, bortezomib-based therapy, can improve heart involvement only in less than one third of patients with AL amyloidosis, and many patients (approximately one third) still die within 12 months from

diagnosis. Early cardiac deaths remain an acute unmet need and the major determinant of overall outcome in this disease. Thus, there is the need of alternative means to treat heart involvement in AL amyloidosis. Doxycycline is a widely used, well tolerated, antibiotic that has been marketed for decades and used to treat a number of different infectious diseases caused by bacteria. This molecule has been extensively studied in the laboratory, in animal models and, more recently, in small studies involving patients, for its potential of improving cardiac damage in amyloidosis. These studies showed that doxycycline disrupts amyloid deposits, reduces the amyloid load in a mouse model, and counteracts the toxicity exerted by amyloid-forming LCs on C. elegans, a worm whose pharynx is used as a model resembling human heart. In a small clinical study, doxycycline was given to patients with cardiac AL amyloidosis during treatment for their underlying plasma cell disease. This resulted in a remarkable improvement of survival compared to "matched historical controls" (i.e. similar patients who had received only anti-plasma cell therapy without doxycycline in the past). Based on these promising preliminary results, we designed the present clinical trial to assess whether the addition of doxycycline to anti-plasma cell therapy can improve survival in patients with cardiac AL amyloidosis who were not previously treated. The rate of survival at 12 months will be compared in patients receiving doxycycline and in controls receiving standard antibiotic therapy, together with anti-plasma cell therapy. Patients will be assessed for parameters of plasma cell disease, heart involvement and possible involvement of other organs, as well as for quality of life. To make sure that patients who will receive doxycycline and those who will not have comparable severity of cardiac disease, patients will be stratified according to the stage of cardiac involvement. Patients with very advanced heart dysfunction will not be enrolled in the trial, because preliminary data indicate that doxycycline is of little or no benefit in these subjects. Patients will be randomized to receive doxycycline or standard antibiotics in combination with anti-plasma cell therapy. Bortezomib-based treatment directed against plasma cells will be delivered according to each participating institutions' guidelines. Doxycycline will be administered at a dosage of 100 mg two times a day, which is usual in the treatment of bacterial diseases. Standard antibiotics will be delivered according to each participating institutions' guidelines (provided that drugs of the same class as doxycycline are not administered) in the control arm. Patients will be provided a diary to record possible adverse events and will be instructed accordingly. Patients will be evaluated at trial centers every 2 months for treatment efficacy and toxicity. In case of unsatisfactory response second-line therapy will be initiated. In the absence of unacceptable toxicity, doxycycline administration will be continued for the entire duration of follow-up (12 months).
Study Results: NO
Conditions: Cardiac AL Amyloidosis
Interventions: DRUG: Doxycycline|DRUG: Standard of care therapy

Primary Outcome Measures: proportion surviving, proportion surviving, 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: IRCCS Policlinico S. Matteo
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 19
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: AC-012-EU
Start Date: 2019-02-11
Primary Completion Date: 2022-05-30
Completion Date: 2022-05-30
First Posted: 2018-03-22
Results First Posted:
Last Update Posted: 2022-05-05
Locations: Cross Cancer Insititue, University of Alberta, Edmonton, Canada|CHU Limoges, Limoges, France|University Hospital, Heidelberg, Germany|Alexandra Hospital, Athens, Greece|Fondazione IRCCS Policlinico San Matteo, Pavia, 27100, Italy|Hospital Clinic de Barcelona, Barcelona, Spain|Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey|University College London Medical School and Royal Free Hospital, London, United Kingdom
Study Documents:

NCT Number: NCT03885258
Study Title: Melatonin Replacement Therapy in Pinealectomized Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT03885258
Acronym:
Study Status: COMPLETED
Brief Summary: This is an open-label, single-arm, single-center, proof-of-concept study to assess the effects of melatonin on cardiac autonomic activity in melatonin non-proficient pinealectomized patients.
Study Results: NO
Conditions: Pineal Tumor
Interventions: DRUG: Melatonin Replacement Therapy
Primary Outcome Measures: cardiac autonomic function - heart rate variability, The cardiac autonomic function was determined through heart rate variability (HRV) measures after polysomnography ECG recordings., 9 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Sao Paulo
Collaborators:

Sex:
Age: CHILD, ADULT, OLDER_ADULT
Phases: EARLY_PHASE1
Enrollment: 5
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 30460114.5.0000.0068
Start Date: 2017-05-02
Primary Completion Date: 2018-11-30
Completion Date: 2019-02-28
First Posted: 2019-03-21
Results First Posted:
Last Update Posted: 2019-03-21
Locations: University of São Paulo, São Paulo, Sao Paulo, 05508-000, Brazil
Study Documents:

NCT Number: NCT01742702
Study Title: HaemoDYNAMICs in Primary and Secondary Hypertension
Study URL: https://beta.clinicaltrials.gov/study/NCT01742702
Acronym: DYNAMIC
Study Status: RECRUITING
Brief Summary: The primary aim of the present study was to examine the haemodynamic changes in primary hypertension and secondary hypertension (renal diseases, endocrine diseases, obesity-associated hypertension) with a non-invasive haemodynamic measurement protocol utilizing radial pulse wave analysis and whole-body impedance cardiography in both supine position and during head-up tilt. For comparison, haemodynamics of subjects with chronic fatigue syndrome will also be recorded.
Study Results: NO
Conditions: Primary Hypertension|Secondary Hypertension|Aortic Stenosis|Renal Insufficiency
Interventions: DRUG: Nitroglycerin 0.25 mg (single dose, no longer given since January 2017)|DRUG: Salbutamol 400 µg (single dose, no longer given since January 2017)|DRUG: L-arginine (10 min infusion, no longer given since January 2017)|DIETARY_SUPPLEMENT: Liquorice (2 weeks, glycyrrhizin 290-370 mg daily, no longer given since 2012)|DIETARY_SUPPLEMENT: Small milk casein-derived polypeptides (12 weeks daily, recordings completed 2011)|DRUG: Bisoprolol (5 mg daily for 3 weeks, recordings completed 2011)
Primary Outcome Measures: Change in haemodynamic variables during the follow-up, Haemodynamic measurements are performed at baseline, and after approximately 10 years of follow-up, baseline, ten years|Cardiovascular events, All cardiovascular events during follow-up, ten years of follow-up
Secondary Outcome Measures: Haemodynamic response to head-up tilt and research drugs, Rapid haemodynamic responses are assessed during the

same measurement session (the response to head-up tilt and to research drugs salbutamol, nitroglycerin and L-arginine), 0, 5, 10, 15, 20, 25 and 30 minutes|Haemodynamic response to bisoprolol or dietary supplements (liquorice, milk casein-derived polypeptides), The change in haemodynamic variables after daily consumption of liquorice (2 weeks); bisoprolol (3 weeks); small milk casein-derived polypeptides (12 weeks), baseline and after 2 weeks (liquorice); 3 weeks (bisoprolol), or 12 weeks (polypeptides)|Haemodynamic changes induced by Ironman competition, Recordings are performed during normal conditions (training peroid) and after completion of a full-length Ironman competition, Recordings within 2 hours after completion Ironman competition, 12-18 hours later, and within 1-4 before or 4-8 weeks after the competition
Other Outcome Measures:
Sponsor: Tampere University
Collaborators: Finnish Foundation for Cardiovascular Research|Paavo Nurmi Foundation|Sigrid Jusélius Foundation|Finnish Cultural Foundation|Tampere Tuberculosis Foundation|Medical Research Fund of the Tampere University Hospital, Finland|Aarne Koskelo Foundation|Finnish Medical Foundation|Finnish Kidney Foundation|Päivikki and Sakari Sohlberg Foundation, Finland
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 2000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: R06086M|2006-002065-39|2009-014542-29|R07110M|R07053M|R08012|R09103M|R10056|R06086M|R21094
Start Date: 2006-05-25
Primary Completion Date: 2025-12-31
Completion Date: 2025-12-31
First Posted: 2012-12-05
Results First Posted:
Last Update Posted: 2021-08-19
Locations: Tampere University, Tampere, Southern Finland, 33014, Finland|Tampere University Hospital, Tampere, Southern Finland, 33521, Finland
Study Documents:

NCT Number: NCT02052102
Study Title: Study to See Whether Breath-Hold Techniques During RT Are Effective in Helping to Improve Sparing of the Heart
Study URL: https://beta.clinicaltrials.gov/study/NCT02052102
Acronym:
Study Status: UNKNOWN
Brief Summary: The study hopes to determine whether patients with left-sided breast cancer are at an increased risk of cardiac changes due to radiation to the breast +/- Anthracycline-based chemotherapy

+/- Herceptin and whether a deep inspiration breath hold (DIBH) technique during radiotherapy treatments would further reduce dosimetric dose to the heart as compared to the conventional free breathing (FB) technique thus reducing cardiac toxicity as measured by cardiac MRI using left ventricular end-diastolic volume (LVEDV) as a metric. Bio fluid samples will also be collected to investigate specific biomarkers of breast cancer: BNP, PIIINP and CITP
Study Results: NO
Conditions: Breast Cancer|Adverse Effect of Radiation Therapy
Interventions: RADIATION: Radiation therapy
Primary Outcome Measures: Radiation related acute and long term functional changes in patients treated with deep-inspiration breath hold compared to free-breathing technique, Using MRI-based cardiac functional imaging to measure radiation-related acute and long term cardiac functional changes in patients treated with deep-inspiration breath-hold (DIBH) compared to free breathing (FB) treatment, 12 months
Secondary Outcome Measures: Radiation dosimetric comparison, Radiation dosimetry is the accurate calculation and measurement of radiation doses received by tissue resulting from the exposure to radiation. A radiation dosimetric comparison will be performed between the deep inspiration breath hold (DIBH) technique treatment plan and the free breathing (FB) technique treatment plan to explore sparing of cardiac sub-structures from radiation, if any, 12 months
Other Outcome Measures:
Sponsor: AHS Cancer Control Alberta
Collaborators: Cross Cancer Institute
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 63
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: Breast-26159
Start Date: 2014-10
Primary Completion Date: 2017-02
Completion Date: 2017-03
First Posted: 2014-01-31
Results First Posted:
Last Update Posted: 2017-01-06
Locations: Cross Cancer Institute, Edmonton, Alberta, T6G 1Z2, Canada
Study Documents:

NCT Number: NCT02858778
Study Title: Timing of Acute Palliative Care Consultation in Critically Ill Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02858778
Acronym:

Study Status: UNKNOWN
Brief Summary: A prospective randomized controlled trial studying the ordering of palliative care consultations in the emergency department (Ig) versus later palliative care consultations in the hospital--ICU or hospital ward(Cg). Patients will be randomly allocated to Ig or Cg with a 1:1 ratio.
Study Results: NO
Conditions: Multiple Organ Failure|End Stage Cardiac Failure|End Stage Chronic Obstructive Airways Disease|Chronic Kidney Disease Stage 5|Hepatic Encephalopathy|Sepsis|Dementia|Multiple Sclerosis|Parkinson's Disease|In-Hospital Cardiac Arrest|Solid Organ Cancer
Interventions: OTHER: Early order of palliative care consultation
Primary Outcome Measures: The difference in the percentage of patients with a completed advance directive (AD) in Ig vs.Cg, 1 year
Secondary Outcome Measures: The proportion of billed CMS ACP-CPT codes in Ig vs. Cg, The proportion of patients who received an ACP CMS billing codes (which took effect in January 2016), in Ig vs. Cg will be evaluated using one or both of the new CPT codes for Advance care planning (ACP) services...including the explanation and discussion of advance directives such as standard forms (with the completion of such forms, when performed) by the physician or other qualified health profession; first 30 (15-45)minutes, face to face with the patients, family member(s) and/or surrogate Code 99497; and each additional 30 (46-75 minutes)-Code 99498 (Federal Register, 2015)., 30 days from enrolled patients' hospital discharge|Matches of care received to patient-specific preferences in Ig vs. Cg, The investigators will align treatment preferences with medical orders, replicated as reported in the study by Mack et al. Proportions of patients coded as having a match will be compared across the treatment and control groups. For everyone who gets ACP during the study, patients or their surrogates will be asked by a member of the care team-either palliative care if they are consulted, or the hospital based care team if they are not: "If you could choose, would you prefer (a) treatment that focuses on attempting to extend your time as much as possible, even if doing so means more pain and discomfort, or (b) a plan of care that focuses on relieving pain and discomfort and improving quality of life, even though that may mean not living as long., 1 year|Patient/family satisfaction with care in Ig vs. Cg, This outcome will be measured on a continuous scale. The net-promoter score will be measured at baseline (at randomization) and at hospital discharge for a change in value. It is measured on a scale of 1-10. Whoever signs the consent (patient of LAR) will be asked the net promoter score, and that will be reassessed by them at discharge, unless the patient has died-and the variable will then be recorded as missing. The PSQ will be administered by research assistants at the time of the patient's discharge. If the patient is incapacitated, then it will be asked of the patient's closest family caregiver. So PSQ is only at discharge of patient or available, most involved, family caregiver., Baseline|Amount of hospice referrals in Ig vs. Cg, 1 year|Hospital total direct costs for the index visit in Ig vs. Cg, 1 year|Hospital and ICU length

of stay in Ig vs. Cg, 1 year|Average days in hospice in Ig vs. Cg, 1 year|Hospital margin contribution for the index visit in Ig vs. Cg, 1 year|Time to consultation in Ig vs. Cg groups, 1 year
Other Outcome Measures:
Sponsor: Wayne State University
Collaborators: Blue Cross Blue Shield of Michigan Foundation
Sex: ALL
Age: OLDER_ADULT
Phases: NA
Enrollment: 120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: BCBSMF PSACO
Start Date: 2016-06
Primary Completion Date: 2017-01
Completion Date:
First Posted: 2016-08-08
Results First Posted:
Last Update Posted: 2016-08-08
Locations: Detroit Medical Center Detroit Receiving Hospital, Detroit, Michigan, 48201, United States|Detroit Medical Center Sinai Grace Hospital, Detroit, Michigan, 48235, United States
Study Documents:

NCT Number: NCT01032278
Study Title: Effectiveness of Using Biomarkers to Detect and Identify Cardiotoxicity and Describe Treatment (PREDICT)
Study URL: https://beta.clinicaltrials.gov/study/NCT01032278
Acronym:
Study Status: UNKNOWN
Brief Summary: The goal of this clinical research study is to learn if certain biomarker testing on blood samples can help to detect heart damage that may occur during chemotherapy. Biomarkers are chemical "markers" found in the blood that may be related to heart function. High levels of these markers may be linked with heart problems such as heart damage.
Study Results: NO
Conditions: Cardiac Toxicity|Unspecified Adult Solid Tumor, Protocol Specific
Interventions: OTHER: Laboratory Biomarker Analysis|BEHAVIORAL: Questionnaires
Primary Outcome Measures: Use of Cardiac Biomarkers, B-type Natriuretic Peptide (BNP) and Troponin I (TnI), for Detecting Cardiotoxicity in Patients Undergoing Anthracycline-based Chemotherapy, Cardiotoxicity defined as presentation of one or more cardiac events within 12 months of initiation of chemotherapy. Cardiac event defined as any new symptomatic cardiac arrhythmia, acute

coronary syndrome, symptomatic HF, development of asymptomatic left ventricular dysfunction (defined as left ventricular ejection fraction (LVEF) reduction of 10% to less than 50% or a decrease of greater than 15% from baseline), or sudden cardiac death (defined as rapid and unexpected death from cardiac causes with or without known underlying heart disease). BNP greater than 200 pg/ml is considered abnormal. Troponin I greater than 0.4 ng/ml is also considered abnormal. Patients having at least one abnormal evaluation preceding cardiotoxicity for either biomarker (i.e., one abnormal troponin or one abnormal BNP assessments) classified as having an abnormal test.

Primary analysis performed using data from all subjects with at least one post baseline biomarker measure for BNP and/or troponin I., 12 months
Secondary Outcome Measures: Sensitivity and specificity of serial LVEF measurements in detecting cardiotoxicity, 12 months|Clinical management and outcomes of patients with abnormal cardiac biomarkers or clinically defined cardiotoxicity during chemotherapy, 12 months|Supportive utility of patient-reported symptoms for the development of cardiac-related toxicity, 12 months
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators: Alere San Diego
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 597
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: CDR0000660615|MDA-2007-0914A|CDR0000660615|NCI-2011-01466
Start Date: 2011-01-25
Primary Completion Date: 2020-01
Completion Date: 2021-01
First Posted: 2009-12-15
Results First Posted:
Last Update Posted: 2019-05-21
Locations: Lyndon B. Johnson General Hospital (LBJ), Houston, Texas, 77026, United States|University of Texas MD Anderson Cancer Center, Houston, Texas, 77030-4009, United States
Study Documents:

NCT Number: NCT04298372
Study Title: Frontline Lenalidomide for AL Amyloidosis Involving Myocardium
Study URL: https://beta.clinicaltrials.gov/study/NCT04298372
Acronym:
Study Status: UNKNOWN
Brief Summary: This phase II clinical trial aimed at influencing the

improvement of major organ functions, especially the objective response rate, in Amyloid light-chain amyloidosis involving myocardium.
Study Results: NO
Conditions: Amyloidosis Cardiac
Interventions: DRUG: Lenalidomide 25mg
Primary Outcome Measures: Objective response rate (ORR), ORR is defined as the percentage of subjects with evidence of a confirmed CR(complete response), VGPR(very good partial response) or PR(partial response), After completion of 12 cycles of treatment(each cycle is 28 days)
Secondary Outcome Measures: Change of the cardiac function, Change of the cardiac function will be observed with the NTproBNP levels., At Baseline and the end of each 1-12 cycles (baseline and 1-12 months)|Change of the renal function, Change of the renal function will be observed with the 24h urine protein levels., At Baseline and the end of each 1-12 cycles (baseline and 1-12 months)|Change of the hepatic function, Change of the hepatic function will be observed with the alkaline phophatase levels., At Baseline and the end of each 1-12 cycles (baseline and 1-12 months)
Other Outcome Measures:
Sponsor: Seoul National University Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 30
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 1810-089-981
Start Date: 2019-02-20
Primary Completion Date: 2021-03-15
Completion Date: 2021-12-31
First Posted: 2020-03-06
Results First Posted:
Last Update Posted: 2020-03-06
Locations: Seoul National University Hospital, Seoul, 03080, Korea, Republic of
Study Documents:

NCT Number: NCT05298072
Study Title: Identification of Novel Inflammation-related Biomarkers for Early Detection of Anthracycline-induced Cardiotoxicity in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05298072
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: This study aims to identify possible set of

inflammatory biomarkers before, during and after anthracycline-based chemotherapy in breast cancer patients to identify (sub)clinical chemotherapy-related cardiac dysfunctionCRCD to identify patients who would benefit from additional cardioprotective therapy.
Study Results: NO
Conditions: Cardiotoxicity|Breast Cancer|Heart Failure
Interventions:
Primary Outcome Measures: Cardiotoxicity during observational period, Defined according to IC-OS 2021 Consensus Criteria, continuous evaluation during observational period of 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University Hospital, Essen
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 180
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 22-10590-BO
Start Date: 2022-04
Primary Completion Date: 2023-04
Completion Date: 2023-12
First Posted: 2022-03-28
Results First Posted:
Last Update Posted: 2022-03-28
Locations:
Study Documents:

NCT Number: NCT03760588
Study Title: Prevention of Cardiac Dysfunction During Breast Cancer Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT03760588
Acronym: PRADAII
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Breast cancer is the most common cancer among women. The modern post-surgery treatment with chemotherapy, immunotherapy, radiation and hormone therapy has improved the overall 5-years survival drastically. However, an unwanted effect of the post-surgery treatment is its potentially deleterious effect on the heart resulting in cardiac dysfunction. Angiotensin antagonists are used as part of the heart failure treatment. In smaller studies angiotensin antagonists have shown to have a cardioprotective effect during breast cancer treatment. Sacubitril/valsartan is a potent drug that in addition to an angiotensin antagonist contains a neprilysin inhibitor. Sacubitril/valsartan has proved to be superior to enalapril in chronic heart failure. In this randomized placebo controlled double blind trial we hypothesize that sacubitril/valsartan used concomitantly

during anthracycline containing chemotherapy for breast cancer treatment prevents cardiac dysfunction as measured by cardiac magnetic resonance imaging (CMR). PRADA II is a Norwegian multicenter trial intending to recruit 214 patients and follow them for 18 months with CMR, cardiac ultrasound, blood samples, functional capacity tests and health related quality of life questionnaires.
Study Results: NO
Conditions: Breast Cancer Female|Heart Failure
Interventions: DRUG: Sacubitril/valsartan
Primary Outcome Measures: Change in left ventricular ejection fraction by cardiovascular magnetic resonance, From randomization to end of blinded therapy (18 months)
Secondary Outcome Measures: Change in left ventricular ejection fraction by echocardiography, From randomization to end of blinded therapy (18 months)|Change in left ventricular systolic global longitudinal strain by echocardiography, From randomization to end of blinded therapy (18 months)|Change in left ventricular systolic global longitudinal strain by cardiovascular magnetic resonance (CMR), From randomization to end of blinded therapy (18 months)|Change in left ventricular end-systolic volume measured by CMR, From randomization to end of blinded therapy (18 months)|Incidence of a significant reduction in left ventricular systolic function measured by CMR or echocardiography, An absolute reduction in LVEF ≥ 5% by CMR or a relative percentage reduction of global longitudinal strain (GLS) \> 15%, From randomization to end of blinded therapy (18 months)|Incidence of cardiotoxicity measured by CMR or echocardiography, Absolute reduction in LVEF ≥ 10% to a value below 50% as measured either by CMR or Echocardiography, or incidence of clinical heart failure, From randomization to end of blinded therapy (18 months)|Change in circulating cardiac biomarkers, Cardiac biomarkers defined as cardiac troponins I and T measured by high sensitivity assays (hs-TnI and hs-TnT) and N-terminal proB-type natriuretic peptide (NT-proBNP), From randomization to end of blinded therapy (18 months)
Other Outcome Measures: Incidence of adverse events and serious adverse events, From randomization to end of blinded therapy (18 months)
Sponsor: Torbjorn Omland
Collaborators: University Hospital, Akershus|Oslo University Hospital|University Hospital of North Norway|St. Olavs Hospital|Helse Stavanger HF|Klinbeforsk|Norwegian Cancer Society|Novartis
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 214
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 2017-004909-41

Start Date: 2019-01-14
Primary Completion Date: 2024-09-14
Completion Date: 2025-09-14
First Posted: 2018-11-30
Results First Posted:
Last Update Posted: 2023-03-17
Locations: Akershus University Hospital, Lørenskog, 1478, Norway| Stavanger University Hospital, Stavanger, Norway|University of North Norway, Tromsø, Norway|St Olavs Hospital, Trondheim, Norway
Study Documents:

NCT Number: NCT03886155
Study Title: Cardiac Amyloidosis Screening at Trigger Finger Release
Study URL: https://beta.clinicaltrials.gov/study/NCT03886155
Acronym: CAST
Study Status: COMPLETED
Brief Summary: The investigators will prospectively evaluate for the presence of amyloid deposits in soft tissue samples obtained from patients undergoing trigger finger release surgery. Patients who have tissue that stains positive for amyloid will be referred to an amyloidosis specialist.
Study Results: NO
Conditions: Amyloidosis|Trigger Finger|Transthyretin Amyloidosis| Primary Amyloidosis of Light Chain Type
Interventions: PROCEDURE: Biopsy
Primary Outcome Measures: Incidence of amyloidosis in older patients undergoing trigger finger release, Incidence of amyloid deposits in soft tissue removed from trigger finger tenosynovium in older patients undergoing trigger finger release surgery, Baseline to 30 days
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: The Cleveland Clinic
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 107
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 18-1511
Start Date: 2019-05-01
Primary Completion Date: 2020-07-02
Completion Date: 2021-12-02
First Posted: 2019-03-22
Results First Posted:
Last Update Posted: 2021-12-22
Locations: Cleveland Clinic, Cleveland, Ohio, 44195, United States
Study Documents:

NCT Number: NCT03940625
Study Title: Anthracycline Induced Cardiotoxicity - Early Detection by Combination of Diastolic Strain and T2-mapping
Study URL: https://beta.clinicaltrials.gov/study/NCT03940625
Acronym: ANKE
Study Status: COMPLETED
Brief Summary: Anthracyclines (e.g. Doxorubicin) are an important and highly effective chemotherapeutic. They are used in various tumor entities and are established for breast cancer treatment. The most significant prognostic side effect is cardiotoxicity, which occurs in up to 50 patients. Female gender must be considered an independent risk factor for the incidence and severity of associated heart failure. The aim of this study is to demonstrate that dose-dependent anthracycline-induced cardiotoxicity has a measurable effect on T2 mapping on MRI. The second aim is to demonstrate if the combination of diastolic strain (echo and MRI) and T2 mapping can detect earlier anthracycline-induced myocardial damage than via the established method of the echocardiographic measurement of LV-EF and the conventional quantification of diastolic function.
Study Results: NO
Conditions: Breast Cancer|Myocardial Damage|Cardiotoxicity
Interventions: DIAGNOSTIC_TEST: Cardiac MRI and echocardiography, laboratory parameters
Primary Outcome Measures: reduction of the left ventricular ejection fraction (LV-EF) by 10% to under 50%, volumetric determination of LV-EF, after 12 months
Secondary Outcome Measures: reduction of the left ventricular global longitudinal strain (GLS) by over 15%, determination of GLS via strain analysis, after 12 months
Other Outcome Measures:
Sponsor: Heinrich-Heine University, Duesseldorf
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 69
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 15-002
Start Date: 2015-06-03
Primary Completion Date: 2022-04-30
Completion Date: 2022-04-30
First Posted: 2019-05-07
Results First Posted:
Last Update Posted: 2022-05-25
Locations: Division of Cardiology, Pulmonary Disease and Vascular Medicine, Dusseldorf, 40225, Germany
Study Documents:

NCT Number: NCT05473325
Study Title: Benchtop NMR Spectroscopy for Assessment of Clinical Human Pathologies (BRANCH-P STUDY)
Study URL: https://beta.clinicaltrials.gov/study/NCT05473325
Acronym: BRANCH-P
Study Status: NOT_YET_RECRUITING
Brief Summary: This research programme seeks to combine the resources of NHS primary care, with the leading spectroscopic work in low-magnetic fields of the Wilson Group (Nottingham Trent University) to demonstrate the potential for benchtop Nuclear Magnetic Resonance (NMR) spectroscopy in human clinical pathology. This is an instrument assessment study for point of care viability which will also result in enhanced patient care (pending their consent) in blood screenings and metabolic health data.
Study Results: NO
Conditions: Diabetes|Chronic Kidney Diseases|Cancer|Bowel Disease|Cardiovascular Diseases|Mononucleosis|Flu|Heart Diseases|HIV Infections|AIDS and Infections|Bulimia|Chest Infections|Arthritis|Leukaemia|Alcoholic Liver Disease|Allergies|Alzheimer Disease|Appendicitis|Eczema|Bronchitis|Cellulitis|Cirrhosis|Depression|Gout|High Cholesterol|Indigestion|Obesity|Osteoporosis
Interventions:
Primary Outcome Measures: Signal to Noise, An \>0.97 (or 97%) area under the receiver operating characteristic (AUROC) of benchtop Nuclear Magnetic Resonance versus current Point of Care (POC) testing sensitivity/specificity in conditional classification of samples., PhD study duration (Final Submission Date: 22 June 2025)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Willows Health
Collaborators: Nottingham Trent University
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 2000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CRT00442|315046
Start Date: 2023-01-01
Primary Completion Date: 2024-01-01
Completion Date: 2025-06-22
First Posted: 2022-07-25
Results First Posted:
Last Update Posted: 2022-08-15
Locations: Willows Medical Centre, Leicester, Leicestershire, LE5 4LJ, United Kingdom
Study Documents:

NCT Number: NCT04962425
Study Title: Risk Assessment Model of Trastuzumab-related Cardiotoxicity in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT04962425
Acronym:
Study Status: UNKNOWN
Brief Summary: According to the existing clinical data in our hospital, retrospective study was conducted to screen the risk factors with predictive value for TRC(trastuzumab-related cardiotoxicity) risk, and to construct the risk prediction model for TRC.
Study Results: NO
Conditions: Cardiac Toxicity|Antitumor Drugs|Breast Cancer
Interventions: DRUG: Trastuzumab
Primary Outcome Measures: Cardiac toxicity, The asymptomatic LVEF decreases ≥ 10% of the baseline value or to an absolute value \< 50%, 12 months|Cardiac toxicity, acute or chronic heart failure, 12 months|Cardiac toxicity, New or aggravated arrhythmias or coronary heart disease, 12 months|Cardiac toxicity, Myocardial infarction or other cardiac death, 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Peking University Third Hospital
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 240
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Cardiotoxicity study
Start Date: 2021-01-08
Primary Completion Date: 2021-06-01
Completion Date: 2021-12-30
First Posted: 2021-07-15
Results First Posted:
Last Update Posted: 2021-07-15
Locations: Peking University Third Hospital, Peking, Beijing, 100191, China
Study Documents:

NCT Number: NCT00342992
Study Title: Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study
Study URL: https://beta.clinicaltrials.gov/study/NCT00342992
Acronym:
Study Status: COMPLETED
Brief Summary: The project is a passive follow-up of the Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study cohort. Originally, this was a large, randomized, double-blind, placebo-

controlled, 2x2 factorial primary prevention trial testing the effects of alpha-tocopherol and beta-carotene supplementation on cancer incidence and mortality. The study was conducted in Finland as a collaboration between the U.S. National Cancer Institute (NCI) and the National Public Health Institute of Finland. NCI has maintained passive surveillance of the cohort through Finnish national registries, including the cancer registry.

The primary purpose of the ATBC cohort follow-up is to use the existing risk factor data and biological specimens (i.e., serum, whole blood, DNA, red blood cells, and toenails) to test hypotheses relevant to cancer etiology, survival, early detection, and prevention. These data and biospecimens continue to provide an invaluable resource for the study of biochemical, nutritional, genetic, and molecular hypotheses. These analyses are made all the more informative and powerful by the addition of cases identified annually during the follow-up period, and the research benefits from a longer pre-diagnosis period (now over 30 years).
Study Results: NO
Conditions: Stroke|Diabetes Mellitus|Heart Disease|Cancer
Interventions:
Primary Outcome Measures: Cancer, Annual linkage with Finnish Cancer Registry, Annually
Secondary Outcome Measures: Causes of mortality, Anually
Other Outcome Measures:
Sponsor: National Cancer Institute (NCI)
Collaborators: Finnish Institute for Health and Welfare
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 29133
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 999995012|OH95-C-N012
Start Date: 1995-03-03
Primary Completion Date: 2020-09-04
Completion Date: 2020-09-04
First Posted: 2006-06-21
Results First Posted:
Last Update Posted: 2020-09-09
Locations: National Institute of Health and Welfare, Helsinki, Finland, Helsinki, Finland
Study Documents:

NCT Number: NCT04246125
Study Title: Patient Skin Dose in Interventional Radiology
Study URL: https://beta.clinicaltrials.gov/study/NCT04246125
Acronym: DPPRI
Study Status: COMPLETED

Brief Summary: Studies on radiation induced patients' skin lesions in interventional radiology highlighted the need for optimized and personalized patient dosimetry and adapted patient follow-up. Measurements using Gafchromic® films or thermoluminescent dosimeters have long been the only way to accurately evaluate the maximum absorbed dose to the patient skin. However as these dose measurements are tedious and expensive, they could not be systematically applicable in clinical practice. Therefore, more practical calculation methods have been developed. These software programs calculate the skin dose using dosimetric information from images DICOM header or radiation dose structured reports (RDSRs). Validation studies of these software programs are rare and when existent have many limitations.

Radiation Dose Monitor (RDM from Medsquare) is a software program for archiving and monitoring of radiation dose (DACS, Dosimetry Archiving Communication System) used in routine in the investigator's hospitals. A new functionality developed in RDM allows quick estimation without in-vivo measurements of the absorbed dose to the skin of the patient. Comparing RDM calculations with in-vivo measurements will enable this software validation so that it can be used in clinical routine.

Main objective: to validate RDM software for calculating patient skin dose in interventional radiology.
Study Results: NO
Conditions: Aneurysm|Arteriovenous Malformations|Coronary Occlusion|Lung Neoplasms|Liver Neoplasms
Interventions: PROCEDURE: Interventional radiology : skin dose measurements
Primary Outcome Measures: Maximum absorbed skin dose and dose distribution, Measurement of the maximum absorbed dose value and dose mapping by the Gafchromic® film dosimeter (in-vivo measurements within interventional radiology procedure). Comparison between measured and calculated values by the RDM software., Standard duration of the interventional radiology procedure carried out as part of usual care (maximum of 8 hours)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Assistance Publique - Hôpitaux de Paris
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 87
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: APHP191082|2019-A02411-56
Start Date: 2020-10-13
Primary Completion Date: 2022-06-07
Completion Date: 2022-06-07

First Posted: 2020-01-29
Results First Posted:
Last Update Posted: 2023-02-16
Locations: AP-HP, Bicêtre Hospital, Nuclear medicine department, Le Kremlin-Bicêtre, 94275, France|AP-HP, Lariboisière Hospital, Cardiology department, Paris, 75010, France|AP-HP, Lariboisière Hospital, Neuroradiology department, Paris, 75010, France|AP-HP, Cochin Hospital, Radiology A department, Paris, 75014, France|AP-HP, Necker-Enfants Malades Hospital, Pediatric radiology department, Paris, 75743, France
Study Documents:

NCT Number: NCT00165425
Study Title: Cardiac Screening in Survivors of Hodgkin's Disease Treated With Mediastinal Irradiation
Study URL: https://beta.clinicaltrials.gov/study/NCT00165425
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: The main purpose of this study is to determine if it is possible to put into practice a cardiac screening program for survivors of Hodgkin's disease. In this study, we would also like to screen for cardiac risk factors that can be modified either through life-style changes or medications, to uncover significant abnormal heart findings in which treatments may be needed, and to see if there is a link between cardiac health and quality of life.
Study Results: NO
Conditions: Hodgkin's Disease
Interventions: PROCEDURE: Echo/Stress Echo
Primary Outcome Measures: To determine the feasibility of a cardiac screening program in patients who are 5 to 10 years our from initial mediastinal irradiation for Hodgkin's disease., Compliance of screening and follow up visits are tracked, 3 years
Secondary Outcome Measures: To prospectively collect data on the prevalence of modifiable cardiac risk factors and the spectrum of cardiac structural abnormalities in this patient populations, Data on modifiable cardiac risk factors, and outcome of screening studies, are collected prospectively, 3 years|to correlate cardiac structural abnormalities with quality of life, Responses to the generic quality-of-life questionnaire Short-Form 36 (SF-36) collected at the time of initial visit, will be correlated with cardiac screening results, 3 years|to correlate cardiac structural abnormalities with level of fatigue., Responses to the fatigue subscale of FACT-Fatigue (FACT-F), collected at the time of initial visit, will be correlated with cardiac screening results, 3 years
Other Outcome Measures:
Sponsor: Dana-Farber Cancer Institute
Collaborators: Brigham and Women's Hospital
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA

Enrollment: 210
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 03-295
Start Date: 2004-02
Primary Completion Date: 2007-10
Completion Date: 2025-12
First Posted: 2005-09-14
Results First Posted:
Last Update Posted: 2023-06-23
Locations: Brigham and Women's Hospital, Boston, Massachusetts, 02115, United States|Dana-Farber Cancer Institute, Boston, Massachusetts, 02115, United States
Study Documents:

NCT Number: NCT01362855
Study Title: Advance Care Planning Evaluation in Hospitalized Elderly Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT01362855
Acronym: ACCEPT
Study Status: COMPLETED
Brief Summary: The purpose of the study is to inform decision-makers of the best strategies to implement advanced care planning (ACP).

An advanced care plan (ACP) is a verbal or written instruction describing what kind of care an individual would want (or not want)if they are no longer able speak for themselves to make health care decisions.
Study Results: NO
Conditions: Critical Illness|Chronic Obstructive Lung Disease|Congestive Heart Failure|Cirrhosis|Cancer
Interventions:
Primary Outcome Measures: Extent of Implementation of ACP, a. Does the patient have an advance directive or living will or some other written document expressing their wishes? b.patient and/or family been informed of the patients' prognosis? c.Has the patient and/or family been informed about the expected benefits and burdens of various treatment options? d.Has the patient considered how s/he wants to live in the final stages of life and what kinds of medical treatments they would want or not want? e.Have they discussed this with their family? A health care provider? g.Has there been a discussion about their goals of care with their health care provider? If so, are they aware of them? h.Has there been a decision made about medical treatments at the end of life? If so, what role did the patient/family play in that decision-making and was this consistent with their preferred role? i.Is there documentation in the medical record of the overall goals of care?, Year 3
Secondary Outcome Measures: Effect of an audit and feedback process

plus tailored interventions ACP, Compared to baseline, what is the effect of an audit and feedback process coupled with tailored interventions on use of and satisfaction with ACP at the site level?, Year 3|Impact of ACP on patient/family satisfaction, Compared to those patients who have not undergone an ACP process upon enrolment, what is the impact of ACP on patient/family satisfaction with care, use of life-sustaining technologies, and hospital resources during index hospital admission and long-term health care utilization?, Year 3|ACP components associated with overall satisfaction, Which components of ACP are more strongly associated with overall satisfaction with EOL communication and decision making?, Year 3|Comparison of sites with low vs high system level implementation of ACP on satisfaction, At baseline, compared to sites with low degrees of system level implementation, do sites with higher levels of system level integration have a higher prevalence of ACP and greater satisfaction with EOL communication and decision-making?, Year 3
Other Outcome Measures:
Sponsor: Daren K. Heyland
Collaborators: Canadian Institutes of Health Research (CIHR)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 503
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: ACCEPT Study
Start Date: 2011-09
Primary Completion Date: 2015-03
Completion Date: 2015-05
First Posted: 2011-05-30
Results First Posted:
Last Update Posted: 2020-12-16
Locations: Peter Lougheed Hospital, Calgary, Alberta, T1Y 6J4, Canada|Foothills Medical Centre, Calgary, Alberta, Canada|Royal Alexandra Hospital, Edmonton, Alberta, T5H 3V9, Canada|Royal Columbian Hospital, New Westminster, British Columbia, V3L 3W4, Canada|Vancouver Hospital, Vancouver, British Columbia, V5Z 1C6, Canada|St Paul's Hospital, Vancouver, British Columbia, V6Z 1Y6, Canada|St.Paul's Hospital, Vancouver, British Columbia, V6Z 1Y6, Canada|Hamilton General Hospital, Hamilton, Ontario, Canada|Kingston General Hospital, Kingston, Ontario, K7L 2V7, Canada
Study Documents:

NCT Number: NCT04023110
Study Title: Risk-Guided Cardioprotection With Carvedilol in Breast Cancer Patients Treated With Doxorubicin and/or Trastuzumab
Study URL: https://beta.clinicaltrials.gov/study/NCT04023110
Acronym: CCTGuide Pilot
Study Status: ACTIVE_NOT_RECRUITING

Brief Summary: Investigators will evaluate the safety, tolerability, and feasibility of a risk-guided cardioprotective treatment strategy with carvedilol, as compared to usual care, in breast cancer patients undergoing treatment with doxorubicin, trastuzumab, or the combination.
Study Results: NO
Conditions: Cardiotoxicity|Risk Factor, Cardiovascular|Toxicity Due to Chemotherapy|Breast Cancer|Cardiomyopathies|Heart Failure
Interventions: DRUG: Carvedilol
Primary Outcome Measures: Left Ventricular Ejection Fraction (LVEF), LVEF derived from quantitative analyses of echocardiography-derived measurements of left ventricular volumes in diastole and systole., up to 24 months|Treatment adherence as measured by pill count, Rate of compliance with prescribed dose of carvedilol by pill count, 12 months|Adverse Events, Adverse Events will be assessed using the CTCAE v5.0. The number of Grade 2-5 toxicities observed will be tabulated by risk group and by treatment arm. Differences will be evaluated using Fisher exact tests., Up to 24 months
Secondary Outcome Measures: Diastolic function (E/e') by echocardiogram, The mitral valve inflow velocity divided by the average early diastolic tissue velocities of the mitral valve annulus (septal, lateral) measured by tissue Doppler echocardiography., up to 24 months|Ventricular-arterial coupling measured by echocardiogram, Defined by echocardiography-derived measures of end systolic elastance divided by effective arterial elastance, up to 24 months|Cardiac Strain measurements by echocardiogram, Echocardiography-derived measures of longitudinal, circumferential, and radial strain., up to 24 months|Frequency of individuals with clinical heart failure, Frequency of clinical heart failure diagnosis, up to 24 months|High-sensitivity Troponin (hsTnT) level, Change in the cardiac biomarker of injury hsTnT over time, defined as a continuous variable, up to 24 months|N-terminal pro B-type natriuetic peptide (NTproBNP) level, Change in the cardiac biomarker of neurohormonal stress NT-proBNP over time, defined as a continuous variable, up to 24 months
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 69
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: UPCC12118
Start Date: 2019-08-09
Primary Completion Date: 2024-08-31
Completion Date: 2024-12-31
First Posted: 2019-07-17

Results First Posted:
Last Update Posted: 2022-10-17
Locations: Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT05836246
Study Title: The Development of Quantitative Ultrasound Imaging Software Platform
Study URL: https://beta.clinicaltrials.gov/study/NCT05836246
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: The goal of this observational study is to compare the image differences between conventional ultrasound and artificial intelligence-based ultrasound software in conscious adults.

The main question it aims to answer is to evaluate the effectiveness by determining that the new image analysis method is considered valid if it helps to identify more than 30% of histological characteristics.

Participants will undergo the examination using the two methods mentioned earlier after signing the consent form.
Study Results: NO
Conditions: Chronic Liver Disease|Thyroid Disease|Benign Breast Disease|Malignant Breast Neoplasm|Acute Myocardial Infarction
Interventions:
Primary Outcome Measures: Quantitative ultrasound information, Quantitative ultrasound images of heart, thyroid, and breast disease, 5 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Seoul National University Bundang Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 196
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: B-1910-570-301
Start Date: 2020-09-01
Primary Completion Date: 2026-03-31
Completion Date: 2026-03-31
First Posted: 2023-05-01
Results First Posted:
Last Update Posted: 2023-05-01
Locations: Seoul National University Bundang Hospital, Seongnam, Gyeonggi-do, 13620, Korea, Republic of
Study Documents:

NCT Number: NCT03928210
Study Title: Digoxin Induced Dissolution of CTC Clusters
Study URL: https://beta.clinicaltrials.gov/study/NCT03928210
Acronym:
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: This single arm therapeutic exploratory study of digoxin in patients with advanced or metastatic breast cancer investigates whether cardiac glycosides are able to disrupt CTC clusters in breast cancer patients.
Study Results: NO
Conditions: Breast Cancer|Circulating Tumor Cells (CTCs)
Interventions: DRUG: Digoxin
Primary Outcome Measures: Change in mean CTC cluster size (in ng/ml), mean CTC cluster size (in patients with a digoxin serum level above 0.7 ng/ml) after treatment will be compared to mean CTC-cluster size before treatment, Blood samples drawn at Screening, on day 0 (2 hours after first oral intake of digoxin), on day 3, on day 7, on day 10, on day 14, on day 17 and on day 21 after first oral intake of digoxin
Secondary Outcome Measures: Change in mean CTC cluster number, number of CTC-clusters before and after treatment will be compared, Blood samples drawn at Screening, on day 0 (2 hours after first oral intake of digoxin), on day 3, on day 7, on day 10, on day 14, on day 17 and on day 21 after first oral intake of digoxin|Average time to dissolution of CTC Clusters (in days), average time to dissolution of CTC clusters, Blood samples drawn at Screening, on day 0 (2 hours after first oral intake of digoxin), on day 3, on day 7, on day 10, on day 14, on day 17 and on day 21 after first oral intake of digoxin
Other Outcome Measures:
Sponsor: University Hospital, Basel, Switzerland
Collaborators: ETH Zurich - The Aceto Lab
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: EARLY_PHASE1
Enrollment: 9
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 2019-00673; sp19Kurzeder
Start Date: 2020-07-08
Primary Completion Date: 2023-07
Completion Date: 2023-09
First Posted: 2019-04-26
Results First Posted:
Last Update Posted: 2023-07-13
Locations: Kantonspital Baselland (KSBL), Liestal, Baselland, 4410, Switzerland|Breast Cancer Center, University Hospital Basel, Basel, 4031, Switzerland|University Hospital Zurich (USZ), Zürich, 8091, Switzerland

Study Documents:

NCT Number: NCT00671346
Study Title: NORVIT and WENBIT - Long-term Follow-up
Study URL: https://beta.clinicaltrials.gov/study/NCT00671346
Acronym: NORVITWENBIT
Study Status: UNKNOWN
Brief Summary: Two large homocysteine-lowering B-vitamin intervention trials have been performed in Norway during the period 1998 to 2005, NORVIT and WENBIT. The main objective in these trials was to study the clinical effects of homocysteine-lowering therapy with folic acid and vitamin B12 in patients with established coronary artery disease. Follow-up was terminated for NORVIT on Marc 31st 2004 and for WENBIT October 5th 2005, and none of the two trials proved any protective effect of the B-vitamin intervention on cardiovascular outcomes.

There is so far no data on possible long-term effects following years of such B-vitamin treatment.

Thus, the main objective of the combinded NORVIT-WENBIT study will will be to evaluate the long-term effect of the B-vitamin intervention on incident life-style diseases including cardiovascular disease, diabetes, osteoporotic fractures and cancer.

A secondary object will be the identification of risk phenotypes or genotypes, and if such risk associations are midified by the B-vitamin intervention
Study Results: NO
Conditions: Cancer|Myocardial Infarction|Cerebrovascular Stroke
Interventions:
Primary Outcome Measures: Possible effects of B-vitamin treatment on risk of developing cancer during the trial periods (completed by 2004 and 2005) and during post-trial follow-up., 1998-2014
Secondary Outcome Measures: The possible effects of B-vitamin treatment on major cardiovascular events, all cause mortality and cause specific death during the trial periods (completed by 2004 and 2005) and during post-trial follow-up., 1998-2014
Other Outcome Measures:
Sponsor: Haukeland University Hospital
Collaborators: University of Tromso|Norwegian Foundation for Health and Rehabilitation
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 6839
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NSD-17895|REK-267.07|DT-08/00230-2/RVB|Hdir-08/623-
Start Date: 1998-12

Primary Completion Date: 2020-12
Completion Date: 2021-01
First Posted: 2008-05-05
Results First Posted:
Last Update Posted: 2015-11-05
Locations: Department of Heart Disease, Haukeland University Hospital, Bergen, 5021, Norway|University of Tromsø, Tromsø, 9037, Norway
Study Documents:

NCT Number: NCT03042910
Study Title: A Study to Assess the Effects of Talazoparib on Cardiac Repolarization in Patients With Advanced Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT03042910
Acronym:
Study Status: COMPLETED
Brief Summary: This study is designed to evaluate the effects of talazoparib on cardiac repolarization in patients with advanced solid tumors with no available standard treatment options.
Study Results: YES
Conditions: Solid Tumor
Interventions: DRUG: Talazoparib
Primary Outcome Measures: Time-matched Mean Change From Baseline in Corrected QT Intervals Based on the Fridericia's Correction Fomulation (QTcF), QT interval is the time from electrocardiogram Q wave to the end of the T wave corresponding to electrical systole., Baseline (Day -1 time matched for each time point); 1, 2, 4 and 6 hours post-dose on Day 1; pre-dose on Day 2; pre-dose, 1, 2, 4 and 6 hours post-dose on Day 22|Intercept of Predicted Linear Mixed Effects Models for Change From Baseline in QTcF Versus Plasma Talazoparib Concentrations at Day 22, A linear mixed effects modeling approach was used to examine the relationship between the change from baseline in QTcF and the plasma concentration of talazoparib. The model included plasma concentration, time (categorical), and treatment with random participant effects on plasma concentration and the intercept. Equation used for modeling was: $Y_{lkt} = \mu_l + p_t + \theta \times C_{lkt} + W_k + D_k \times C_{kt} + \varepsilon_{lkt}$, where the dependent variable Y_{lkt} was for the l (treatment), k (participants) and t (time point). Parameter were: μ_l was the treatment specific intercept, θ was the slope, C was the concentration, W_k was the random patient effect on the intercept, D_k was the random patient effect on the slope, p_t was the time effect on the intercept and ε_{lkt} was the residual error., Baseline (Day -1) to Day 22|Concentration Slope of Predicted Linear Mixed Effects Models for Change From Baseline in QTcF Versus Plasma Talazoparib Concentrations at Day 22, A linear mixed effects modeling approach was used to examine the relationship between the change from baseline in QTcF and the plasma concentration of talazoparib. The model included plasma concentration, time (categorical), and treatment with random participant effects on plasma concentration and the intercept. Equation used for modeling was: $Y_{lkt} = \mu_l + p_t + \theta \times C_{lkt} + W_k + D_k \times C_{kt} + \varepsilon_{lkt}$, where the dependent variable Y_{lkt} was for the l

(treatment), k (participants) and t (time point). Parameter were: μ_l was the treatment specific intercept, θ was the slope, C was the concentration, W_k was the random patient effect on the intercept, D_k was the random patient effect on the slope, p_t was the time effect on the intercept and ε_lkt was the residual error., Baseline (Day -1) to Day 22
Secondary Outcome Measures: Time-matched Mean Change From Baseline in Corrected QT Intervals Based on the Bazett's Correction Fomulation (QTcB), QT interval is the time from electrocardiogram Q wave to the end of the T wave corresponding to electrical systole., Baseline (Day -1 time matched for each time point); 1, 2, 4 and 6 hours post-dose on Day 1; pre-dose on Day 2; pre-dose, 1, 2, 4 and 6 hours post-dose on Day 22|Time-matched Mean Change From Baseline in Heart Rate, Baseline (Day -1 time matched for each time point); 1, 2, 4 and 6 hours post-dose on Day 1; pre-dose on Day 2; pre-dose, 1, 2, 4 and 6 hours post-dose on Day 22|Time-matched Mean Change From Baseline in PR Interval, PR interval is the time between the beginning of the P wave and the start of the QRS interval, corresponding to the end of atrial depolarization and onset of ventricular depolarization., Baseline (Day -1 time matched for each time point); 1, 2, 4 and 6 hours post-dose on Day 1; pre-dose on Day 2; pre-dose, 1, 2, 4 and 6 hours post-dose on Day 22|Time-matched Mean Change From Baseline in QRS Interval, QRS interval is the time from electrocardiogram Q wave to the end of the S wave, corresponding to ventricle depolarization., Baseline (Day -1 time matched for each time point); 1, 2, 4 and 6 hours post-dose on Day 1; pre-dose on Day 2; pre-dose, 1, 2, 4 and 6 hours post-dose on Day 22|Time-matched Mean Change From Baseline in QT Interval, QT interval is the time from electrocardiogram Q wave to the end of the T wave corresponding to electrical systole., Baseline (Day -1 time matched for each time point); 1, 2, 4 and 6 hours post-dose on Day 1; pre-dose on Day 2; pre-dose, 1, 2, 4 and 6 hours post-dose on Day 22|Time-matched Mean Change From Baseline in RR Interval, RR interval is the time elapsing between two consecutive R waves in the electrocardiogram., Baseline (Day -1 time matched for each time point); 1, 2, 4 and 6 hours post-dose on Day 1; pre-dose on Day 2; pre-dose, 1, 2, 4 and 6 hours post-dose on Day 22|Number of Participants With Treatment-emergent Abnormalities in 12-lead Electrocardiogram (ECG) Morphpology, Morphological analyses were performed with regard to the ECG waveform interpretation as defined by the central ECG laboratory's cardiologist. Numbers of participants with new onsets for the following variables were counted: atrial fibrillation or flutter, second-degree heart block, third degree heart block, complete right bundle branch block, complete left bundle branch block, ST segment depression, ST segment elevation, T-wave abnormalities (negative T waves only), myocardial infarction pattern, and any new abnormal U waves. "New" was defined as "not present on any baseline ECG but present on any on-treatment ECG". Number of participants with abnormality in any of the variables were reported., Baseline to Day 22|Number of Participants With Clinically Significant Findings in 12-lead Electrocardiogram (ECG) Parameters Meeting

Predefined Criteria, Criteria for clinically significant: Maximum QTcF \>450 msec, Maximum QTcF \>480 msec, Maximum QTcF \>500 msec, Maximum QTcB \>450 msec, Maximum QTcB \>480 msec, Maximum QTcB \>500 msec, Maximum QT Interval \>500 msec, Maximum QTcF Increase \<=30 msec, Maximum QTcF Increase 30 to \<=60 msec, Maximum QTcF Increase \<=60 msec, Maximum PR interval increase \>200 msec and \>=25%, Maximum QRS interval increase \>100 msec and \>=25%, Maximum heart rate increase \>100 bpm and \>25% and Maximum heart rate decrease \<50 bpm and \>25%., Baseline (mean of all ECGs on Day -1 and pre-dose on Day 1) to Day 22|Number of Participants With Treatment-emergent Adverse Events (AEs), Serious Adverse Events (SAEs), Discontinuation Due to AEs, AEs of Special Interest, and Deaths, An adverse event(AE)was any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug, whether or not related to the study drug. A serious adverse event(SAE)was an AE that resulted in: death; persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; congenital anomaly/birth defect; was life-threatening (immediate risk of death); hospitalization or prolongation of existing hospitalization; or considered to be an important medical event. Treatment-emergent AEs (TEAEs) are AEs occurred on or after the administration of study drug. AEs related to study drug was any AE with at least a possible relationship to the study drug as assessed by the investigator. AEs of special interest were diagnosis of myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML), and abnormal liver test results that met predefined criteria., Day 1 to follow-up (30 days post last dose, i.e. up to 52 days)|Number of Participants With Clinically Notable Changes in Vital Signs Measurements, Clinically notable changes included: High systolic blood pressure (SBP):\>=155 millimeters of mercury (mmHg) with increase \>=30 mmHg, low SBP \<=90 mmHg with decrease \>=20 mmHg, Both high and low SBP (i.e high SBP \>=155 mmHg with increase \>=30 mmHg and low SBP \<=90 mmHg with decrease \>=20 mmHg), High diastolic blood pressure (DBP):\>=100 mmHg with increase \>=15 mmHg), Low DBP (\<=50 mmHg with decrease \>=15 mmHg), Both high and low DBP, Heart rate \>=100 bpm with increase \>=30 bpm, Heart rate \<=50 bpm with decrease \>=15 bpm, Respiratory rate \>=25 bpm, Respiratory rate \<10 bpm, Oral body temperature \>39 degree and Oral body temperature \<=35 degree., Screening (Day -29 to Day -2) to follow-up (30 days post last dose on Day 22)|Number of Participants With Clinically Significant Laboratory Test Abnormalities, Laboratory test included: hematology (hematocrit, hemoglobin, mean corpuscular volum, red blood cell count, platelet count, white blood cell count with differential \[total neutrophils, eosinophils, monocytes, basophils, and lymphocytes\]),chemistry (albumin, total protein, alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, total bilirubin, blood urea nitrogen, creatinine, non-fasting glucose, carbon dioxide, calcium, chloride, magnesium, phosphate, potassium, sodium and lactate dehydrogenase), and additional tests (urine or serum pregnancy tests for women of childbearing potential). Clinically significant

laboratory abnormality was determined by the investigator., Baseline to follow-up (30 days post last dose on Day 22, i.e. up to Day 52)|Area Under the Plasma Concentration-time Profile From Time 0 to 24 Hours After Dosing (AUC24) of Plasma Talazoparib on Day 1 and Day 22, Day 22 subpopulation: amongst the participants with reported pharmacokinetic (PK) parameters on Day 22, exclusion of values from the summary statistics calculations due to dose modifications (eg, dose interruptions, dose reductions) was handled on a case by case basis, resulting in a subpopulation of participants with no prior dose modifications., Pre-dose, 1, 2, 4, 6, and 24 hours post-dose on Day 1; pre-dose, 1, 2, 4, and 6 hours post-dose on Day 22|Maximum Plasma Concentration (Cmax) of Plasma Talazoparib on Day 1 and Day 22, Day 22 subpopulation: amongst the participants with reported pharmacokinetic (PK) parameters on Day 22, exclusion of values from the summary statistics calculations due to dose modifications (eg, dose interruptions, dose reductions) was handled on a case by case basis, resulting in a subpopulation of participants with no prior dose modifications., Pre-dose, 1, 2, 4, 6, and 24 hours post-dose on Day 1; pre-dose, 1, 2, 4, and 6 hours post-dose on Day 22|Time for Cmax (Tmax) of Plasma Talazoparib on Day 1 and Day 22, Day 22 subpopulation: amongst the participants with reported pharmacokinetic (PK) parameters on Day 22, exclusion of values from the summary statistics calculations due to dose modifications (eg, dose interruptions, dose reductions) was handled on a case by case basis, resulting in a subpopulation of participants with no prior dose modifications., Pre-dose, 1, 2, 4, 6, and 24 hours post-dose on Day 1; pre-dose, 1, 2, 4, and 6 hours post-dose on Day 22|Predose Concentration (Ctrough) of Plasma Talazoparib on Day 22, Day 22 subpopulation: amongst the participants with reported pharmacokinetic (PK) parameters on Day 22, exclusion of values from the summary statistics calculations due to dose modifications (eg, dose interruptions, dose reductions) was handled on a case by case basis, resulting in a subpopulation of participants with no prior dose modifications., Pre-dose, Day 22|Apparent Clearance After Oral Dose (CL/F) of Plasma Talazoparib on Day 22, Drug clearance is a quantitative measure of the rate at which a drug substance is removed from the blood (rate at which a drug is metabolized or eliminated by normal biological processes). Clearance obtained after intravenous infusion dose (apparent clearance) is influenced by the fraction of the dose absorbed. Day 22 subpopulation: amongst the participants with reported pharmacokinetic (PK) parameters on Day 22, exclusion of values from the summary statistics calculations due to dose modifications (eg, dose interruptions, dose reductions) was handled on a case by case basis, resulting in a subpopulation of participants with no prior dose modifications., Pre-dose, 1, 2, 4, and 6 hours post-dose on Day 22|Accumulation Ratio (Rac) of Plasma Talazoparib on Day 22, Rac was calculated as, area under the curve from time zero to end of dosing interval on Day 22 (AUCtau) divided by area under the curve from time zero to end of dosing interval on Day 1 (AUCtau). Area under the concentration curve from time 0 to end of dosing interval

(AUCtau), where dosing interval was 6 hours. Day 22 subpopulation: amongst the participants with reported pharmacokinetic (PK) parameters on Day 22, exclusion of values from the summary statistics calculations due to dose modifications (eg, dose interruptions, dose reductions) was handled on a case by case basis, resulting in a subpopulation of participants with no prior dose modifications., Pre-dose, 1, 2, 4, and 6 hours post-dose on Day 22
Other Outcome Measures:
Sponsor: Pfizer
Collaborators: Medivation, Inc.
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 38
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: MDV3800-14|C3441005
Start Date: 2016-10-13
Primary Completion Date: 2017-05-30
Completion Date: 2017-06-22
First Posted: 2017-02-03
Results First Posted: 2018-05-24
Last Update Posted: 2019-12-17
Locations: CBCC Global Research, Inc. at Comprehensive Blood and Cancer Center, Bakersfield, California, 93309, United States|UCLA Hematology/Oncology - Burbank, Burbank, California, 91505, United States|St. Jude Hospital Yorba Linda DBA St. Joseph Heritage Healthcare, Fullerton, California, 92835, United States|UCLA West Medical Pharmacy, Attn: Steven L. Wong, Pharm.D., Los Angeles, California, 90095-7349, United States|Ronald Reagan UCLA Medical Center, Drug Information Center, Los Angeles, California, 90095, United States|TRIO-US Central Administration, Los Angeles, California, 90095, United States|UCLA Hematology/Oncology, Los Angeles, California, 90095, United States|UCLA West Medical Pharmacy. Attn: Steven L. Wong, Pharm.D., Los Angeles, California, 90095, United States|UCLA Hematology/Oncology - Pasadena, Pasadena, California, 91105, United States|UCLA Hematology/Oncology - Porter Ranch, Porter Ranch, California, 91326, United States|Torrance Health Association, DBA Torrance Memorial Physician Network/Cancer Care Associates, Redondo Beach, California, 90277, United States|UCLA Hematology/Oncology - Santa Monica, Santa Monica, California, 90404, United States|UCLA Hematology/Oncology - Santa Clarita, Valencia, California, 91355, United States|Memorial Cancer Institute at Memorial Regional Hospital, Hollywood, Florida, 33021, United States|Memorial Regional Hospital, Hollywood, Florida, 33021, United States|Orlando Health, Inc., Orlando, Florida, 32806, United States|Memorial Hospital West, Pembroke Pines, Florida, 33028, United States|Fort Wayne Medical Oncology and Hematology, Inc., Fort Wayne, Indiana, 46804, United

States|Fort Wayne Medical Oncology and Hematology, Inc., Fort Wayne, Indiana, 46845, United States
Study Documents: Study Protocol|Statistical Analysis Plan

NCT Number: NCT01239446
Study Title: Hybrid SPECT/CTCA for the Assessment of the Presence and Hemodynamic Significance of CAD in Asymptomatic Patients.
Study URL: https://beta.clinicaltrials.gov/study/NCT01239446
Acronym:
Study Status: UNKNOWN
Brief Summary: Mediastinal irradiation for treatment of malignancy increases the risk for coronary artery disease (CAD), while diabetes mellitus or other known risk factors can be absent at the time of the first coronary event. Radiation-induced atherosclerosis affects the coronary ostia and proximal coronary segments, or causes diffuse microvascular damage. Younger patients and those exposed to high radiation doses (\> 35 Gy) have a higher risk for developing premature CAD and likely may benefit from coronary assessment.

A novel hybrid imaging technique that combines SPECT and CTCA has been shown to overcome the individual pitfalls and the diagnostic challenges of stand-alone SPECT and CCTA, improve the lesion detectability and sensitivity in patients with balanced diffuse lesions as well as the specificity and mainly PPV of CTCA.

The aim of the study is to perform hybrid SPECT/CTCA in asymptomatic patients with HL who have received radiotherapy to the mediastinum in order to allow an early diagnosis of hemodynamically significant CAD that will need further therapeutic interventions.
Study Results: NO
Conditions: Hodgkin Lymphoma Treated With Mediastinal Irradiation
Interventions: OTHER: Not relevant (there is no intervention in the present study)
Primary Outcome Measures: Extent of coronary artery plaques and number of perfusion defects in patients enrolled., 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Rambam Health Care Campus
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 0390-10-RMB_BRODOV
Start Date: 2011-01
Primary Completion Date: 2012-01

Completion Date:
First Posted: 2010-11-11
Results First Posted:
Last Update Posted: 2010-11-11
Locations: Rambam Healthcare Campus, Haifa, Israel
Study Documents:

NCT Number: NCT01210846
Study Title: A Cardiac Safety Study of Tivozanib to Evaluate the Electrocardiogram and Pharmacokinetic-Electrocardiogram Dynamics in Subjects With Advanced Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT01210846
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to obtain QTc data, to assess the effects of tivozanib on ECG morphology, and to determine the pharmacokinetic pharmacodynamic (PK-PD) relationship between any observed changes in cardiac repolarization (defined by QTcF duration) and the serum concentration of tivozanib.
Study Results: NO
Conditions: Advanced Solid Tumors
Interventions: DRUG: tivozanib
Primary Outcome Measures: Change from baseline in QTcF, 22 days
Secondary Outcome Measures: Change from baseline in QTc with Bazett correction method (QTcB), 22 days|Change from baseline in heart rate (HR), 22 days|Change from baseline in PR interval, 22 days|Change from baseline in QRS interval, 22 days|Change from baseline in Uncorrected QT interval, 22 days|Change from baseline in ECG morphological patterns, 22 days|Correlation between the QTcF change from baseline and serum concentrations of tivozanib, 22 days
Other Outcome Measures:
Sponsor: AVEO Pharmaceuticals, Inc.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 50
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose:
Other IDs: AV-951-10-112
Start Date: 2010-10
Primary Completion Date: 2011-03
Completion Date: 2011-07
First Posted: 2010-09-29
Results First Posted:
Last Update Posted: 2011-09-26
Locations: TGEN Clinical Research Service at Scottsdale Healthcare, Scottsdale, Arizona, United States|Florida Cancer Specialists, Ft.

Myers, Florida, United States|Horizon Oncology Research, Inc., Lafayette, Indiana, United States|Jayne Gurtler MD, Laura Brinz MD, Angelo Russo MD and Janet Burroff MD APMC, Metairie, Louisiana, United States|Associates in Oncology/Hematology, Rockville, Maryland, United States|Oklahoma University Cancer Institute (OUCI), Oklahoma City, Oklahoma, United States|Tennessee Onocology, Nashville, Tennessee, United States|Multicare Research Institute/Tacoma General Hospital, Tacoma, Washington, United States
Study Documents:

NCT Number: NCT02628665
Study Title: Clinical Study of Time Optimizing of Endoscopic Photodynamic Therapy on Esophageal and/or Gastric Cardiac Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02628665
Acronym:
Study Status: UNKNOWN
Brief Summary: The therapy of photofrin PDT was effective in improving life quality of patients with advanced esophageal and/or gastric cardiac cancer and the time optimizing for employing laser irradiation was of great importance.The purpose of this study is to evaluate the clinical efficacy and adverse effects of Photodynamic Therapy (PDT) on esophageal and/or gastric cardiac cancer during different time after inject photofrin.
Study Results: NO
Conditions: Stage I Esophageal Adenocarcinoma|Stage II Esophageal Adenocarcinoma|Stage III Esophageal Adenocarcinoma|Stage I Esophageal Squamous Cell Carcinoma|Stage II Esophageal Squamous Cell Carcinoma|Stage III Esophageal Squamous Cell Carcinoma
Interventions: DRUG: photosensitizer(photofrin)|DEVICE: 630 nm laser irradiation (DIOMED)
Primary Outcome Measures: Partial remission rate, Photodynamic therapy for 3 months after the review of gastroscope for pathologic examination, to check the response rate, 3 months
Secondary Outcome Measures: The recent incidence of adverse reactions, Observe 7-10 days postoperatively in patients with the ratio of pain and difficulty swallowing, 7-10 days
Other Outcome Measures:
Sponsor: The First Affiliated Hospital of Henan University of Science and Technology
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: FirstHenanUST,cancer center
Start Date: 2015-10

Primary Completion Date: 2017-10
Completion Date: 2019-12
First Posted: 2015-12-11
Results First Posted:
Last Update Posted: 2015-12-11
Locations: The First Affiliated Hospital of Henan University of Science and Technology, Luoyang, Henan, 471003, China
Study Documents:

NCT Number: NCT05125965
Study Title: Contribution of Cardiac MRI in the Early Diagnosis of Myocarditis Induced by Immunotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT05125965
Acronym: MEDIIMYO
Study Status: NOT_YET_RECRUITING
Brief Summary: Anti-cancer immunotherapy, one of the therapeutic revolutions of recent years. It is based on the use of antibodies that block immune system checkpoints that have been hijacked by cancer cells to benefit themselves. Blocking these checkpoints, such as PD-1, unleashes the action of anti-cancer T cells that can then destroy the tumor. The efficacy of these targeted therapies is significant, with an average 40% response rate in patients with metastatic cancers.Immune checkpoint inhibitors (ICIs) are becoming a 1st line therapy in many oncology indications due to their therapeutic line in many oncology indications due to their favorable effect on the prognosis of various prognosis of various cancers Since checkpoints play a key role in controlling the intensity and duration of an immune response, their immune response, therefore, their inhibition exposes to adverse inflammatory or autoimmune effects inflammatory or autoimmune adverse effects that can be severe and sometimes lethal.Most side effects of ICIs occur within the first few months after initiation of treatment. The toxicity of immunotherapy is immunological, all organs including the heart can be including the heart, can be affected.

Cardiac autoimmune involvement in ICIs can involve the myocardium, pericardium, and/or vascular endothelium. These entities may be interrelated or, on the contrary, isolated.

In the last 5 years, the number of described cases of myocarditis associated with ICIstreatment has increased. Their incidence remains low, estimated between 0.5 and 2%. This probably represents the most serious cardiovascular complication, as the mortality attributed to it reaches almost 50%.

In recent years MRI has become very important in the noninvasive diagnosis of acute myocarditis. The latest update of the Lake Louise criteria in 2018 has thus confirmed cardiac MRI in its first place among noninvasive examinations for the diagnosis of myocarditis with a sensitivity of 87.5%, a specificity of 96.2%, and a positive

predictive value of 97.2%.
Study Results: NO
Conditions: Myocarditis
Interventions: OTHER: additional time for the MRI
Primary Outcome Measures: cardiac MRI, ejection fraction, 1 day
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Centre Chirurgical Marie Lannelongue
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 200
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: ID RCB : 2021-A01656-35
Start Date: 2021-11-15
Primary Completion Date: 2023-11-15
Completion Date: 2024-11-15
First Posted: 2021-11-18
Results First Posted:
Last Update Posted: 2021-11-18
Locations: Centre Chirurgical Marie Lannelongue, Le Plessis Robinson, 92350, France
Study Documents:

NCT Number: NCT03211442
Study Title: Implications of MEDIcal Low Dose RADiation Exposure - BReast Cancer Acute Coronary Events
Study URL: https://beta.clinicaltrials.gov/study/NCT03211442
Acronym: MEDIRAD-BRACE
Study Status: UNKNOWN
Brief Summary: MEDIRAD-BRACE aims to determine the relationship between 3D dose distributions in cardiac structures and the risk of acute coronary events (ACE) and other cardiac complications in breast cancer (BC) patients to develop and externally validate multivariable Normal Tissue Complication Probability (NTCP) models to assess the risk of ACE in individual patients based on cardiac dose metrics in the first 10 years after BC radiotherapy.
Study Results: NO
Conditions: Breast Cancer Female|Acute Coronary Events|Cardiac Complications
Interventions: RADIATION: Radiotherapy
Primary Outcome Measures: Number of patients with an Acute Coronary Event after completion of RT treatment, First 10 years after RT treatment
Secondary Outcome Measures: Number of patients with other cardiac complications after completion of RT treatment, First 10 years after

RT treatment|Number of patients with radiotherapy-induced late non-cardiac toxicity (e.g. secondary tumors), First 10 years after RT treatment
Other Outcome Measures:
Sponsor: University Medical Center Groningen
Collaborators: The Netherlands Cancer Institute|Technical University of Munich|Institut de Radioprotection et de Surete Nucleaire
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 7000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: RT2017-08
Start Date: 2017-08-01
Primary Completion Date: 2020-08-01
Completion Date: 2022-11
First Posted: 2017-07-07
Results First Posted:
Last Update Posted: 2020-11-13
Locations: University Medical Center Groningen, Groningen, 9700RB, Netherlands
Study Documents:

NCT Number: NCT04737265
Study Title: Pilot Study of an NTproBNP Guided Strategy of Cardioprotection
Study URL: https://beta.clinicaltrials.gov/study/NCT04737265
Acronym: NTproBNP-Guide
Study Status: RECRUITING
Brief Summary: Investigators will evaluate the safety and feasibility of a biomarker-guided cardioprotection strategy using NTproBNP, as compared to usual care, in breast cancer and lymphoma patients treated with anthracyclines.
Study Results: NO
Conditions: Cardiotoxicity|Toxicity Due to Chemotherapy|Breast Cancer|Lymphoma|Cardiomyopathies|Heart Failure
Interventions: OTHER: Biomarker Guided Intervention
Primary Outcome Measures: Recruitment Rate, percent of eligible patients who are randomized, At baseline|Retention rate, percent of randomized patients who complete the study per protocol, Through study completion (expected to be 1 year)|Adherence rate, percent of study activities completed in window, Through study completion (expected to be 1 year)|Compliance rate, Compliance by PROMIS Scale v1.0 for patients in the biomarker guided arm initiated on heart failure medications, Through study completion (expected to be 1 year)|Maximum tolerated dose, Maximum tolerated dosage of neurohormonal antagonist medications for patients in the biomarker-guided arm with NTproBNP above upper limit of normal, Through study completion (expected to be

1 year)|Incidence of Adverse Events, Rate of Grade 2 or higher adverse events by CTCAEv5.0, 12 months
Secondary Outcome Measures: Change in NTproBNP, Change in clinically measured NTproBNP following initiation of neurohormonal antagonists in patients with NTproBNP above upper limit of normal in the biomarker guided arm, Through study completion (expected to be 1 year)|Change in Left ventricular ejection fraction (LVEF) by Echocardiogram, Change in core-lab quantitated left ventricular ejection fraction, 12 months|Incidence of cardiotoxicity, Incidence of cardiotoxicity defined as LVEF decline of at least 10% to less than 50%, 12 months|Incidence of Hear Failure (HF), Incidence of new or worsened clinical heart failure, defined as urgent or new office or emergency department visit or hospitalization for HF, adjudicated by a clinical events committee, 12 months|Frequency of cancer treatment interruptions, Frequency of cancer treatment interruptions due to cardiotoxicity, Through study completion (expected to be 1 year)
Other Outcome Measures: Change in diastolic function on echo, Change in E/e' by echo, 12 months|Change in longitudinal strain, Change in global longitudinal strain by echocardiogram, 12 months|Change in circumferential strain, Change in circumferential strain by echocardiogram, 12 months|Change in high sensitivity troponin (hsTnT), Change in hsTnT measured in batches from banked samples, 12 months|Change in Growth Differentiation Factor 15 (GDF-15), Change in GDF-15 measured in batches from banked samples, 12 months|Change in myeloperoxidase (MPO), Change in MPO measured in batches from banked samples, 12 months|Change in NTproBNP (post hoc batch analysis), Change in NTproBNP measured in batches from banked samples for all patients on both arms, 12 months|Change in patient reported activity level, Change in total weekly leisure activity in METS (assessed by GODIN Leisure Time Exercise Questionnaire), 12 months|Change in patient reported symptoms, Change in MD Anderson Symptoms Inventory - Heart Failure (MDASI-HF). Higher scores indicate increased symptom severity or symptom distress., 12 months|Change in patient reported fatigue, Change in Patient Reported Outomes Information System (PROMIS) Fatigue Score. A higher score corresponds to higher levels of reported fatigue., 12 months|Change in patient reported quality of life, Change in Patient Reported Outomes Information System (PROMIS) Global Health score. Higher scores indicate a healthier patient., 12 months|Change in patient reported adverse events, Change in NCI Patient Reported Outcomes - Common Terms and Criteria for Adverse Events (PRO CTCAE)., 12 months|Incidence of treatment interruptions in administration of anthracycline chemotherapy, Incidence of anthracycline chemotherapy being held or discontinued secondary to side effects or toxicity, 12 months
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators: National Heart, Lung, and Blood Institute (NHLBI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1|PHASE2
Enrollment: 105

Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: UPCC 25920|R21HL152148
Start Date: 2021-03-18
Primary Completion Date: 2025-06
Completion Date: 2025-06
First Posted: 2021-02-03
Results First Posted:
Last Update Posted: 2023-04-13
Locations: City of Hope, Duarte, California, 91010, United States|Abramson Cancer Center at University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States|Chester County Hospital, West Chester, Pennsylvania, 19380, United States
Study Documents:

NCT Number: NCT03377465
Study Title: Biomarkers, Hemodynamic and Echocardiographic Predictors of Ischemic Strokes and Their Influence on the Course and Prognosis
Study URL: https://beta.clinicaltrials.gov/study/NCT03377465
Acronym:
Study Status: COMPLETED
Brief Summary: A stroke is the second cause of deaths after heart attack, one of the most important causes of malfunction as far as adults are concerned and the second as for the frequency cause of dementia. In spite of a possibility of the therapy of stroke (tissue plasminogen activator) and recognized most of risk factors there is expected that incidence rate on stroke connected with ageing of the society will be growing. It will cause medical and social consequences.

There are many of potential causes of cardiac strokes, which are not entirely examined.

More over many cryptogenic strokes are presumed to have an embolic etiology, and the frequent cause of these kind of strokes at young age is probably the mechanism of paradoxical embolism through patent foramen ovale.

As far as the investigators are concerned, at present there is lack of any recommendations for these scientific hypothesis.
Study Results: NO
Conditions: Embolic Stroke of Undetermined Source|Ischemic Stroke|Atrial Fibrillation and Flutter|Myocardial Infarction|Cardiac Tumor|Endocarditis|Patent Foramen Ovale
Interventions: DIAGNOSTIC_TEST: ADMA (asymmetric dimethylarginine) , NTproBNP (N-terminal pro b-type natriuretic peptide), IL-6 (Interleukin 6), Adiponectina, Leptine, Syndecan, Resistin
Primary Outcome Measures: physiological parameter, CRP (C reactive

protein), 24 months|physiological parameter, IL-6 (interleukin 6), 24 months|physiological parameter, ADMA (asymmetric dimethylarginine), 24 months|physiological parameter, NTproB (N-terminal pro b-type natriuretic peptide), 24 months|physiological parameter, Adiponectin, 24 months|physiological parameter, Leptine, 24 months|physiological parameter, Resistin, 24 months|physiological parameter, Syndecan, 24 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Medical University of Lodz
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (INVESTIGATOR)|Primary Purpose: PREVENTION
Other IDs: 01122017
Start Date: 2016-11-15
Primary Completion Date: 2017-11-30
Completion Date: 2017-12-05
First Posted: 2017-12-19
Results First Posted:
Last Update Posted: 2017-12-19
Locations:
Study Documents:

NCT Number: NCT05939089
Study Title: Cardiovascular Assessment of Pediatric Cancer Survivors
Study URL: https://beta.clinicaltrials.gov/study/NCT05939089
Acronym: CASPER
Study Status: COMPLETED
Brief Summary: The goal of this observational study is to evaluate cardiac and vascular health status of pediatric cancer survivors.
Study Results: NO
Conditions: Left Ventricular Dysfunction|Heart Failure
Interventions: DIAGNOSTIC_TEST: ECG, Echocardiography, cTnI, NT-ProBNP
Primary Outcome Measures: Rate of LV Dysfunction, Echocardiographic evaluation of left ventricular functions, From the first visit at cardio-oncology division through study completion, an average of 2 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Istanbul University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:

Enrollment: 54
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: COEXIST-2
Start Date: 2023-01-01
Primary Completion Date: 2023-06-15
Completion Date: 2023-06-22
First Posted: 2023-07-11
Results First Posted:
Last Update Posted: 2023-07-11
Locations: Istanbul Faculty of Medicine, Fatih, Istanbul, 34093, Turkey
Study Documents:

NCT Number: NCT01933789
Study Title: Improving Communication About Serious Illness
Study URL: https://beta.clinicaltrials.gov/study/NCT01933789
Acronym: ICSI
Study Status: COMPLETED
Brief Summary: The purpose of this study is to improve care delivered to patients with serious illness by enhancing communication among patients, families, and clinicians in the outpatient setting. We are testing a new way to help patients share their preferences for talking about end-of-life care with their clinicians and families. To do this we created a simple, short feedback form. The form is designed to help clinicians understand what patients would like to talk about. The goal of this research study is to show that using a feedback form is possible and can be helpful for patients and their families.
Study Results: YES
Conditions: Critical Illness|Chronic Disease|Terminal Care|Palliative Care|Communication|Advance Care Planning|Neoplasm Metastasis|Lung Neoplasms|Pulmonary Disease, Chronic Obstructive|Heart Failure|End Stage Liver Disease|Kidney Failure, Chronic
Interventions: BEHAVIORAL: Communication Feedback Form for Patients with Serious Illness
Primary Outcome Measures: Occurrence of Discussion About Goals of Care at Target Visit, Patient's response to question, "Did you discuss with this doctor the kind of medical care you would want if you were too sick to speak for yourself?", 2 weeks after target visit
Secondary Outcome Measures: Occurrence of Discussion About Goals of Care at Target Visit, Electronic Health Record (EHR) documentation of discussion about advance care planning, prognosis, treatment preference, hospice, palliative care, or Physician Orders for Life-Sustaining Treatment (POLST) at target visit, Target visit|Occurrence of Discussion About Goals of Care at Target Visit Among Patients Who Did Not Object to Future Discussion at Baseline, Patient's response to question, "Did you discuss with this doctor the kind of medical care you would want if you were too sick to speak for yourself?", 2 weeks after target visit|Occurrence of Discussion About Goals of Care at

Target Visit Among Patients Who Did Not Object to Future Discussion at Baseline, Electronic Health Record (EHR) documentation of discussion about advance care planning, prognosis, treatment preference, hospice, palliative care, or Physician Orders for Life-Sustaining Treatment (POLST) at target visit, Target visit|Goal-Concordant Care, Binary variable indicating whether patient's reported focus of current treatment was concordant with treatment preference, 3 months after target visit|Goal-Concordant Care Among Patients With Stable Treatment Preference, Binary variable indicating whether patient's reported focus of current treatment was concordant with treatment preference, 3 months after target visit|Quality of Communication (QOC): Four-Indicator Latent Construct, Quality of Communication: patient ratings of clinician on seven aspects of end-of-life communication, each aspect having a pseudo-continuous response range of 0 ('clinician didn't do this') to 11 ('the very best I could imagine').

Measured with QOC items 1, 2, 5, \& 6 (measurement invariance imposed between groups and over time). Outcome is a latent variable, which is not observable, nor is it a composite score that can be mathematically computed (e.g., as a sum or average) from its measured indicators. Instead, it is an abstract construct that is inferred through a mathematical model; it represents a concept and is, therefore, a hypothetical variable.

Theoretical range: unknown; the latent variable is a hypothetical - not an actual - variable Actual range: inapplicable; cannot be determined; this is an indirectly-measured latent variable; Higher value indicates better outcome (i.e., higher quality communication) Unit of measurement: scores on a scale, 2 weeks from target visit| Quality of Communication (QOC): Individual QOC Items, Quality of Communication: patient ratings of clinician on seven aspects of end-of-life communication, each aspect having a pseudo-continuous response range of 0 ('clinician didn't do this') to 11 ('the very best I could imagine').

Individual QOC Items.

Theoretical range: 0-11 Actual range: 0-11 Higher value indicates better outcome (i.e., higher quality communication) Unit of measurement: units on a scale, 2 weeks from target visit|Patient Health Questionnaire (PHQ-8): Two-Indicator Latent Construct, Patient Health Questionnaire: A self-report measure of depressive symptoms. Eight symptoms, each with ordinal response options, each option associated with a text description ranging from 'Not at all' to 'Nearly every day'.

Two-Indicator Latent Construct: Measured with PHQ items 1 \& 2 (measurement invariance imposed between groups and over time). Outcome is a latent variable, which is not observable, nor is it a composite score that can be mathematically computed (e.g., as a sum or average)

from its measured indicators. Instead, it is an abstract construct that is inferred through a mathematical model; it represents a concept and is, therefore, a hypothetical variable.

Theoretical range: unknown; the latent variable is a hypothetical - not an actual - variable Actual range: inapplicable; cannot be determined; this is an indirectly-measured latent variable Higher value indicates worse outcome (i.e., higher level of depressive symptoms) Unit of measurement: scores on a scale, 3 months after target visit|Patient Health Questionnaire (PHQ-8): Eight-Item Scale, Patient Health Questionnaire: A self-report measure of depressive symptoms. Eight symptoms, each with ordinal response options, each option associated with a text description ranging from 'Not at all' to 'Nearly every day'.

Eight-Item Scale: Sum of responses for the eight symptoms (weighted by 8/7 if only 7 items answered).

Theoretical range: 0-24 Actual range: 0-24 Higher value indicates worse outcome (i.e., higher level of depressive symptoms) Unit of measurement: scores on a scale, 3 months after target visit|Patient Health Questionnaire (PHQ-8): Two-Indicator Latent Construct, Patient Health Questionnaire: A self-report measure of depressive symptoms. Eight symptoms, each with ordinal response options, each option associated with a text description ranging from 'Not at all' to 'Nearly every day'.

Two-Indicator Latent Construct: Measured with PHQ items 1 \& 2 (measurement invariance imposed between groups and over time). Outcome is a latent variable, which is not observable, nor is it a composite score that can be mathematically computed (e.g., as a sum or average) from its measured indicators. Instead, it is an abstract construct that is inferred through a mathematical model; it represents a concept and is, therefore, a hypothetical variable.

Theoretical range: unknown; the latent variable is a hypothetical - not an actual - variable Actual range: inapplicable; cannot be determined; this is an indirectly-measured latent variable Higher value indicates worse outcome (i.e., higher level of depressive symptoms) Unit of measurement: scores on a scale, 6 months after target visit|Patient Health Questionnaire (PHQ-8): Eight-Item Scale, Patient Health Questionnaire: A self-report measure of depressive symptoms. Eight symptoms, each with ordinal response options, each option associated with a text description ranging from 'Not at all' to 'Nearly every day'.

Eight-Item Scale: Sum of responses for the eight symptoms (weighted by 8/7 if only 7 items answered).

Theoretical range: 0-24 Actual range: 0-24 Higher value indicates

worse outcome (i.e., higher level of depressive symptoms) Unit of measurement: scores on a scale, 6 months after target visit| Generalized Anxiety Disorder (GAD-7): Two-Indicator Latent Construct, Generalized Anxiety Disorder: A self-report measure of anxiety symptoms. Seven symptoms, each with ordinal response options, each option associated with a text description ranging from 'Not at all' to 'Nearly every day'.

Two-Indicator Latent Construct: Measured with GAD items 1 \& 2 (measurement invariance imposed between groups and over time). Outcome is a latent variable, which is not observable, nor is it a composite score that can be mathematically computed (e.g., as a sum or average) from its measured indicators. Instead, it is an abstract construct that is inferred through a mathematical model; it represents a concept and is, therefore, a hypothetical variable.

Theoretical range: unknown; the latent variable is a hypothetical - not an actual - variable Actual range: inapplicable; cannot be determined; this is an indirectly-measured latent variable Higher value indicates worse outcome (i.e., higher level of anxiety symptoms) Unit of measurement: scores on a scale, 3 months after target visit| Generalized Anxiety Disorder (GAD-7): Seven-Item Scale, Generalized Anxiety Disorder: A self-report measure of anxiety symptoms. Seven symptoms, each with ordinal response options, each option associated with a text description ranging from 'Not at all' to 'Nearly every day'.

Seven-Item Scale: Sum of responses for the seven symptoms (weighted by 7/6 if only 6 items answered). (Strong floor effect.)

Theoretical range: 0-21 Actual range: 0-21 Higher value indicates worse outcome (i.e., higher level of anxiety symptoms) Unit of measurement: scores on a scale, 3 months after target visit| Generalized Anxiety Disorder (GAD-7): Two-Indicator Latent Construct, Generalized Anxiety Disorder: A self-report measure of anxiety symptoms. Seven symptoms, each with ordinal response options, each option associated with a text description ranging from 'Not at all' to 'Nearly every day'.

Two-Indicator Latent Construct: Measured with GAD items 1 \& 2 (measurement invariance imposed between groups and over time). Outcome is a latent variable, which is not observable, nor is it a composite score that can be mathematically computed (e.g., as a sum or average) from its measured indicators. Instead, it is an abstract construct that is inferred through a mathematical model; it represents a concept and is, therefore, a hypothetical variable.

Theoretical range: unknown; the latent variable is a hypothetical - not an actual - variable Actual range: inapplicable; cannot be determined; this is an indirectly-measured latent variable Higher

value indicates worse outcome (i.e., higher level of anxiety symptoms) Unit of measurement: scores on a scale, 6 months after target visit| Generalized Anxiety Disorder (GAD-7): Seven-Item Scale, Generalized Anxiety Disorder: A self-report measure of anxiety symptoms. Seven symptoms, each with ordinal response options, each option associated with a text description ranging from 'Not at all' to 'Nearly every day'.

Seven-Item Scale: Sum of responses for the seven symptoms (weighted by 7/6 if only 6 items answered). (Strong floor effect.)

Theoretical range: 0–21 Actual range: 0–21 Higher value indicates worse outcome (i.e., higher level of anxiety symptoms) Unit of measurement: scores on a scale, 6 months after target visit|Avoidance of Life-Sustaining Therapies, All Patients, Review of EHR documentation to assess use of three indicators of life-sustaining therapies (LST): admission to an ICU, receipt of CPR, and receipt of mechanical ventilation, 6-month period following the target visit| Avoidance of Life-Sustaining Therapies, Patients With Comfort Care Preference, Review of EHR documentation to assess use of three indicators of life-sustaining therapies (LST): admission to an ICU, receipt of CPR, and receipt of mechanical ventilation for patients preferring "comfort" (quality of life over extending life) at the end-of-life, 6-month period following the target visit|Palliative Care Consultation, Inpatient Stay - All Patients, EHR documentation of palliative care consultation during an inpatient stay for all patients with target visit and chart abstraction., 3-month period following the target visit|Palliative Care Consultation, Inpatient Stay - Patients Most Likely to Benefit, EHR documentation of palliative care consultation during an inpatient stay for patients who reported preference for "comfort care" (quality of life over extending life) and wanted a discussion., 3-month period following the target visit| Palliative Care Consultation, Inpatient Stay - All Patients, EHR documentation of palliative care consultation during an inpatient stay for all patients with target visit and chart abstraction., 6-month period following the target visit|Palliative Care Consultation, Inpatient Stay - Patients Most Likely to Benefit, EHR documentation of palliative care consultation during an inpatient stay for patients who reported preference for "comfort care" (quality of life over extending life) and wanted a discussion., 6-month period following the target visit|Palliative Care Referral, Outpatient Visit - All Patients, EHR documentation of referral to palliative care services, or discussion about a referral, during an outpatient visit., 3-month period following the target visit|Palliative Care Referral, Outpatient Visit - Patients Most Likely to Benefit, EHR documentation of referral to palliative care services, or discussion about a referral, during an outpatient visit for patients who reported preference for "comfort care" (quality of life over extending life) and wanted a discussion., 3-month period following the target visit|Palliative Care Referral, Outpatient Visit - All Patients, EHR documentation of referral to

palliative care services, or discussion about a referral, during an outpatient visit., 6-month period following the target visit|Palliative Care Referral, Outpatient Visit - Patients Most Likely to Benefit, EHR documentation of referral to palliative care services, or discussion about a referral, during an outpatient visit for patients who reported preference for "comfort care" (quality of life over extending life) and wanted a discussion., 6-month period following the target visit|Palliative Care Consultation and/or Referral - All Patients, EHR documentation of palliative care referral during an outpatient visit and/or palliative care consultation during an inpatient stay., 3-month period following the target visit|Palliative Care Consultation and/or Referral - Patients Most Likely to Benefit, EHR documentation of palliative care referral during an outpatient visit and/or palliative care consultation during an inpatient stay for patients who reported preference for "comfort care" (quality of life over extending life) and wanted a discussion., 3-month period following the target visit|Palliative Care Consultation and/or Referral - All Patients, EHR documentation of palliative care referral during an outpatient visit and/or palliative care consultation during an inpatient stay., 6-month period following the target visit|Palliative Care Consultation and/or Referral - Patients Most Likely to Benefit, EHR documentation of palliative care referral during an outpatient visit and/or palliative care consultation during an inpatient stay for patients who reported preference for "comfort care" (quality of life over extending life) and wanted a discussion., 6-month period following the target visit
Other Outcome Measures: Group Differences - Treatment Preference (Adjustment Variable for Outcome Measuring Goal-concordant Care), Binary variable indicating whether patient's current preference was for life-extension or comfort care, 3 months after target visit|Group Differences - Stable Treatment Preference (Filter for Subgroup Analysis of Goal-concordant Care), Binary variable indicating whether patient's treatment preference was stable between target visit (or baseline, if no 2-week questionnaire was returned) and 3 months., 3 months after target visit
Sponsor: University of Washington
Collaborators: Patient-Centered Outcomes Research Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 817
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 44023
Start Date: 2013-09
Primary Completion Date: 2016-12
Completion Date: 2016-12
First Posted: 2013-09-02

Results First Posted: 2017-11-28
Last Update Posted: 2019-03-20
Locations: Valley Medical Center, Renton, Washington, 98058, United States|Harborview Medical Center, Seattle, Washington, 98104, United States|Swedish Medical Center, Seattle, Washington, 98122, United States|Northwest Hospital and Medical Center, Seattle, Washington, 98133, United States|University of Washington Medical Center, Seattle, Washington, 98195, United States|UW Neighborhood Clinics, Seattle, Washington, 98195, United States
Study Documents:

NCT Number: NCT05596188
Study Title: Anxiety Before Non-cardiac Surgery in Adults
Study URL: https://beta.clinicaltrials.gov/study/NCT05596188
Acronym:
Study Status: RECRUITING
Brief Summary: Adult patients undergoing elective non-cardiac surgery were enrolled. Anxiety before the operation was evaluated by The State Anxiety Inventory (S-AI). Logistics regression would be used for identifying the independent factors of preoperative anxiety and prediction model would be established.
Study Results: NO
Conditions: Myoma of Uterus|Colon Cancer|Gastric Carcinoma|Prostate Cancer|Femoral Head Necrosis
Interventions:
Primary Outcome Measures: Independent risk factors of preoperative anxiety and establishment of prediction model, To identify the independent factors related to preoperative anxiety, which would be analyzed by Logistic regression according to anxiety or not before surgery evaluated by the State anxiety inventory (20-80, lower is better) . Meanwhile, the prediction model of preoperative anxiety would be established based on independent factors., From the 1 day before surgery to 7 days after surgery or discharge, whichever came first
Secondary Outcome Measures: Incidence of preoperative anxiety, The State anxiety inventory (20-80, lower is better) was used to investigate the incidence of Preoperative anxiety, The 1 day before surgery
Other Outcome Measures:
Sponsor: RenJi Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 424
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: SSY04070224
Start Date: 2022-11-10

Primary Completion Date: 2023-10-17
Completion Date: 2024-03-31
First Posted: 2022-10-27
Results First Posted:
Last Update Posted: 2023-05-31
Locations: Renji Hospital, Shanghai, 200127, China
Study Documents:

NCT Number: NCT03098589
Study Title: Revlimid® Capsules Drug Use-results Surveillance (Relapsed or Refractory ATLL)
Study URL: https://beta.clinicaltrials.gov/study/NCT03098589
Acronym:
Study Status: RECRUITING
Brief Summary: To understand the safety and efficacy of Revlimid® Capsules 2.5 mg and 5 mg (hereinafter referred to as Revlimid) under actual conditions of use in patients with relapsed or refractory adult T-cell leukemia lymphoma (hereinafter referred to as relapsed or refractory Adult T-cell Leukemia Lymphoma (ATLL)).

1. Planned registration period 3 years
2. Planned surveillance period 4 years and 6 months after a month after the approval for partial changes in the approved items is granted for relapsed or refractory ATLL
Study Results: NO
Conditions: Lymphoma
Interventions: DRUG: Revlimid
Primary Outcome Measures: Adverse Events (AEs), Number of participants with adverse events, Up to approximately 4 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Celgene
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 80
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NIS-Celgene-JP-PMS-004
Start Date: 2017-05-30
Primary Completion Date: 2023-09-27
Completion Date: 2023-09-27
First Posted: 2017-04-04
Results First Posted:
Last Update Posted: 2022-06-21
Locations: ASO KK Iizuka Hospital, Iizuka, Fukuoka, 820-8505, Japan
Study Documents:

NCT Number: NCT02379988
Study Title: Prone Breath Hold Technique to Decrease Cardiac and Pulmonary Doses in Women Receiving Left Breast Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT02379988
Acronym:
Study Status: COMPLETED
Brief Summary: This is a pilot study to determine whether the addition of inspiratory hold (breath holding) can decrease the radiation dose that the heart and lung receive for patients being treated for left sided breast cancer.
Study Results: YES
Conditions: Breast Cancer
Interventions: RADIATION: Verify radiation dose to heart and lung
Primary Outcome Measures: The Radiation Dose in Gy to the Heart and Lung Using Two Radiation Techniques., The primary endpoints of this study were to evaluate the feasibility of the combination of prone positioning and RPM pDIPH for breast cancer radiation treatment. Each woman enrolled in the study had 2 radiation plans generated: one for the pFB scan and one for the pDIBH scan. The mean difference between the dosimetrically determined heart, left anterior descending (LAD) artery, and left lung radiation doses were computed with the associated 95% confidence interval; however, the Wilcoxin paired signed rank test was used and listed below as the primary analysis because of the non-normal distributions., Treatment Day 1 (both pFB and pDIBH scans were done on the same day)
Secondary Outcome Measures: Determination of Cardiac Dose and Lung Dose Reduction in Women Receiving Prone Breast Radiotherapy When Inspiratory Gating is Added., This outcome was measured by looking at the maximum dose to the heart and maximum dose to the left lung in patients using the free breathing method versus the breath holding method in the prone position. The mean of the maximum doses for each patient was taken and compared using the Wilcoxin Paired Signed Rank Test., Treatment Day 1|Heart Mean Dose Based on Breast Volume, The breast volume was evaluated using the dose-volume histogram. A paired t-test was used to assess if breast volume and the mean difference for heart was statistically significant. Because paired data were generated the number of women required was less than if 2 independent samples of women were to be used., Treatment Day 1|Determination of Left Anterior Artery (LAD) Dose Reduction in Women Receiving Prone Breast Radiotherapy When Inspiratory Gating is Added., This outcome was measured by looking at the maximum dose to the LAD in patients using the free breathing method versus the breath holding method in the prone position. The mean of the maximum doses for each patient was taken and compared using the Wilcoxin Paired Signed Rank Test., Treatment Day 1
Other Outcome Measures:
Sponsor: University of Arizona
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT

Phases: NA
Enrollment: 15
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 1409500149
Start Date: 2014-11-06
Primary Completion Date: 2016-07-03
Completion Date: 2016-07-03
First Posted: 2015-03-05
Results First Posted: 2023-01-31
Last Update Posted: 2023-05-17
Locations: Radiation Oncology Department at the University of Arizona Heath Network, Tucson, Arizona, 85724-5024, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT02993172
Study Title: The Copenhagen City Heart Study
Study URL: https://beta.clinicaltrials.gov/study/NCT02993172
Acronym: CCHS
Study Status: COMPLETED
Brief Summary: The Copenhagen City Heart Study is an ongoing cardiovascular population study initiated in 1976 which has examined approximately 25,000 individuals from the general population. The initial sample has been re-invited up to four times and supplemented by younger individuals. The study includes questionnaires, clinical assessment and biomarkers. The population have been followed in a number of outcome registries and more than 900 scientific papers have been published.
Study Results: NO
Conditions: Coronary Heart Disease|Stroke|Heart Failure|Cancer|Myocardial Infarction|Chronic Obstructive Pulmonary Disease
Interventions:
Primary Outcome Measures: Registry based disease outcomes, mainly cardiovascular, pulmonary and cancer outcomes, Latest registry update december 31 2014
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Bispebjerg Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 23891
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CCHS
Start Date: 1976-01

Primary Completion Date: 2014-01
Completion Date:
First Posted: 2016-12-15
Results First Posted:
Last Update Posted: 2016-12-15
Locations:
Study Documents:

NCT Number: NCT05197972
Study Title: Assessment of Cardiac Coherence Associated With Medical Hypnosis on Preoperative Anxiety in Oncological Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT05197972
Acronym: COHEC2
Study Status: RECRUITING
Brief Summary: The investigator proposes to use the cardiac coherence technique (Cardiac Coherence) coupled with a hypnosis session to reduce pre-operative anxiety.
Study Results: NO
Conditions: Surgery|Oncology
Interventions: OTHER: cardiac coherence program coupled with hypnosis
Primary Outcome Measures: Visual Analogue Scale (VAS) of global anxiety, Visual Analogue Scale (VAS) of global anxiety is a anxiety self-assessment scale that allows the patient to self-assess his or her anxiety using a cursor. The scale ranges from 0 (no anxiety) to 100 (maximum anxiety)., The morning of the surgery (Day 0) upon arrival in the operating room
Secondary Outcome Measures: Program compliance, Program compliance rate of patients in the experimental group. A patient is considered compliant if he declares to have completed at least 2/3 of the proposed Cardiac Coherence sessions + listening to hypnotic tape (at least 5 days /7)., Between -15 to -7 days before surgery (Day -15 to Day -7) until the day of surgery (Day 0)|Measurement of global and specific anxiety level by using a Visual Analogue Scale (VAS), Visual Analogue Scale (VAS) of anxiety is a anxiety self-assessment scale that allows the patient to self-assess his or her anxiety using a cursor. The scale ranges from 0 (no anxiety) to 100 (maximum anxiety). The patient assesses his global and specific anxiety related to: surgery, anesthesia, COVID infectious risk, fear of the unknown, oncological disease, Between -15 to -7 days before surgery (Day -15 to Day -7)|Measurement of global anxiety level by using a Visual Analogue Scale (VAS), Visual Analogue Scale (VAS) of global anxiety is a anxiety self-assessment scale that allows the patient to self-assess his or her anxiety using a cursor. The scale ranges from 0 (no anxiety) to 100 (maximum anxiety)., Between -15 to -7 days before surgery and the day of surgery (Day 0)|The preoperative anxiety score by using the Amsterdam Preoperative Anxiety and Information Scale (APAIS), The Amsterdam Preoperative Anxiety and Information Scale (APAIS) is a self-report questionnaire comprising six questions that have been developed and validated to evaluate the preoperative anxiety of patients. This global index assesses three separate areas: anxiety

about anaesthesia, anxiety about surgery, and the desire for information.

The scale scores six items from 1 to 5 (1 = absence, 5 = extreme). The APAIS scale will be used to determine the psychological profile of patients between "blunting" and "monitoring" types, Between -15 to -7 days before surgery|VAS values and individual psycho-clinical characteristics, Visual Analogue Scale (VAS) of global anxiety is a anxiety self-assessment scale that allows the patient to self-assess his or her anxiety using a cursor. The scale ranges from 0 (no anxiety) to 100 (maximum anxiety) (defined as VAS at Day 0 ≥ 40), and individual psycho-clinical characteristics (gender, smoking, psychological questionnaires)., Between -15 to -7 days before surgery and the day of surgery (Day 0)|Number of patients taking benzodiazepine, Rate of patients taking benzodiazepines in the 2 groups, The day after surgery (Day 1)|Number of days of hospitalization, Length of hospital stay in the 2 groups, The day after surgery (Day -1) and up to 1 month|VAS values and mode of hospitalization and importance of the surgical procedure, Visual Analogue Scale (VAS) of global anxiety is a anxiety self-assessment scale that allows the patient to self-assess his or her anxiety using a cursor, and the mode of hospitalization (ambulatory or conventional) and the importance of the surgical procedure (minor, intermediate or major), The morning of the surgery (Day 0) upon arrival in the operating room|Doses of hypnotic and morphine drugs, Doses of hypnotic and morphine drugs administered during anesthetic induction (Day 0) in the 2 groups, During anesthetic induction (Day 0)|Value of preoperative VAS and adverse events, Visual Analogue Scale (VAS) of global anxiety is a anxiety self-assessment scale that allows the patient to self-assess his or her anxiety using a cursor and adverse event variables: pain, agitation, postoperative nausea and vomiting (PONV), ..., The morning of the surgery (Day 0) upon arrival in the operating room|Number of Self-questionnaire completed, Self-questionnaire completion rates for each of the 2 pre- and postoperative periods, From the day of the anesthesia consultation until the end of the study|Evaluation of the Vecu of General Anesthesia questionnaire (EVAN-G), The EVAN-G questionnaire includes 26 questions whose results are grouped together to define 6 dimensions: Attention Focus, Information, Privacy, Pain, Discomfort and Wait Times. From these scores, an overall satisfaction score is calculated. The total score of the six dimensions reduced to 100., Two day after surgery (Day 2)|Visual Analogue Scale (VAS) of pain, Visual Analogue Scale (VAS) of pain is a pain self-assessment scale that allows the patient to self-assess his or her pain using a cursor, At 1, 2 and 3 month after surgery|Quality of Recovery (QoR), The QoR-15 questionnaire assesses five dimensions of recovery : physical comfort; emotional state; physical independence; physiological support; and pain. Each item was rated on a ten-point Likert scale: none of the time, some of the time, usually, most of the time, and all the time. The total score of 15 ranges from 0 (poorest quality of recovery) to

150 (best quality of recovery)., The day after surgery (Day 1)|Insomnia Severity Index Scale (ISI), The Insomnia Severity Index (ISI) includes 7 questions which assesses the nature of the insomnia, the person's satisfaction with sleep, daily functioning and anxiety about sleep problems. Add scores for all seven items, sum from 0-7 = No clinically significant insomnia to 22-28 = Clinical insomnia (severe)., The day after surgery (Day 1)|VAS of on satisfaction with overall management and anesthesia, Visual Analogue Scale (VAS) of on satisfaction with overall management and anesthesia is a satisfaction self-assessment scale that allows the patient to self-assess his or her satisfaction using a cursor. The scale ranges from 0 (not at all satisfied) to 100 (completely satisfied), The day after surgery (Day 1)
Other Outcome Measures:
Sponsor: Institut du Cancer de Montpellier - Val d'Aurelle
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 296
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: PROICM 2021-09 COH|2021-A01524-37
Start Date: 2022-04-21
Primary Completion Date: 2023-06
Completion Date: 2023-09
First Posted: 2022-01-20
Results First Posted:
Last Update Posted: 2022-05-09
Locations: Institut régional du cancer de Montpellier, Montpellier, Hérault, 34298, France|Institut Universitaire du Cancer Toulouse - Oncopole, Toulouse, France|Institut Gustave Roussy, Villejuif, France
Study Documents:

NCT Number: NCT01641562
Study Title: Diagnosis and Prediction of Taxanes Induced Cardiac Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT01641562
Acronym: CARDIOTAX
Study Status: COMPLETED
Brief Summary: Breast cancer represents the most frequent form of neoplasia in women worldwide, being responsible of 1.6% of annual deaths. Therefore, it is a major public health issue and research in this field should be a priority. Taxanes, such as paclitaxel and docetaxel, are extremely powerful antineoplastic drugs, which alone or in association to anthracyclines, increase survival and lower the recurrence rate of cancer, but their use is limited by cardiotoxicity. Cardiotoxicity can appear early or late after therapy, and may vary

from subclinical myocardial dysfunction to irreversible heart failure. Currently, cardiac dysfunction induced by taxanes is diagnosed through classical echocardiographic parameters. However, these cannot detect subtle, early changes of cardiac structure and function. Consequently, description of new parameters, which could detect cardiac dysfunction in an early stage, becomes essential for detecting the group of patients at risk for irreversible heart failure. The objectives of the investigators project, in patients with breast cancer treated with taxanes, are to investigate their mechanisms which lead to cardiac dysfunction, to describe new parameters for the early diagnosis of cardiotoxicity, and to define predictive models for cardiotoxicity. Meanwhile, project will publish the results in prestigious journals, leading to an increase of the visibility of Romanian research internationally.
Study Results: NO
Conditions: Breast Cancer
Interventions:
Primary Outcome Measures: CARDIOTOXICITY PREDICTION SCORE, To determine the change in left ventricular ejection fraction (LVEF) after 6 months, 1 or 2 years after treatment with taxanes for defining cardiotoxicity (LVEF less than 55% or reduction with more than 10% from baseline)., 6 MONTHS, 1 YEAR, 2 YEARS
Secondary Outcome Measures: GENETIC DISORDERS AND CARDIOTOXICITY, To test implication of some genetic disorders in predicting cardiotoxicity, mainly through decrease of antioxidant capacity;, BASELINE|DIAGNOSTIC ACCURACY FOR CARDIOTOXICITY, Diagnostic accuracy of new echo parameters, as well as new biomarkers, for the early diagnosis of cardiotoxicity., 2 YEARS|EVALUATION PROTOCOL FOR CARDIOTOXICITY, To establish a standard evaluation protocol, by using these parameters and their predictive value, in order to identify patients at risk for cardiac dysfunction., 2 YEARS
Other Outcome Measures:
Sponsor: Carol Davila University of Medicine and Pharmacy
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 60
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 4192910|112/27.10.2011
Start Date: 2012-01-01
Primary Completion Date: 2016-10-30
Completion Date: 2017-01-31
First Posted: 2012-07-17
Results First Posted:
Last Update Posted: 2020-07-17
Locations: University and Emergency Hospital, Bucharest, 050098, Romania

Study Documents:

NCT Number: NCT05892146
Study Title: Strategy Therapy on Cancer Therapy-Related Cardiac Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT05892146
Acronym:
Study Status: RECRUITING
Brief Summary: The investigators use the cancer registration system of National Cheng Kung University Hospital to timely screen and evaluate those patients having breast cancer or lymphoma to enroll patients to participate in this clinical trial. The investigators planned an earlier initiation of Sacubitril/Valsartan treatment on breast cancer and lymphoma patients before the chemotherapy, and starting therapeutic intervention by Sacubitril/Valsartan once the heart damage sign appeared via novel echocardiography. The investigators aim to assess the protective and therapeutic benefit of cardioprotective drugs on the cardiotoxicity of anti-cancer therapy.
Study Results: NO
Conditions: Chemotherapeutic Toxicity|Cardiotoxicity|Heart Failure|Breast Cancer|Lymphoma
Interventions: DRUG: Prevention therapy|DRUG: Rescue therapy
Primary Outcome Measures: Change in absolute global longitudinal strain value measured by left ventricular global peak systolic longitudinal strain, Left ventricular global peak systolic longitudinal strain by cardiac echo, 1 year
Secondary Outcome Measures: Change in left ventricular ejection fraction value measured by echocardiography, Left ventricular ejection fraction by cardiac echo, 1 year|Heart failure hospitalization, admission due to heart function deterioration, 1 year|All-cause mortality, All types of death, 1 year|Change in cardiac biomarkers: including N terminal pro B type natriuretic peptide (NT-proBNP) and high-sensitivity cardiac Troponin (hs-cTnT), Cardiac biomarkers (NT-proBNP and hs-cTnT) changes, 1 year
Other Outcome Measures:
Sponsor: National Cheng-Kung University Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: A-BR-110-021
Start Date: 2021-05-05
Primary Completion Date: 2025-12-31
Completion Date: 2025-12-31

First Posted: 2023-06-07
Results First Posted:
Last Update Posted: 2023-06-07
Locations: National Cheng Kung University Hospital, Tainan, Taiwan
Study Documents:

NCT Number: NCT05781672
Study Title: Prediction of Delayed Toxic Cardiomyopathy in Children
Study URL: https://beta.clinicaltrials.gov/study/NCT05781672
Acronym: SpeckleAnthra2
Study Status: RECRUITING
Brief Summary: Longitudinal analysis of myocardial function using "Speckle Tracking Echocardiography" STE analysis and prediction of delayed toxic induced cardiomyopathy in young patients who received anthracycline therapy in childhood.
Study Results: NO
Conditions: Cardiotoxicity|Childhood Cancer
Interventions: DIAGNOSTIC_TEST: cardiac ultrasound with speckle tracking analysis
Primary Outcome Measures: Left Ventricle Global Longitudinal 2D strain (LVGLS) expressed in percentage and obtained from cardiac ultrasound cineloop of 2D 4,3 and 2 apical views analyzed by the Tomtec STE Software., To compare the evolution at 5 years ("Anthra2" study timeframe) of LVGLS obtained by STE analysis on patients treated with anthracyclines in childhood and previously included in first "Speckle Anthra" study, with the normal evolution of this parameter with age in healthy matched volunteers., 5 years
Secondary Outcome Measures: Left Ventricle Ejection fraction (LVEF) by Simpson method (%), Compare the standard ultrasound parameter LVEF and the LVGLS obtained in "Speckle Anthra 2" on patients treated with anthracyclines in childhood and in the group of healthy volunteers., The day of inclusion|Left ventricular myocardial dysfunction defined by LVEF < 55%, Correlation between the left ventricular myocardial dysfunction is defined by FeVG \< 55% and the left global longitudinal 2D strain expressed in percentage and measured during the previous SpeckleAnthra study, 5 years|Death secondary to toxic cardiomyopathy, Correlation between the rate of patients died with a toxic cardiomyopathy and the left global longitudinal 2D strain expressed in percentage and measured during the previous SpeckleAnthra study, 5 years
Other Outcome Measures: Known risk factors for cardiotoxicity, To assess the effect of known risk factors for anthracycline cardiotoxicity, the anthracycline cumulative dose will be collected, the day of inclusion|Troponin T on the experimental group, Troponin T is a biological markers of cardiotoxicity obtained in a standard blood test analysis and expressed in ng/ml. normal troponin value is between 0 and 0.04 ng/mL, The day of inclusion|NT-pro-BNP on the experimental group, NT-pro-BNP (N terminal-pro-brain natriuretic peptides) is a biological markers of cardiotoxicity obtained in a standard blood test analysis and expressed in pg/ml. Normal NT-proBNP value is \< 400pg/

ml, The day of inclusion|Known risk factors for cardiotoxicity, To assess the effect of known risk factors for anthracycline cardiotoxicity, young age at administration will be collected, the day of inclusion|Known risk factors for cardiotoxicity, To assess the effect of known risk factors for anthracycline cardiotoxicity, female gender, will be collected, the day of inclusion|Known risk factors for cardiotoxicity, To assess the effect of known risk factors for anthracycline cardiotoxicity, association with mediastinal radiotherapy will be collected, The day of inclusion
Sponsor: University Hospital, Montpellier
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: NA
Enrollment: 160
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: RECHMPL22_0513
Start Date: 2023-03-16
Primary Completion Date: 2025-03-16
Completion Date: 2025-09-30
First Posted: 2023-03-23
Results First Posted:
Last Update Posted: 2023-03-27
Locations: Pediatric and Congenital Cardiology and Pulmonology Department, Arnaud De Villeneuve University Hospital, Montpellier, 34295, France
Study Documents:

NCT Number: NCT04598646
Study Title: The HIMALAYAS Pilot Study
Study URL: https://beta.clinicaltrials.gov/study/NCT04598646
Acronym: HIMALAYAS-P
Study Status: NOT_YET_RECRUITING
Brief Summary: Cardiovascular disease (CVD) is a major contributor to morbidity and mortality in pediatric, adolescent and young adult (AYA) cancer survivors (hereafter referred to as PAYA-CS). Exercise is a cornerstone of CVD prevention and treatment; yet, exercise has not been adopted as a standard of care in PAYA-CS at high CVD risk. The HIMALAYAS trial is designed to evaluate the feasibility and preliminary impact of an exercise-based CR on cardiovascular (CV) and psychosocial health, as well as CVD risk, in PAYA-CS with mild heart dysfunction (stage B heart failure (SBHF)). The primary objective of the HIMALAYAS pilot study is to assess the feasibility of a two-arm randomized controlled trial designed to evaluate impact of a 'CR-like' cardio-oncology rehabilitation (CORE) intervention on CV, psychosocial, and behavioural outcomes at 6 and 24 months, compared to behavioural support only (Support) in PAYA-CS. Screened PAYA-CS

without SBHF and those with SBHF who do not participate in the RCT will be enrolled in an passive behavioural support (PBS) group. The primary outcome is study feasibility, defined according to three primary criteria (i.e., participant recruitment, safety, and adherence). Secondary outcomes include additional feasibility metrics (e.g., intervention safety and tolerability) and exploratory efficacy outcomes including peak cardiorespiratory fitness (VO2peak), cardiac function (e.g., global longitudinal strain (GLS)), CVD risk factor control (e.g. insulin resistance), and patient-reported outcomes (e.g. anxiety). Our central hypothesis is that the conduct of a larger phase II RCT comparing the impact of CORE versus Support will be feasible indicated by the achievement of our primary feasibility criteria. Our exploratory hypothesis is that we will generate preliminary evidence that CORE can improve VO2peak, cardiac function, CVD risk factor, and patient-reported outcomes over 6- and 24-month timepoints, relative to Support.
Study Results: NO
Conditions: Heart Failure|Cardiotoxicity|Cancer
Interventions: BEHAVIORAL: Cardio-oncology Rehabilitation (CORE)|BEHAVIORAL: Support|BEHAVIORAL: Passive Behavioural Support
Primary Outcome Measures: Patient Access and Recruitment (feasibility target: >50% of eligible participants), Defined as the percent of consenting patients based on the total number of otherwise eligible participants (OEP; patients meeting all eligibility criteria) approached, Throughout study recruitment, up to 2 years|Testing- and intervention-related serious adverse events (feasibility target: none), Defined as the number and frequency of testing- and intervention-related serious adverse events (SAEs) according to the Common Terminology Criteria for Adverse Events, Initiation through end of study recruitment 12 months|Patient exercise adherence (feasibility target: >=70% of prescribed), Defined as relative dose intensity as the percent of total dose of exercise performed relative to the total planned dose prescribed and quantified according to metabolic equivalents, Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization
Secondary Outcome Measures: Patient identification rate (feasibility target: >=50% of OEP), Defined as the average number of OEP identified each month, Initiation through end of study recruitment 12 months|Baseline assessment rate (feasibility target >=90% of consenting participants), Defined as the percent of consenting patients who successfully complete baseline assessments based on the total number of consenting patients, Initiation through end of study recruitment 12 months|Testing- and intervention-related non-serious adverse events (feasibility target <=20% of consenting participants), Defined as the number and frequency of testing- and intervention-related non-serious adverse events, Initiation through end of study recruitment 12 months|Testing performance (feasibility target >=95% of consenting participants), Defined as the percent completion of all cardiopulmonary exercise tests (CPETs) tests at baseline (T0) and primary follow-up (T1), Initiation through end of study recruitment 12

months|Testing modality adaptation (descriptive), Defined as the percent of all tests which are adapted for functional or safety reasons, Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization|Training modality adaptation (descriptive), Defined as the percent of all exercise sessions which are adapted for functional or safety reasons, Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization|Permanent treatment discontinuation (feasibility target <=15% of participants), Defined as the percent of patients who discontinue intervention participation prior to the planned end of the intervention period, Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization|Treatment interruption (feasibility target <=15% of participants), Defined as the percent of patients who miss =\>3 consecutive sessions within the intervention period, Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization|Dose modification (feasibility target <=25% of participants), Defined as the percent of exercise sessions requiring a dose reduction during training (i.e., intensity or duration) relative to the total number of sessions completed. Total number of exercise sessions with a reduction in intensity or a reduction in duration will be combined into the numerator when calculating the percentage of affected sessions., Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization|Early session termination (feasibility target <=25% of participants), Defined as the percent of exercise sessions requiring unplanned early termination, Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization|Pretreatment intensity modification (feasibility target <=25% of participants), Defined as the percent of sessions which required pre-exercise modification of the target exercise intensity due to a pre-exercise screening indication (e.g., fatigue, pain), Initiation throughout end of CORE intervention, an average of 6 months|Exercise compliance (feasibility target >=70% of prescribed), Defined as the percent of exercise sessions completed based on the total number of sessions prescribed., Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization|Medication compliance (feasibility target >=70% of prescribed), Defined as the percent of pharmaceutical doses taken based on the total number of doses prescribed (applicable only to those that are provided pharmaceutical therapy for CVD risk factor modification., Initiation throughout end of CORE intervention at a maximum of 6 months post-randomization|Behavioural compliance (feasibility target >=70% of prescribed), Defined as the percent of behavioural support resources accessed, based on the number of doses prescribed, Initiation throughout end of study, an average of 2 years|Physical activity compliance (feasibility target >=70% of prescribed), defined as the average number of participants achieving their weekly PA goals of meeting and maintaining either a PAI-Score of ≥100 or weekly cancer exercise guidelines (i.e., 90 to 150 minutes of moderate to vigorous intensity PA per week)., Initiation throughout end of study, an average of 2

years|Attrition (feasibility target <=15% loss to follow-up), Defined as the percent loss to follow-up (not completing follow-up assessments), Initiation throughout end of 6 months post-intervention period
Other Outcome Measures: VO2peak, VO2peak measured by CPET, baseline, 6-, 12- and 24-month follow ups|Cardiac function, 2D LVEF measured by echocardiogram, baseline, 6-, 12- and 24-month follow ups|Cardiac function, 3D LVEF measured by echocardiogram, baseline, 6-, 12- and 24-month follow ups|Cardiac function, GLS measured by echocardiogram, baseline, 6-, 12- and 24-month follow ups|Resting blood pressure, Measured with an average of 3 readings (after discarding an initial test reading) by an automated measurement device as per the Hypertension Canada guidelines., baseline, 6-, 12- and 24-month follow ups|Resting heart rate, Measured with an average of 2 readings taken via ECG during the resting period during the cardiac screening procedures., baseline, 6-, 12- and 24-month follow ups|Hyperlipidemia, Measured through fasting cholesterol profile and Apo B levels, baseline, 6-, 12- and 24-month follow ups|Diabetes and diabetes risk, Measured through fasting glucose, baseline, 6-, 12- and 24-month follow ups|Diabetes and diabetes risk, Measured through whole-body insulin sensitivity (Matsuda index), baseline, 6-, 12- and 24-month follow ups|Diabetes and diabetes risk, Measured through hepatic insulin sensitivity (HOMA-IR), baseline, 6-, 12- and 24-month follow ups|Diabetes and diabetes risk, Measured through pancreatic beta-cell function (ISSI-2)., baseline, 6-, 12- and 24-month follow ups|Diabetes and diabetes risk, Measured through fasting insulin, baseline, 6-, 12- and 24-month follow ups|Physical activity, Measured through Godin Leisure Time PA Questionnaire (GLTPAQ). Score of \>24 = active, score of 14-23 = moderately active, score of \<14 = insufficiently active, baseline, 6-, 12- and 24-month follow ups|Physical activity, Measured through wrist-worn heart rate with physical activity monitor, baseline, 6-, 12- and 24-month follow ups|Social support, Measured using the Social Support Survey-Clinical (SSS-C) form, a 5-item survey designed to measure five dimensions of social support (listening, task challenge, emotional reality confirmation, and tangible assistance); higher score = more social support, baseline, 6-, 12- and 24-month follow ups|Exercise self-efficacy, Measured using the Multidimensional Self-Efficacy for Exercise Scale (MSES) to measure three behavioural subdomains: task, scheduling, and coping; Scale 0-90, higher score indicates higher self-efficacy for exercise., baseline, 6-, 12- and 24-month follow ups|Dietary habits, Measured using the National Health and Nutrition Examination Survey (NHANES) Food Frequency Questionnaire (FFQ), a 139-item, semi-quantitative inventory to assess the potential influence of dietary changes on primary and secondary outcomes., baseline, 6-, 12- and 24-month follow ups|Smoking status, Measured using self-reported measures to determine the potential influence of changes in smoking habits on primary and secondary outcomes., baseline, 6-, 12- and 24-month follow ups|Anxiety, Measured using the Generalized Anxiety Disorder (GAD-7), a 7-item inventory that assesses 2-week anxiety symptom frequency on a 0-3 scale, with higher scores

reflecting higher symptom frequency. A cut-off of ≥10 indicates some degree of clinical anxiety, baseline, 6-, 12- and 24-month follow ups|Depression, Measured using the Patient Health Questionnaire (PHQ-9), a 9-item inventory that assesses 2-week depressive symptom frequency on a 0-3 scale, with higher scores reflecting higher symptom frequency. The PHQ-9 has been validated in cancer survivors using a cut-off of ≥8 to indicate some degree of clinical depression., baseline, 6-, 12- and 24-month follow ups|Health-related quality of life, Measured using the Medical Outcomes Survey Short-Form, (SF-12)., baseline, 6-, 12- and 24-month follow ups|Therapeutic alliance, Measured using the Working Alliance Inventory Short-Revised (WAI-SR) form. Increased score indicates therapeutic alliance., baseline, 6-, 12- and 24-month follow ups
Sponsor: University Health Network, Toronto
Collaborators:
Sex: ALL
Age: ADULT
Phases: NA
Enrollment: 162
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 20-5236.0
Start Date: 2021-01
Primary Completion Date: 2024-09
Completion Date: 2024-12
First Posted: 2020-10-22
Results First Posted:
Last Update Posted: 2020-10-22
Locations:
Study Documents:

NCT Number: NCT03297346
Study Title: Early Detection of Cardiovascular Changes After Radiotherapy for Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03297346
Acronym: EARLY-HEART
Study Status: UNKNOWN
Brief Summary: Breast cancer (BC) radiotherapy leads to coincidental radiation of the heart, resulting in increased risk of a variety of heart diseases. Identifying BC patients with the highest risk of radiation-induced cardiac complications is crucial for developing strategies for primary and secondary prevention. Little has been done on the relationship between dose distribution to different anatomical cardiac structures during radiotherapy and early cardiovascular changes that may lead to cardiac complications.

In the framework of the European project MEDIRAD, the EARLY-HEART multicenter prospective cohort was launched in August 2017, involving

5 investigating centers from France, Netherlands, Germany, Spain and Portugal. With 250 BC patients prospectively followed for 2 years, the main objective is to identify and validate the most important cardiac imaging (echocardiography, computed tomography coronary angiography, cardiac magnetic resonance imaging) and circulating biomarkers of radiation-induced cardiovascular changes arising in the first 2 years after BC radiotherapy.
Study Results: NO
Conditions: Breast Cancer Female
Interventions: OTHER: Cardiac imaging and circulating biomarkers
Primary Outcome Measures: Number of patients with decreased myocardial function assessed by echocardiography, Number of patients with an increased of at least 2.5% in the Global Longitudinal Strain (GLS) between baseline and 2 years after radiotherapy, 2 years after radiotherapy (baseline measurements performed before radiotherapy)
Secondary Outcome Measures: Changes in myocardial function measurements assessed by echocardiography, Increase of the segmental strain measurements (unit of measures:%), 6 months and 2 years after radiotherapy (baseline measurements performed before radiotherapy)|Anatomical changes in coronary arteries assessed by cardiac CT, Increase of the number of coronary segments containing any plaque or increase of the calcium score, 2 years after radiotherapy (baseline measurements performed before radiotherapy)|Myocardial tissue abnormalities assessed by cardiac MRI, Increase of the native mean myocardial T1 mapping value, 6 months and 2 years after radiotherapy (baseline measurements performed before radiotherapy)|Changes in circulating biomarkers measurements, Significant increase or decrease in the following biomarkers:

classical biomarkers of cardiac injury (C-reactive protein, Troponin I, Troponin T, B-type natriuretic peptide (BNP), N-terminal pro-brain natriuretic peptide (NT-Pro BNP), beta2-Microglobulin, Galectin 3); Inflammatory cytokines; biomarkers of endothelial activation and dysfunction; Microparticles; MicroRNAs; circulating DNA methylation, at the end of radiotherapy (through radiotherapy completion, an average of 5 weeks after starting date of radiotherapy), 6 months and 2 years after radiotherapy (baseline measurements performed before radiotherapy)
Other Outcome Measures:
Sponsor: Institut de Radioprotection et de Surete Nucleaire
Collaborators: Academisch Ziekenhuis Groningen|Technical University of Munich|Institut Català d'Oncologia|Hospital de Santa Maria, Portugal|University of Paris 5 - Rene Descartes
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 250
Funder Type: OTHER_GOV
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking:

NONE|Primary Purpose: PREVENTION
Other IDs: MEDIRAD EARLY-HEART_1.2
Start Date: 2017-09-01
Primary Completion Date: 2020-10-01
Completion Date: 2021-05-31
First Posted: 2017-09-29
Results First Posted:
Last Update Posted: 2018-06-19
Locations: IRSN - Clinique Pasteur, Toulouse, France|Klinikum rechts der Isar der Technischen Universität München, Munich, Germany|Academisch Ziekenhuis Groningen, Groningen, Netherlands|Associação para Investigação e Desenvolvimento da Faculdade de Medicina, Lisbon, Portugal|Institut Català d'Oncologia, Girona, Spain
Study Documents: Study Protocol, Statistical Analysis Plan, and Informed Consent Form

NCT Number: NCT00875238
Study Title: Side Effects Involving the Heart in Women With Breast Cancer Receiving Doxorubicin and Trastuzumab
Study URL: https://beta.clinicaltrials.gov/study/NCT00875238
Acronym: PACE in BC
Study Status: COMPLETED
Brief Summary: RATIONALE: Studying samples of blood and tissue in the laboratory from women receiving doxorubicin and trastuzumab for breast cancer may help doctors learn more about changes that occur in DNA and identify biomarkers for increased risk of cardiac effects.

PURPOSE: This clinical trial is studying side effects involving the heart in women with breast cancer receiving doxorubicin and trastuzumab.
Study Results: NO
Conditions: Breast Cancer|Cardiac Toxicity|Cardiovascular Complications
Interventions: BIOLOGICAL: trastuzumab|DRUG: doxorubicin hydrochloride|GENETIC: polymorphism analysis|OTHER: laboratory biomarker analysis|OTHER: questionnaire administration|PROCEDURE: assessment of therapy complications|PROCEDURE: magnetic resonance imaging
Primary Outcome Measures: Change in cardiac function by echocardiogram, change in cardiac function as measured by serial echocardiograms, 5 years
Secondary Outcome Measures: Overall feasibility, 3 years
Other Outcome Measures:
Sponsor: Vanderbilt University
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 133
Funder Type: OTHER

Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CDR0000613213|P30CA068485|VU-VICC-BRE-0767
Start Date: 2008-06
Primary Completion Date: 2015-03
Completion Date: 2015-03
First Posted: 2009-04-03
Results First Posted:
Last Update Posted: 2018-02-19
Locations: University of Louisville James Graham Brown Cancer Center, Louisville, Kentucky, 40202, United States|Vanderbilt Heart One Hundred Oaks, Nashville, Tennessee, 37204, United States|MBCCOP - Meharry Medical College - Nashville, Nashville, Tennessee, 37208, United States|Vanderbilt-Ingram Cancer Center, Nashville, Tennessee, 37232-6838, United States
Study Documents:

NCT Number: NCT05407272
Study Title: Explore the Sharing Model Intervene to Improve the Knowledge, Attitudes, Service Intentions and Service Start-up Effects of the Eight Major Non-cancer Disease End-stage Caregivers on Well-being and Palliative Care
Study URL: https://beta.clinicaltrials.gov/study/NCT05407272
Acronym:
Study Status: COMPLETED
Brief Summary: Since September 1st, 2009, Taiwan has begun to pay attention to the care of patients with organ failure, dementia and the elderly, and brought eight of non-cancer terminal patients into health insurance subsidies to implement the goal of universal palliative care and local aging. Taiwan has entered the aged society since March 2018, become the heavy burden of expenditure in Taiwan because of the health care needs and costs associated with the rapid aging of the population. With advanced medical technology, when facing inevitable death situation, should not use too much medical treatment on terminally ill patients. The waste of medical resources and bring both patients and family members so much pain. In Taiwan, people have misconception about tranquil palliative care. The low rate of home palliative care for non-terminal cancer patients. The purpose of this study is investigating the eight non-cancer terminal caregivers' knowledge, attitudes and service intentions of palliative care, and getting the result by research intervention.

In this study, a randomized experimental research design was applied by two-group pre-and post-test. The targets are the eight non-cancer terminal caregivers in a home care institution of a regional teaching hospital located in Yilan. Targets' ID end with odd numbers are in experimental group received shared mode intervention, and even numbers are in control group received home routine care. The experimental group was implementing measures of weekly shared mode intervention in 20 to 60 minutes for six weeks; the control group started to implement

measures of home care medical instructions booklet in the third week. The content of the outcome measurement questionnaire includes: basic information of the eight non-cancer terminal caregivers, the palliative care knowledge scale, the palliative care attitude scale, and palliative care service initiation intention scale. Data were analyzed by statistical methods such as descriptive analysis, independent sample t-test, paired-samples t-test, Pearson correlation analysis and one-way ANOVA.
Study Results: NO
Conditions: Alzheimer Disease, Late Onset|Stroke|Heart Failure|Pulmonary Disease, Chronic Obstructive|Cystic Fibrosis Pulmonary Exacerbation|Chronic Liver Disease and Cirrhosis|Kidney Failure, Acute|Kidney Failure, Chronic
Interventions: OTHER: Health Education Manual|OTHER: manual
Primary Outcome Measures: the knowledge, attitudes, service intentions and service start-up effects of the eight major non-cancer disease end-stage caregivers on well-being and palliative care, The content of the outcome measurement questionnaire includes: basic information of the eight non-cancer terminal caregivers, the palliative care knowledge scale, the palliative care attitude scale, and palliative care service initiation intention scale. Data were analyzed by statistical methods such as descriptive analysis, independent sample t-test, paired-samples t-test, Pearson correlation analysis and one-way ANOVA., six weeks
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Wen-Shiou Pan
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: NA
Enrollment: 60
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SEQUENTIAL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: HEALTH_SERVICES_RESEARCH
Other IDs: WSPan
Start Date: 2021-09-14
Primary Completion Date: 2022-02-14
Completion Date: 2022-05-30
First Posted: 2022-06-07
Results First Posted:
Last Update Posted: 2022-06-08
Locations: Wen-Shiou Pan, Yilan, 260, Taiwan
Study Documents:

NCT Number: NCT05114772
Study Title: Pre Procedural Biomarkers Might Predict Recurrent Atrial Fibrillation After Catheter Ablation

Study URL: https://beta.clinicaltrials.gov/study/NCT05114772
Acronym:
Study Status: COMPLETED
Brief Summary: Evaluation of the predictive value of serum levels of adipocytokines and primary phase reactant for recurrent atrial fibrillation (RAF) after catheter ablation in 26 patients had persistent and 91 patients had paroxysmal AF. During 12-m follow-up, 41 patients had RAF (35%). Patients had RAF were significantly older, had significantly higher BMI, lower ejection fraction and wider maximal left atrial diameter (LAD). Serum hs-CRP, IL-6, TNF-α, visfatin, and adiponectin levels were significantly higher in patients developed. Elevated serum levels of TNF-α, visfatin and adiponectin are a significant positive predictors for RAF.
Study Results: NO
Conditions: Atrial Fibrillation
Interventions: DIAGNOSTIC_TEST: Measuring Serum bio-markers
Primary Outcome Measures: Recurrent Atrial Fibrillation, Recurrent Atrial Fibrillation after Catheter ablation, 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Tanta University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 117
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, INVESTIGATOR)|Primary Purpose: DIAGNOSTIC
Other IDs: 34816/7/19
Start Date: 2019-07-01
Primary Completion Date: 2021-07-01
Completion Date: 2021-08-01
First Posted: 2021-11-10
Results First Posted:
Last Update Posted: 2021-11-10
Locations: Tanta university, Tanta, Egypt
Study Documents:

NCT Number: NCT03416972
Study Title: Detecting Radiation-Induced Cardiac Toxicity After Non-Small Cell Lung Cancer Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT03416972
Acronym: RICT-LUNG
Study Status: UNKNOWN
Brief Summary: Lung cancer is the most common cause of cancer death in Canada. For approximately 30% of patients that present with locally-advanced non-small cell lung cancer (NSCLC), the standard treatment is

curative-intent concurrent chemoradiotherapy. Outcomes remain poor, with 5-year survival of only 20%. Despite the long-held belief that higher radiation doses lead to improved overall survival (OS), the landmark randomized trial (RTOG 0617) showed the opposite. The investigators hypothesize that the inferior survival observed may be due to unexpected heart toxicity as secondary analysis revealed that the heart dose was a strong predictor of inferior OS. Up to now, change in heart function is typically detected histologically, requiring autopsy tissue. Therefore, a non-invasive marker of early heart damage is required. Hybrid PET-MRI has become available in Canada only recently. The ability to simultaneously perform metabolic imaging with functional and tissue imaging allows for novel assessment of heart toxicity. The primary objective is to examine the utility of hybrid PET-MRI and DCE-CT to assess acute changes in heart function and to measure inflammation before, and six weeks after NSCLC radiotherapy. A pilot of 20 patients with Stage I-III NSCLC will be enrolled. The findings of this study will aid in the design of new studies to reassess dose escalation for locally advanced NSCLC while limiting the risk of heart toxicity. FDG PET will be used to simultaneously assess both cardiac inflammation and tumour response. Quantitative DCE-CT will also be used to measure ventilation and perfusion changes in the normal lung and tumour after radiotherapy, providing image data that can comprehensively assess both tumour response and potential toxicity in both the heart and lungs. Such information is crucial in understanding the disease and its response to treatment. This data will also aid in the design of radiation techniques that spare the heart in other patients with any thoracic malignancies, including breast cancer, lymphoma, and esophageal cancer.
Study Results: NO
Conditions: Non-small Cell Lung Cancer|Radiation Toxicity
Interventions: RADIATION: Standard platinum-based chemoradiotherapy
Primary Outcome Measures: Detection of Imaging Biomarkers of acute cardiac inflammation, FDG-PET imaging to detect increase in cardiac inflammation compared to baseline with corresponding blood markers (Erythrocyte Sedimentation Rate (ESR), high sensitivity C-reactive protein, and troponin levels in blood (inflammation))., 6 weeks| Detection of Imaging Biomarkers of acute cardiac perfusion changes, DCE-CT imaging to detect changes in acute cardiac perfusion changes compared to baseline., 6 weeks|Detection of Imaging Biomarkers of acute changes in Left-ventricular ejection fraction (LVEF), Contrast-enhanced CT imaging to detect acute changes in LVEF compared to baseline., 6 weeks|Detection of cardiac fibrosis, Gadolinium Enhanced MR imaging to detect cardiac fibrosis compared to baseline, 6 weeks
Secondary Outcome Measures: Tumour Response (metabolism), FDG-PET imaging to detect tumour metabolism changes compared to baseline., 6 weeks|Tumour Response (perfusion), DCE-CT imaging to detect changes in tumour perfusion compared to baseline, 6 weeks|Acute Changes in Lung Ventilation, 4D-CT imaging to detect changes in lung ventilation compared to baseline, 6 weeks|Acute Changes in Lung Perfusion, DCE-CT

imaging to detect changes in lung perfusion compared to baseline, 6 weeks
Other Outcome Measures:
Sponsor: Lawson Health Research Institute
Collaborators: Canadian Institutes of Health Research (CIHR)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 20
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: R-17-360
Start Date: 2018-01-11
Primary Completion Date: 2019-03-01
Completion Date: 2020-03-01
First Posted: 2018-01-31
Results First Posted:
Last Update Posted: 2018-01-31
Locations: Lawson Health Research Institute, London, Ontario, N6C 2R5, Canada
Study Documents:

NCT Number: NCT05832138
Study Title: ONLOOP Trial: Evaluating a New Surveillance and Support System for Survivors of Childhood Cancer in Ontario
Study URL: https://beta.clinicaltrials.gov/study/NCT05832138
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: The treatments that aim to cure cancer in children can lead to "late effects" such as second cancers and heart disease. Screening tests can help find late effects, but most adult survivors of childhood cancer do not complete these tests. These survivors are at risk for harm that can be prevented.

We have developed a program called ONLOOP to remind survivors in Ontario, Canada to get the screening tests they need. ONLOOP reminds survivors who are at higher risk for heart disease, breast cancer, and/or colorectal cancer to complete their echocardiograms, mammograms and breast MRIs, and/or colonoscopies.

The goal of this clinical trial is to find out how well ONLOOP helps adult survivors of childhood cancer complete their screening tests. We also want to see if it could be turned into a long-term program in Ontario. Eligible survivors will be randomly assigned to either receive intervention materials or continue with usual care for 13 months before receiving intervention materials.

The intervention includes usual care plus these ONLOOP materials:

1. Study invitation letter and invitation reminder
2. Those who sign up for ONLOOP will receive personalized health information and a screening reminder. Survivors will receive information about:

   1. their cancer treatment
   2. their risk(s) for late effects
   3. the screening tests they should do

3. Survivors' primary care providers will be provided with the same health information provided to participants in (2)

Study Results: NO
Conditions: Survivorship|Cancer|Heart Diseases|Secondary Cancer|Colorectal Cancer|Breast Cancer
Interventions: BEHAVIORAL: ONLOOP program
Primary Outcome Measures: Completion of guideline-recommended surveillance tests, Proportion of survivors who complete one or more of the guideline-recommended cardiac, breast or colon surveillance tests (echocardiography, mammogram and breast MRI, colonoscopy) during the 12 months after study cohort randomization, 12 months
Secondary Outcome Measures: Completion of guideline-recommended surveillance tests, Proportion of survivors who complete one or more of the guideline-recommended cardiac, breast or colon surveillance tests (echocardiography, mammogram and breast MRI, colonoscopy) during the 24 months after study cohort randomization, 24 months|Completion of each type of surveillance test, Proportion of survivors who complete each type of surveillance test (among those eligible for the test), 12 months, 24 months|Completion of all guideline-recommended surveillance tests, Proportion of survivors who are fully up-to-date according to surveillance guidelines, 12 months, 24 months|Visits to primary care professionals and cancer specialists, Number of outpatient visits to primary care professionals and to cancer specialists, 12 months, 24 months|Use of other healthcare services, Rates of emergency department visits and/or hospitalizations to understand impact on health system resources, 12 months, 24 months
Other Outcome Measures:
Sponsor: The Hospital for Sick Children
Collaborators: Women's College Hospital|Ottawa Hospital Research Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 900
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (PARTICIPANT)|Primary Purpose: SCREENING
Other IDs: 4152
Start Date: 2023-06
Primary Completion Date: 2025-06
Completion Date: 2026-06

First Posted: 2023-04-27
Results First Posted:
Last Update Posted: 2023-04-27
Locations:
Study Documents:

NCT Number: NCT05174338
Study Title: Cardiac Amyloidosis Registry Study
Study URL: https://beta.clinicaltrials.gov/study/NCT05174338
Acronym: CARS
Study Status: ENROLLING_BY_INVITATION
Brief Summary: This registry is a observational, multi-center study designed to collect data and analyze it retrospectively on patients with cardiac amyloidosis who have been evaluated and treated at major amyloid centers across the US and internationally between 1997 and 2025.
Study Results: NO
Conditions: Amyloidosis, Immunoglobulin Light-chain
Interventions: OTHER: Registry
Primary Outcome Measures: Quantify disease severity at diagnosis, progression and survival in patients with cardiac amyloidosis,
Clinical Outcomes: Disease severity at presentation, progression, and survival \[time frame 3 years\]. Severity and progression determined by change in NYHA Class, NT-ProBNP and troponin., 1997 - 2025|Quantify incidence of complications from cardiac amyloidosis, Determine incidence of arrhythmias (atrial fibrillation; ventricular arrhythmias) after diagnosis, renal dysfunction (rise in creatinine and development of end-stage renal disease), stroke, bleeding complications \[time frame 3 years\], 1997 - 2025
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Cedars-Sinai Medical Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 2000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: STUDY00000442
Start Date: 2020-01-08
Primary Completion Date: 2025-12
Completion Date: 2025-12
First Posted: 2021-12-30
Results First Posted:
Last Update Posted: 2023-03-17
Locations: University of Arizona Sarver Heart Center, Tucson, Arizona, 85724, United States|UC San Diego Health, Sulpizio Cardiovascular Center, La Jolla, California, 92037, United States|Scripps Health, La

Jolla, California, 92137, United States|University of California Davis, Sacramento, California, 95817, United States|University of California, San Francisco, San Francisco, California, 94103, United States|Johns Hopkins University School of Medicine, Baltimore, Maryland, 21287, United States|Tufts Medical Center, Boston, Massachusetts, 02111, United States|Massachusetts General Hospital, Boston, Massachusetts, 02114, United States|Boston Medical Center, Boston, Massachusetts, 02118, United States|Saint Luke's Hospital of Kansas City, Kansas City, Missouri, 64111, United States|Washington University in St. Louis, Saint Louis, Missouri, 63110, United States|NYU Langone Health, New York, New York, 10016, United States|The Mount Sinai Hospital, New York, New York, 10029, United States|Columbia University Irving Medical Center, Clinical Cardiovascular Research Laboratory for the Elderly (CUMC/CCRLE), New York, New York, 10032, United States|Duke Health, Durham, North Carolina, 27710, United States|Penn Presbyterian Medical Center, Philadelphia, Pennsylvania, 19104, United States|Medical University of South Carolina, Charleston, South Carolina, 29425, United States|University of Texas Southwestern Medical Center, Dallas, Texas, 75390, United States|University of Texas Health Science Center at Houston, Houston, Texas, 77030, United States|University of Utah, Salt Lake City, Utah, 84112, United States
Study Documents: Study Protocol

NCT Number: NCT05096338
Study Title: Mechanisms, Predictors, and Social Determinants of Cardiotoxicity in Prostate Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05096338
Acronym: PCT
Study Status: RECRUITING
Brief Summary: This is an observational study for patients with prostate cancer that will be treated with Androgen Deprivation Therapy. The study will help the investigators learn more about how these medications affect the heart and how those effects relate to patients' medical history and social determinants of health (such as race, gender identity, education, occupation, access to health services and economic resources). Patients on this study will have echocardiograms, blood draws, and answer questions about their symptoms and activity level. Patients will be followed on this study for up to 5 years.
Study Results: NO
Conditions: Prostate Cancer|Cardiotoxicity|Drug-Related Side Effects and Adverse Reactions|Cardiovascular Diseases
Interventions: OTHER: Social Determinants of Health
Primary Outcome Measures: Change in Left Ventricular Ejection Fraction (LVEF), Absolute change in LVEF by echocardiogram at follow-up, through study completion (expected to be 15 years)
Secondary Outcome Measures: Cancer therapy-related cardiac dysfunction (CTRCD), Incidence of CTRCD defined as at least a 10% absolute change in LVEF by echocardiogram at follow-up relative to baseline to a value \< 50%, through study completion (expected to be 15 years)|Symptomatic

Heart Failure (HF), Incidence of symptomatic heart failure (centrally adjudicated), through study completion (expected to be 15 years)| Change in Longitudinal Strain, Change in longitudinal strain by echo from baseline, through study completion (expected to be 15 years)| Change in Circumferential Strain, Change in circumferential strain by echo from baseline, through study completion (expected to be 15 years)|Change in Diastolic function, Change in diastolic function defined as E/e' by echo from baseline, through study completion (expected to be 15 years)|Change in Left Ventricular (LV) Mass, Change in LV Mass by echo from baseline, through study completion (expected to be 15 years)|Change in Relative LV Wall Thickness, Change in relative LV wall thickness from baseline, through study completion (expected to be 15 years)|Change in Ventricular-Arterial Coupling, Change in Ventricular-Arterial Coupling defined as Ea/Ees by echo from baseline, through study completion (expected to be 15 years)|Change in LV Twist, Change in LV Twist measured by 3D echo from baseline, through study completion (expected to be 15 years)|Change in LV Torsion, Change in LV Torsion measured by 3D echo from baseline, through study completion (expected to be 15 years)|Change in NTproBNP, Change in NTproBNP measured in batches from banked samples from baseline., through study completion (expected to be 15 years)|Change in high-sensitivity troponin (hsTnT), Change in hs-TnT measured in batches from banked samples from baseline., through study completion (expected to be 15 years)|Change in patient reported fatigue, Change in Patient Reported Outcomes Information System (PROMIS) Fatigue Score from baseline. A higher score corresponds to higher reported levels of fatigue., through study completion (expected to be 15 years)|Change in patient reported quality of life, Change in Patient Reported Outcomes Information System (PROMIS) Global Health score from baseline. Higher scores indicate a healthier patient., through study completion (expected to be 15 years)|Change in patient reported activity level, Change in total weekly leisure activity in METS assessed by Godin Leisure Time Exercise Questionnaire from baseline., through study completion (expected to be 15 years)
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators: American Heart Association
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 200
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 12821
Start Date: 2021-10-27
Primary Completion Date: 2028-10
Completion Date: 2028-10
First Posted: 2021-10-27
Results First Posted:

Last Update Posted: 2023-01-20
Locations: University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT00749372
Study Title: MRI Screening for Patients With Myelodysplastic Syndrome (MDS), Who Have Received Multiple Red Blood Cell Transfusions
Study URL: https://beta.clinicaltrials.gov/study/NCT00749372
Acronym: T2*MRI
Study Status: COMPLETED
Brief Summary: A known risk of red blood cell transfusions is that it puts excess iron into the patient's body. Researchers are continually seeking the most effective method of measuring iron concentration. The purpose of this study is to determine how much iron has been deposited in a patient's heart and liver as a result of having received red blood cell transfusions using magnetic resonance imaging (MRI).
Study Results: NO
Conditions: Myelodysplastic Syndrome (MDS)
Interventions: OTHER: T2* Cardiac and Liver MRI
Primary Outcome Measures: To evaluate the incidence of clinically significant cardiac iron overload in heavily transfused MDS patients using T2* MRI., A single T2* MRI will be performed on eligible patients.
Secondary Outcome Measures: Evaluate left ventricular ejection fraction as assessed by T2* MRI., A single T2* MRI will be performed on eligible patients.|Evaluate liver iron concentration as assessed by R2* MRI, A single T2* MRI will be performed on eligible patients.
Other Outcome Measures:
Sponsor: Weill Medical College of Cornell University
Collaborators: Novartis Pharmaceuticals
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 15
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: SCREENING
Other IDs: 0803009687|CICL670A US23T
Start Date: 2008-07-31
Primary Completion Date: 2013-03-29
Completion Date: 2013-03-29
First Posted: 2008-09-09
Results First Posted:
Last Update Posted: 2018-10-25
Locations: Weill Medical College of Cornell University, New York, New York, 10065, United States
Study Documents:

NCT Number: NCT02306538
Study Title: Evaluation of Myocardial Changes During BReast Adenocarcinoma Therapy to Detect Cardiotoxicity Earlier With MRI
Study URL: https://beta.clinicaltrials.gov/study/NCT02306538
Acronym: EMBRACE-MRI
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Breast cancer is the most common cancer amongst Canadian women. 15-20% of early breast cancers have high levels of a protein called HER2 which is associated with worse survival. Treatment of these patients with anthracyclines followed by trastuzumab (which targets HER2) improves survival. Unfortunately, these medications together can cause heart muscle injury resulting in heart dysfunction or failure in about 14% and 3.6% of the patients, respectively. Once heart failure (HF) occurs, about 60% of patients will not live past 2 years. Studies have suggested that patients with heart injury caused by anthracyclines may be more likely to develop HF with addition of trastuzumab. Therefore tests to find early heart injury after anthracyclines may allow doctors to start heart protective medications with the hope of preventing HF. Also, animal and small patient studies have shown that an increase in the water levels of the heart muscle (edema) may be an early sign of heart injury from anthracyclines. Cardiac MRI is a unique technique that has been shown to detect edema in various heart diseases.

The investigators will test the theory that, in women receiving treatment for breast cancer, heart edema detected by MRI at the end of anthracyclines will identify patients who will later develop heart dysfunction. MRI studies with novel techniques will be done pre-therapy, after anthracyclines, during herceptin, and at end of all therapy. The investigators will compare patients with and without heart dysfunction to test if patients with heart dysfunction are more likely to have edema after anthracyclines. Ultimately the investigators hope to use cardiac MRI to identify high risk patients and study various heart protective medications to prevent HF. This will improve the personal health of cancer patients by allowing them to live free of heart disease after their cancer therapy. Ultimately at a population level this will allow doctors to provide care that can be uniquely designed for each patient based on their individual risk.

The first 136 patients enrolled are included in the first part of the study, named EMBRACE-MRI 1. Enrollment for this part of the study is complete.

The remaining 44 patients will be enrolled into EMBRACE-MRI 2, which includes slight differences in obtaining sequences in MRI imaging.
Study Results: NO
Conditions: Breast Neoplasms
Interventions:
Primary Outcome Measures: The presence of myocardial edema stratified by the presence or absence of conventionally defined cardiotoxicity

(this is a binary outcome)., Myocardial edema is defined as an 8% increase in segmental T2 values measured in milliseconds in at least 2 myocardial segments at either of the 2 early time points. Cardiotoxicity is defined as Cardiac Magnetic Resonance Imaging (CMR) measured (1) ≥5% absolute reduction in Left Ventricular Ejection Fraction (LVEF) from baseline to an LVEF \<55% with signs or symptoms of HF, OR (2) a ≥10% absolute reduction in LVEF from baseline to \<55% without accompanying signs or symptoms at the time points when CMR is obtained OR (3) the same amount of reduction in LVEF as above, identified by echo at any time point (done every 3 months) and confirmed by CMR at that time., 2-15 months
Secondary Outcome Measures: The presence of edema stratified by the presence or absence of any drop in LVEF ≥5% by CMR by end of therapy (this is a binary outcome)., Please see definition for edema above, 2-15 months
Other Outcome Measures:
Sponsor: University Health Network, Toronto
Collaborators: Canadian Institutes of Health Research (CIHR)| University of Toronto
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 180
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 13-6543C
Start Date: 2013-10
Primary Completion Date: 2024-08
Completion Date: 2027-01
First Posted: 2014-12-03
Results First Posted:
Last Update Posted: 2023-02-14
Locations: Toronto General Hospital, Toronto, Ontario, M5G 2N2, Canada
Study Documents:

NCT Number: NCT05355662
Study Title: Prognosis Analysis of Elderly Donor Liver in Liver Transplantation
Study URL: https://beta.clinicaltrials.gov/study/NCT05355662
Acronym:
Study Status: COMPLETED
Brief Summary: Based on the follow-up data of elderly donation after cardiac death(DCD) donor liver transplant recipients from the CLTR, a database and official website for national data gathering. patients who met the enrollment criteria were screened for postoperative complications and survival for statistical analysis to understand the prognosis of patients and analyze the risk factors affecting their prognosis.
Study Results: NO

Conditions: Liver Transplantation|Hepatocellular Carcinoma|Survival
Interventions: OTHER: Age
Primary Outcome Measures: Post-operative survival time, Postoperative survival time for patients receiving liver transplantation, Time from the end of liver transplantation to the patient's death, or the end of follow-up by December 31, 2020. whichever came first, assessed up to 72 months.|Transplanted liver status, Postoperative Liver Function in Patients Undergoing Liver Transplantation, Time from the end of liver transplantation to the patient's death, or the end of follow-up by December 31, 2020. whichever came first, assessed up to 72 months.The functional status of the transplanted liver was recorded during this period.|Recurrence of the primary disease after surgery, Recurrence of primary disease in patients who underwent liver transplantation after surgery, The time period between liver transplantation and the initial examination revealing a recurrence of primary disease, or until the end of follow-up on December 31, 2020.whichever came first, assessed up to 72 months.
Secondary Outcome Measures: Surgery details, Detailed information such as operation time, Intraoperative|Post-operative complications in patients who underwent liver transplantation, Specific details of all post-operative complications in patients who underwent liver transplantation, Time from the end of liver transplantation to the patient's death, or the end of follow-up by December 31, 2020. whichever came first, assessed up to 72 months.During this period, all postoperative complications of the patient will be recorded.
Other Outcome Measures:
Sponsor: First Affiliated Hospital Xi'an Jiaotong University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 11569
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: No. XJTU1AF-CRF-2019-029
Start Date: 2015-01-01
Primary Completion Date: 2018-12-31
Completion Date: 2018-12-31
First Posted: 2022-05-02
Results First Posted:
Last Update Posted: 2022-05-02
Locations:
Study Documents:

NCT Number: NCT03301389
Study Title: Cardiac Magnetic Resonance for Early Detection of Chemotherapy or Radiation Therapy Induced Cardiotoxicity in Breast Cancer (CareBest)
Study URL: https://beta.clinicaltrials.gov/study/NCT03301389

Acronym:
Study Status: RECRUITING
Brief Summary: Chemotherapy or radiation therapy-induced cardiotoxicity are well-recognized side effects in patients with cancer. The clinical significance of cardiotoxicity is growing with increasing cancer survivor-ship.

Left ventricular (LV) functional assessment is the standard of reference to diagnose chemotherapy- or radiation therapy-induced cardiotoxicity. The investigators will investigate the usefulness of T1 mapping parameters for early detection and prediction of chemotherapy-, radiation therapy-, or other therapy-induced cardiotoxicity in breast cancer patients This study aimed to achieve early detection of chemotherapy- or radiation therapy-induced cardiotoxicity using T1 mapping magnetic resonance imaging (MRI) and determine a prognostic imaging factor of chemotherapy- or radiation therapy-induced cardiotoxicity in patients treated for breast cancer.
Study Results: NO
Conditions: Chemotherapy Induced Cardiotoxicity
Interventions: OTHER: Cardiac magnetic resonance imaging
Primary Outcome Measures: Decrease in LVEF (left ventricular ejection fraction), Decrease in LVEF : more than 10% compared to the baseline LVEF) or LVEF \< 50%, 1 year after CMR scanning|Decrease in LVEF (left ventricular ejection fraction), Decrease in LVEF : more than 10% compared to the baseline LVEF) or LVEF \< 50%, 2 years after CMR scanning
Secondary Outcome Measures: MACE (Major adverse cardiac events), 1 year after CMR scanning|MACE (Major adverse cardiac events), 2 years after CMR scanning
Other Outcome Measures:
Sponsor: Yonsei University
Collaborators:
Sex: FEMALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 2000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 4-2016-0730
Start Date: 2016-12-01
Primary Completion Date: 2025-01
Completion Date: 2025-01
First Posted: 2017-10-04
Results First Posted:
Last Update Posted: 2019-01-11
Locations: Department of Radiology, Research Institute of Radiological Science, Severance Hospital, Yonsei University College of Medicine, Seoul, 03722, Korea, Republic of
Study Documents:

NCT Number: NCT05851053
Study Title: Breast Cancer Long-term Outcomes on Cardiac Functioning: a Longitudinal Study
Study URL: https://beta.clinicaltrials.gov/study/NCT05851053
Acronym: BLOC-II
Study Status: RECRUITING
Brief Summary: Rationale: In addition to surgery, effective breast cancer (BC) treatment typically requires chemotherapy, radiotherapy, or both. However, it is still unclear whether patients with BC are at increased risk of long-term cardiac dysfunction due to the adverse effects of these therapies. In a cross-sectional study in primary care, a comparison on cardiac dysfunction between 350 BC survivors and 350 age- and general practitioner (GP)- matched controls without cancer was made. In that study, BC survivors were at increased risk of mild systolic cardiac dysfunction (left ventricle ejection fraction (LVEF)\< 54%). By contrast, there was no significant difference in an LVEF \< 50% or in diastolic dysfunction. To date it remains uncertain whether the mild or subclinical dysfunction we observed predicts further cardiac deterioration. Consequently, the translation of these results into guidelines for the daily practice of the GP is unclear.

Objective: The aim of the here proposed study is to clarify whether cardiac function in survivors of BC should be monitored by GPs, by assessing whether an unselected population of long-term BC survivors is at increased risk of developing cardiac dysfunction, whether in this group at-risk subgroups exists, and what factors are associated with the highest risk.

Study design: A new assessment of cardiac function among women included in the BLOC-I study. This produces a longitudinal matched cohort design consisting of two cohorts in primary care.

Study population: Survivors of BC, diagnosed ≥11 years ago who received chemotherapy and/or radiotherapy, and a matched reference population with no history of cancer. All participants participated in the Breast cancer Long-term Outcome of Cardiac function (BLOC-I) study.

Main study parameters/endpoints: Left ventricular systolic dysfunction. Systolic cardiac dysfunction is defined as a LVEF \<54/50/45%.
Study Results: NO
Conditions: Neoplasm, Breast|Heart Failure|Cardiotoxicity|Ventricular Dysfunction
Interventions: DIAGNOSTIC_TEST: Echocardiography
Primary Outcome Measures: Left ventricular systolic dysfunction, Prevalance of systolic cardiac dysfunction defined as a LVEF \<54%, through study completion (from Ocotober 2022 - December 2024)
Secondary Outcome Measures: Clinically used LVEF cut-off points <45%

and <50%, Prevalance of systolic cardiac dysfunction defined as a LVEF \<45% and \<50%, through study completion (from Ocotober 2022 - December 2024)|Course of cardiac function, Rate of change of systolic and diastolic cardiac function by change in LVEF, through study completion (from Ocotober 2022 - December 2024)|Cardiovascular diseases, Prevalence of cardiovascular diseases obtained from electronic patient records, through study completion (from Ocotober 2022 - December 2024)|Symptoms of hearth failure, Clinical symptoms of heart failure measured using a self-constructed questionnaire, through study completion (from Ocotober 2022 - December 2024)
Other Outcome Measures: Patient characteristics, age, BMI, menopausal state, through study completion (from Ocotober 2022 - December 2024)|Physical activity, Changes in Physical Acticity measured with Short Questionnaire to Assess Health-enhancing physical activity (SQUASH), through study completion (from Ocotober 2022 - December 2024)|Depression, Symptoms of depression measured with Hospital Anxiety and Depression Scale - Despression (HADS-D), through study completion (from Ocotober 2022 - December 2024)|Anxiety, Symptoms of anxiety measured with Hospital Anxiety and Depression Scale - Anxiety (HADS-A), through study completion (from Ocotober 2022 - December 2024)|Fatigue, Multidimensional assessment of fatigue mesaured with Multidimensional Fatigue Index - 20 (MFI-20)., through study completion (from Ocotober 2022 - December 2024)|Use of cardiovascular medication, Use of cardiovascular medication based on electronic patient records, through study completion (from Ocotober 2022 - December 2024)|Smoking behavior (self-reported pack years), Smoking behavior, through study completion (from Ocotober 2022 - December 2024)
Sponsor: University Medical Center Groningen
Collaborators: ZonMw: The Netherlands Organisation for Health Research and Development
Sex: FEMALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 455
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 202100903
Start Date: 2022-09-01
Primary Completion Date: 2025-12-31
Completion Date: 2026-12-31
First Posted: 2023-05-09
Results First Posted:
Last Update Posted: 2023-05-09
Locations: University Medical Center Groningen, Groningen, 9700 AD, Netherlands
Study Documents:

NCT Number: NCT04805853

Study Title: Myocardial Pathological Changes in Patients of Type 2 Diabetes With or Without PCOS Using Cardiac Magnetic Resonance
Study URL: https://beta.clinicaltrials.gov/study/NCT04805853
Acronym:
Study Status: UNKNOWN
Brief Summary: The study is prepared to use CMR technology for early screening of myocardial lesions in 561 age-matched women with type 2 diabetes without PCOS, with PCOS without type 2 diabetes and with type 2 diabetes combined with PCOS, compare the differences between the two groups of cardiomyocyte injury changes, and treat and follow-up with type 2 diabetes and PCOS in accordance with the current standard treatment guidelines for type 2 diabetes and PCOS, after 3 years of follow-up we will analyse the changes in cardiomyopathy, cardiac serological indicators, and heart function indicators,which can provide theoretical basis for early clinical intervention in the future.
Study Results: NO
Conditions: Type2 Diabetes|Polycystic Ovary Syndrome
Interventions:
Primary Outcome Measures: the change level of cardiac extracellular volume (ECV), Compared with baseline, the change level of cardiac extracellular volume (ECV) in patients with type 2 diabetes without PCOS, PCOS without type 2 diabetes, and type 2 diabetes with PCOS, 3 years
Secondary Outcome Measures: change in the level of troponin I (TNI), Compared with the baseline in three groups and T2DM with different phenotype of PCOS, the serum index related to myocardial injury such as change of TNI in ng/ml., 3 years|change in the level of creatine kinase isoenzymes (CK-MB), Compared with the baseline in three groups and T2DM with different phenotype of PCOS, the serum index related to myocardial injury such as change of CK-MB in IU/L., 3 years|change in the level of Brain Natriuretic Peptide (BNP), Compared with the baseline in three groups and T2DM with different phenotype of PCOS, the serum index related to myocardial injury such as change of BNP in pg/ml., 3 years|change in the level of atrialnatriureticpeptide (ANP), Compared with the baseline in three groups and T2DM with different phenotype of PCOS, the serum index related to myocardial injury such as change of ANP in pg/ml., 3 years|change in the level of left ventricular ejection fraction (LVEF), Compared with the baseline in three groups and T2DM with different phenotype of PCOS, the cardiac functions change such as: left ventricular ejection fraction (LVEF) in %., 3 years|change in the level of left ventricular end diastolic pressure (LVEDP), Compared with the baseline in three groups and T2DM with different phenotype of PCOS, the cardiac functions change such as: left ventricular end diastolic pressure (LVEDP) in kPa/mmHg., 3 years|change in the level of output per minute (CO) in L/min, Compared with the baseline in three groups and T2DM with different phenotype of PCOS, the cardiac functions change such as: output per minute (CO) in L/min., 3 years|change in the level of left ventricular diameter reduction rate (FS), Compared with the baseline in three groups and

T2DM with different phenotype of PCOS, the cardiac functions change such as: left ventricular diameter reduction rate (FS) in %., 3 years| Changes in score of Minnesota heart failure quality of life scale(LiHFe), Compared with the baseline in three groups, the changes of Minnesota heart failure quality of life scale(LiHFe) in score, higher scores mean a worse outcome. (Scores ranging from 0 to 105), 3 years|Changes in score of short form 12 questionnaire(SF-12), Compared with the baseline in three groups, the changes of SF-12 in score, higher scores mean a better outcome. (Scores ranging from 0 to 65), 3 years|Changes in score of Generalized Anxiety Disorder-7(GAD-7), Compared with the baseline in three groups, the changes of GAD-7 in score, higher scores mean a worse outcome. (Scores ranging from 0 to 21), 3 years|Changes in score of Patient Health Questionnaire-9(PHQ-9), Compared with the baseline in three groups, the changes of PHQ-9 in score, higher scores mean a worse outcome. (Scores ranging from 0 to 27), 3 years
Other Outcome Measures:
Sponsor: RenJi Hospital
Collaborators:
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 561
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: KY2020-198
Start Date: 2020-02-20
Primary Completion Date: 2022-02
Completion Date: 2022-02
First Posted: 2021-03-18
Results First Posted:
Last Update Posted: 2021-03-18
Locations: Renji Hospital Department of Endocrinology and Metabolism, Shanghai, Shanghai, 200127, China
Study Documents:

NCT Number: NCT02494453
Study Title: Pilot Study of Biomarkers and Cardiac MRI as Early Indicators of Cardiac Exposure Following Breast Radiotherapy
Study URL: https://beta.clinicaltrials.gov/study/NCT02494453
Acronym:
Study Status: COMPLETED
Brief Summary: Patients with breast cancer receive low doses to smaller volumes of the heart, but they also have an excellent long-term survival, so it is crucial to study the effects of low dose radiotherapy. Indeed, a recent study suggests that these effects can be seen within the first 5 years after treatment, and that there is no dose threshold. The investigators wish to develop imaging and blood biomarkers of cardiac exposure, as a first step to identifying

patients at increased risk for cardiac effects. These patients can then be targeted for close monitoring and early intervention, potentially with statins or ACE inhibitors. Additionally, by characterizing a time-course and radiation dose-volume relationship, potentially real-time modifications can be made to radiotherapy (RT) field design for patients sensitive to RT effects. Finally, this information can be incorporated into better designs of treatment plans for future patients.
Study Results: NO
Conditions: Breast Cancer
Interventions: PROCEDURE: Research Cardiac MRI|PROCEDURE: Biomarkers
Primary Outcome Measures: Number of patients in which cardiac MRI indicated subclinical cardiac abnormalities after radiotherapy that correlated with cardiac events, The study aims to characterize longitudinal changes in imaging characteristics of cardiac damage. Cardiac MRI endpoints will include myocardial edema, microvascular dysfunction, myocardial fibrosis, and subclinical impairment of systolic and diastolic function., One year
Secondary Outcome Measures: Number patients in which blood and serum biomarkers were identified that correlated with cardiac damage due to radiation, The study aims to characterize longitudinal changes in potential early biomarkers of cardiac damage. Biomarker endpoints derived from blood or its components include measuring levels of galectin-3, NT-Pro brain natriuretic peptide, troponin, C-reactive protein, myeloperoxidase, and growth differentiation factor 15., One year|Number of unique biomarkers identified that were associated with radiation related cardiac injury, Biomarker endpoints derived from blood or its components include measuring levels of galectin-3, NT-Pro brain natriuretic peptide, troponin, C-reactive protein, myeloperoxidase, and growth differentiation factor 15. Additional biomarkers may be included as the research in those fields progresses during the conduct of this clinical trial., One year
Other Outcome Measures:
Sponsor: University of Michigan Rogel Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 23
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UMCC 2014.151
Start Date: 2015-06
Primary Completion Date: 2017-07
Completion Date: 2017-07
First Posted: 2015-07-10
Results First Posted:
Last Update Posted: 2019-07-30
Locations: University of Michigan, Ann Arbor, Michigan, 48109, United

States
Study Documents:

NCT Number: NCT05423860
Study Title: Phase I Human Analytics (HALO) Study
Study URL: https://beta.clinicaltrials.gov/study/NCT05423860
Acronym: HALO
Study Status: RECRUITING
Brief Summary: Discover, optimize, standardize, and validate clinical-trial measures and biomarkers used to diagnose and differentiate cardiovascular, oncologic, neurologic, and other diseases and disorders. Specifically, our research study endeavors to improve disease and disorder diagnosis to the earliest clinical states, in preclinical states, and to develop ensemble multivariate biomarker risk scores leading to cardiovascular, oncologic, neurologic, and other diseases and disorders.

Additionally, the study aims to:

* Evaluate data analysis techniques to improve diagnostic accuracy and reduce time to diagnosis.
* Evaluate data analysis techniques to improve risk stratification for participants through machine learning algorithms.
* Direct participants to relevant and applicable clinical trials.
Study Results: NO
Conditions: Cardiovascular Diseases|Cancer|Dementia|Traumatic Brain Injury
Interventions: OTHER: no interventions will be performed (observational)
Primary Outcome Measures: Prostate cancer Gleason score, Measure a patient's prostate cancer Gleason score for patients with a prostate cancer diagnosis and record the measurement again at 3, 6, 9 months and annually for 5 years after treatment. We will use the pathology report submitted by the pathologist. The Gleason Score ranges from 1-5 and describes how much the cancer from a biopsy looks like healthy tissue (lower score) or abnormal tissue (higher score)., Up to 5 years after treatment|Prostate cancer ISUP grade group, Measure a patient's prostate cancer ISUP grade group for patients with a prostate cancer diagnosis and record the measurement again at 3, 6, 9 months and annually for 5 years after treatment. We will use the pathology report submitted by the pathologist. The International Society of Urological Pathology (ISUP) guidelines grades the cancer between 1 and 5 depending on the Gleason score. The lower the grade the less likely the cancer is to spread., Up to 5 years after treatment|Prostate cancer staging parameters, TNM stage and metastasis-free survival, documentation of tumor, lymph node and osseous involvement, Up to 5 years after treatment|Prostate cancer specific mortality, Proportion of men who expire directly due to prostate cancer, Up to 5 years
Secondary Outcome Measures: Lower urinary tract symptoms (LUTS), Measure patient's prostate symptom score for patients with a prostate

cancer diagnosis and repeat the survey at 3, 6, 9 months and annually for 5 years after treatment. We will use the International Prostate Symptom Score (I-PSS) survey. The International Prostate Symptom Score (IPSS) is an eight-question written screening tool used to screen for, rapidly diagnose, track the symptoms of, and suggest management of the symptoms of benign prostatic hyperplasia (BPH)., Up to 5 years after treatment|Erectile function, Measure a patient's sexual health score for patients with a prostate cancer diagnosis and repeat the survey at 3, 6, 9 months and annually for 5 years after treatment. We will use the Sexual Health Inventory for Men survey. The Sexual Health Inventory for Men (SHIM) is a widely used scale for screening and diagnosis of erectile dysfunction (ED) and severity of ED in clinical practice and research., Up to 5 years after treatment|Emotional well-being, Measure a patient's level of distress for patients with a prostate cancer diagnosis and repeat the survey at 3, 6, 9 months and annually for 5 years after treatment. We will use the NCCN-DT survey. The NCCN Distress Thermometer and Problem List is a well-known screening tool among cancer care providers. The survey is a one-item, 11-point Likert scale represented on a visual graphic of a thermometer that ranges from 0 (no distress) to 10 (extreme distress), with which patients indicate their level of distress over the course of the week prior to assessment., Up to 5 years after treatment|Incontinence level, Measure a patient's incontinence for patients with a prostate cancer diagnosis and repeat the survey at 3, 6, 9 months and annually for 5 years after treatment. We will use the ICIQ-UI Short Form survey. The International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) is a questionnaire for evaluating the frequency, severity and impact on quality of life (QoL) of urinary incontinence in men and women in research and clinical practice across the world., Up to 5 years after treatment|PI-RADS category, Measure a patient's PI-RADS category for patients with a prostate cancer diagnosis and record measurement again at 3, 6, 9 months and annually for 5 years after treatment. We will use the radiology report submitted by the radiologist. Radiologists use the Prostate Imaging Reporting and Data System (PI-RADS) to report how likely it is that a suspicious area is a clinically significant cancer. In the PI-RADS scale, each lesion is assigned a score from 1 to 5 indicating the likelihood of clinically significant cancer., Up to 5 years after treatment
Other Outcome Measures:
Sponsor: HALO Diagnostics
Collaborators: HALO Affiliate Sites
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 2000
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: HALO Dx 001|WIRB Pr. No.: 20213955

Start Date: 2022-03-16
Primary Completion Date: 2027-03
Completion Date: 2037-03
First Posted: 2022-06-21
Results First Posted:
Last Update Posted: 2022-10-14
Locations: Desert Medical Imaging, Indian Wells, California, 92210, United States
Study Documents:

NCT Number: NCT05454553
Study Title: Efficacity of Deep Inspiration Breath Hold and Intensity-modulated Radiotherapy in Preventing PErfusion Defect for Left Sided Breast Cancer (EDIPE)
Study URL: https://beta.clinicaltrials.gov/study/NCT05454553
Acronym: EDIPE
Study Status: RECRUITING
Brief Summary: Breast irradiation is known to cause radiation-induced heart disease (RIHD) many years later after radiotherapy. Recent studies suggest that RIHD could be an earlier complication and that subclinical cardiac injury can be detected such as myocardial perfusion defects. Myocardial perfusion single photon emission computed tomography (SPECT) is a sensitive and specific technique able to detect perfusion abnormalities which are more frequent in left-sided breast cancer patients because of the cardiac exposure.

The most used technique for breast cancer irradiation is tangential opposed field, but this technique exposes the left anterior descending coronary artery to high dose during left breast irradiation.

There are different cardiac sparing techniques to reduce heart exposure such as:

* Deep inspiration breath-hold (DIBH) which displaces the heart out of the radiation beam
* Intensity-modulated radiation therapy (IMRT) which decreases heart exposure to high doses but changes the dose distribution in the heart and increases lower doses.
Study Results: NO
Conditions: Breast Cancer
Interventions: OTHER: myocardial perfusion SPECT
Primary Outcome Measures: Evaluation of DIBH and IMRT efficacy in preventing perfusion defect for left-sided breast cancer after radiotherapy, Incidence of perfusion defects on follow-up myocardial perfusion SPECT scans, at 3 months from the end of radiotherapy| Evaluation of DIBH and IMRT efficacy in preventing perfusion defect for left-sided breast cancer after radiotherapy, Incidence of perfusion defects on follow-up myocardial perfusion SPECT scans, at 6 months from the end of radiotherapy|Evaluation of DIBH and IMRT efficacy in preventing perfusion defect for left-sided breast cancer

after radiotherapy, Incidence of perfusion defects on follow-up myocardial perfusion SPECT scans, at 12 months from the end of radiotherapy
Secondary Outcome Measures: Assession of wall-motion abnormalities and left ventricular ejection fraction (LVEF) decrease, Incidence of left ventricular wall motion disorder and LVEF quantification on follow-up myocardial perfusion SPECT scans., up to 12 months from the end of radiotherapy|Assessing the relevance of mean heart dose in the prevention of Radiation-induced heart disease (RIHD) compared to cardiac substructures., Measurement of the doses delivered to the cardiac volumes and its substructures., up to 12 months from the end of radiotherapy|Influence of cardiac risk factors on post-radiation myocardial perfusion., up to 12 months from the end of radiotherapy|Influence of anticancer therapy exposure on post-radiation myocardial perfusion, Anticancer therapy characteristics (type), up to 12 months from the end of radiotherapy|Influence of anticancer therapy exposure on post-radiation myocardial perfusion, Anticancer therapy characteristics (dose), up to 12 months from the end of radiotherapy|Influence of anticancer therapy exposure on post-radiation myocardial perfusion, Anticancer therapy characteristics (duration), up to 12 months from the end of radiotherapy|Impact of the location of the tumor bed boost on the cardiac dose., Location of the tumor bed boost, up to 12 months from the end of radiotherapy|Impact of the location of the tumor bed boost on the cardiac dose., Cardiac dose, up to 12 months from the end of radiotherapy
Other Outcome Measures:
Sponsor: Institut de cancérologie Strasbourg Europe
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 58
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: 2021-012|ID-RCB
Start Date: 2022-10-27
Primary Completion Date: 2024-10-27
Completion Date: 2024-10-27
First Posted: 2022-07-12
Results First Posted:
Last Update Posted: 2022-11-29
Locations: Institut de cancérologie Strasbourg Europe, Strasbourg, France
Study Documents:

NCT Number: NCT03308773
Study Title: Disease Prevention in Clinical Practice Base on Patient Specific Physiology

Study URL: https://beta.clinicaltrials.gov/study/NCT03308773
Acronym: STOPDISEASE
Study Status: ENROLLING_BY_INVITATION
Brief Summary: It is well known that the Type 2 diabetes and vascular disease are preceded by over ten years by metabolic dysfunction and anatomic changes that can be quantified. In order to develop effective preventive strategies and reduce the cost burden to the health care system, recognition of the earliest pathophysiology of Type 2 diabetes and vascular disease is clinically relevant. The interval retrospective evaluation of data from patient records, reflect the effectiveness of the various treatments implemented in clinical practice.

Prevalence of "prediabetes" among American adults is estimated to be \~84 million, or one out of three Americans. Over a 5-7 year period approximately one third of these prediabetic individuals will progress to type 2 diabetes. Prediabetes is a heterogenous group comprised of individuals with impaired fasting glucose (IFG), impaired glucose tolerance (IGT), and increased A1c (5.7-6.4%). Although different pathophysiologies are present in individuals with IFG and IGT, their conversion rate to overt type 2 diabetes mellitus (T2DM) is similar.

Insulin resistance is a common causal feature of many of the pathophysiologic mechanisms linking macrovascular disease and type 2 diabetes. Because hyperglycemia is the major factor responsible for the development of microvascular complications, it logically follows that prevention of progression of prediabetes to overt diabetes should retard/prevent the development of the microvascular complications. From the measurement of plasma glucose, insulin, and c-peptide levels during the oral glucose tolerance test, one can derive measures of the two core defects responsible for the development of T2DM, i.e. insulin resistance and beta cell dysfunction as well as the degree of dysglycemia.

By combining a standard medical evaluation with the evaluation of cardiovascular biomarkers, patients at intermediate risk of vascular disease can be identified. In these patients, carotid intima media thickness (IMT) and carotid plaque evaluation is offered to attempt to clarify risk.

The hypothesis of this observational study is that the characterization of the physiology and anatomy of patients at risk of developing type 2 diabetes and/or cardiovascular disease can stratify risk of developing disease and direct treatment strategies tailored to the identified physiologic defect, leading to improvements in the delay or prevention of disease.
Study Results: NO
Conditions: PreDiabetes|Insulin Resistance|Type2 Diabetes|NASH - Nonalcoholic Steatohepatitis|Diastolic Dysfunction|Dementia|Atrial Fibrillation|Cancer|Atherosclerosis|Carotid Plaque

Interventions: OTHER: Lifestyle modification in routine care of patients
Primary Outcome Measures: Number of participants who develop type 2 diabetes based on response to oral glucose tolerance test, Patients will be monitored for up to 20 years (10 year retrospective plus 10 year prospective). The outcome measure will reflect the number of patients who develop of type 2 diabetes as evidenced by the response to oral glucose tolerance testing., 6 months and an average of every 2 years through the study completion, approximately 20 years|Time to development of type 2 diabetes, Patients will be monitored for up to 20 years (10 year retrospective plus 10 year prospective). The outcome measure will reflect the time to the development of type 2 diabetes as evidenced by the response to oral glucose tolerance testing., 6 months and an average of every 2 years through the study completion, approximately 20 years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Pacific Coast Family Medical Group
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 5000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2017000308
Start Date: 2009-01-05
Primary Completion Date: 2027-09
Completion Date: 2027-09
First Posted: 2017-10-13
Results First Posted:
Last Update Posted: 2022-04-22
Locations:
Study Documents:

NCT Number: NCT03128060
Study Title: Expanding Access to Home-Based Palliative Care
Study URL: https://beta.clinicaltrials.gov/study/NCT03128060
Acronym:
Study Status: TERMINATED
Brief Summary: This study will test the effectiveness of integrating an evidence-based model of home-based palliative (HBPC) within primary care clinics on patient and caregiver outcomes. The investigators will conduct a randomized controlled trial, randomizing 1,155 seriously ill patients (and approximately 884 family caregivers) who receive primary care from 30-40 regional accountable care organizations (ACOs) in California to one of two study groups: HBPC or enhanced usual care (EUC). Follow-up data will be collected via telephone surveys with patients at 1- and 2-months and with caregivers at 1- and 2-months,

and, as appropriate, following the death of the patient.
Study Results: NO
Conditions: Cancer|Congestive Heart Failure|Chronic Obstructive Pulmonary Disease
Interventions: OTHER: Home-based palliative care|OTHER: Enhanced usual care
Primary Outcome Measures: Change in Score on the Edmonton Symptom Assessment for patients, This is a brief and reliable (Cronbach alpha: 0.85) self-report assessment that measures the frequency and intensity of a variety of physical and psychological symptoms., At baseline and 1- and 2- months following baseline|Change in Score on Hospital Anxiety and Depression Scale (HADS) for patients, The assessment consists of 14 patient-reported items, with seven questions reflecting anxiety (HADS-A) and seven reflecting depression (HADS-D)., At baseline and 1- and 2- months following baseline
Secondary Outcome Measures: Change in Score on the Patient Health Questionnaire-9 (PHQ-9) for patients, This is a 9-item assessment to diagnose depression. It is based on the nine DSM-IV criteria for depression, At baseline and 1- and 2- months following baseline|Change in rating of being at peace among patients, This is a 1-item probe that assesses an individual's feeling of being at peace., At baseline and 1- and 2- months following baseline|Change in Score on Hearth Hope Index for patients, This 12-item scale is used to assess hope as it relates to a person's ability to cope with medical illness, loss, and related psychosocial stressors., At baseline and 1- and 2- months following baseline|Change in Consultation Care Measure (CCM) for patients, This patient-reported assessment evaluates patient-physician relationships, including communication, approach to the problem, and interest in the patient's life., At baseline and 1- and 2- months following baseline|Change in Score on Zarit Burden (ZBI) Interview among caregivers, The Zarit Burden Interview (ZBI) is a 12-item instrument that has been used with caregivers for a wide range of patients, including those with chronic illnesses. The instrument demonstrates good internal reliability, with a Cronbach's alpha of 0.93, and test-retest reliability of 0.89., At baseline and 1- and 2- months following baseline|Caregiver's experience of death rating on Family Assessment of Treatment at End of Life (FATE-S), when applicable, We will use the Family Assessment of Treatment at End of Life (FATE) to measure caregiver's experience of death . This survey is reliable and valid and is used by the Veteran's Administration across the country., Whenever a patient death occurs during the 2-month study period|Change in Score on Hospital Anxiety and Depression Scale (HADS) for caregivers, The assessment consists of 14 patient-reported items, with seven questions reflecting anxiety (HADS-A) and seven reflecting depression (HADS-D)., At baseline and 1- and 2- months following baseline|Change in Consultation Care Measure (CCM) for caregivers, This caregiver-reported assessment evaluates patient-physician relationships, including communication, approach to the problem, and interest in the patient's life., At baseline and 1- and 2- months following baseline

Other Outcome Measures:
Sponsor: University of Southern California
Collaborators: Patient-Centered Outcomes Research Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 28
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: PCORI-1234
Start Date: 2017-08-19
Primary Completion Date: 2019-03-01
Completion Date: 2019-03-01
First Posted: 2017-04-25
Results First Posted:
Last Update Posted: 2019-10-01
Locations: USC Davis School of Gerontology, Los Angeles, California, 90089, United States
Study Documents:

NCT Number: NCT02357953
Study Title: Transpulmonary Thermodilution Using an Implented Central Venous Access Port
Study URL: https://beta.clinicaltrials.gov/study/NCT02357953
Acronym: ThermoD-PAC
Study Status: COMPLETED
Brief Summary: Perioperative hemodynamic optimization requires monitoring adapted to the risks of the surgery and the patient. The investigators currently use a local hemodynamic protocol based on the data of the literature. According to this protocol, specific patients may require cardiac index and central venous oxygen saturation monitoring. the investigators chose to monitor the cardiac index (CI) with the transpulmonary thermodilution technique (TPTD) (PiCCO, Pulsion Medical System, Munich, Allemagne). The technique is based on the injection of a cooled bolus of saline into a central vein with a central venous catheter (CVC). The variation of temperature is measured with an arterial femoral catheter and allows the assessment of the cardiac output according to Stewart-Hamilton's theory. Many studies showed the reliability of this technique (Bein J Cardio Thorac Vasc Anesth 2004, Buhre Cardio thorac vasc anesth 1999, Felbinger J Clin ANesth 2005, Felbinger TW J Clin Anetsh 2002, Godie O Ann Thorac Surg 1999).

In our institute, most of the patients are fitted with a port for chemotherapy or parenteral nutrition. When PiCCO monitoring is necessary, a central venous catheter is inserted on the opposite side of the permanent implantable venous port. Indeed, insertion of the CVC can be more difficult because of the port. It may be interesting to

use the port for TPTD in order to avoid the insertion of a new CVC. This would be possible only if the measurement of CI by the port was as reliable as the classical measurement with a CVC.

The aim of this study was to assess whether measurement of the CI by TPTD was possible and reliable via the port. The investigators conducted a prospective study comparing the measurement of the CI by TPTD before and after fluid challenge via the port versus the CVC.
Study Results: NO
Conditions: Medical Oncology
Interventions: OTHER: Measurement of cardiac index
Primary Outcome Measures: Assessment of the measurement of cardiac index with the transpulmonary thermodilution technique, During surgery, At inclusion
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Gustave Roussy, Cancer Campus, Grand Paris
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 20
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2012-A00003-40|2012/1386
Start Date: 2012-10
Primary Completion Date: 2013-01
Completion Date: 2013-01
First Posted: 2015-02-06
Results First Posted:
Last Update Posted: 2016-06-09
Locations: Gustave Roussy Cancer Campus Grand Paris, Villejuif, Val de Marne, 94805, France
Study Documents:

NCT Number: NCT00563953
Study Title: Caelyx as Primary Treatment for Patients With Breast Cancer and a History of Heart Disease and/or Age Over 65 Years
Study URL: https://beta.clinicaltrials.gov/study/NCT00563953
Acronym: CAPRICE
Study Status: COMPLETED
Brief Summary: This is a multicenter study of a primary chemotherapy regimen in breast cancer patients at risk of developing cardiotoxicity. The aim of the study is to evaluate the response rate at surgery.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Liposomal pegylated doxorubicine
Primary Outcome Measures: Pathological complete response (pCR). pCR is

defined as the absence of invasive cancer in the surgical breast specimen. This definition includes evidence of carcinoma in situ only., At surgery.
Secondary Outcome Measures: Clinical response rate (complete plus partial responses). Clinical response will be assessed by imaging using the WHO criteria., Before and after treatment with paclitaxel.|Breast-conserving surgery: tumorectomy or quadrantectomy with or without lymphadenectomy versus mastectomy., At surgery.|Axillary node involvement after primary chemotherapy., At surgery.|Left ventricular ejection fraction measured by echocardiography or MUGA., At baseline, every 2 doxorubicine cycles and before surgery.|Cardiac sign/symptom questionnaire., At baseline, every 2 doxorubicine cycles and before surgery.|Relapse-free survival at 5 years after surgery and overall survival at 5 years after study entry., Until 5 years after surgery.
Other Outcome Measures:
Sponsor: SOLTI Breast Cancer Research Group
Collaborators: Schering-Plough
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: SOLTI0702|2007-001428-11
Start Date: 2007-09
Primary Completion Date: 2011-02
Completion Date: 2016-08
First Posted: 2007-11-27
Results First Posted:
Last Update Posted: 2017-10-12
Locations: Institut Català d'Oncologia, L'Hospitalet de Llobregat, Barcelona, 08907, Spain|Hospital Son Llàtzer, Palma de Mallorca, Illes Balears, 07198, Spain|Hospital Universitario Sant Joan de Reus, Reus, Tarragona, 42301, Spain|Hospital de la Santa Creu i Sant Pau, Barcelona, 08025, Spain|Hospital Universitari Vall d'Hebron, Barcelona, 08035, Spain|Hospital Universitari Arnau de Vilanova, Lleida, 25198, Spain|Hospital Universitario 12 de Octubre, Madrid, 28041, Spain|Hospital Universitario Morales Meseguer, Murcia, 30008, Spain
Study Documents:

NCT Number: NCT03847753
Study Title: Exploring the Comorbidity Between Mental Disorders and General Medical Conditions
Study URL: https://beta.clinicaltrials.gov/study/NCT03847753
Acronym: COMO-GMC
Study Status: COMPLETED
Brief Summary: Mental disorders have been shown to be associated with

a number of general medical conditions (also referred to as somatic or physical conditions). The investigators aim to undertake a comprehensive study of comorbidity among those with treated mental disorders, by using high-quality Danish registers to provide age- and sex-specific pairwise estimates between the ten groups of mental disorders and nine groups of general medical conditions.

The investigators will examine the association between all 90 possible pairs of prior mental disorders and later GMC categories using the Danish national registers. Depending on whether individuals are diagnosed with a specific mental disorder, the investigators will estimate the risk of receiving a later diagnosis within a specific GMC category, between the start of follow-up (January 1, 2000) or at the earliest age at which a person might develop the mental disorder, whichever comes later. Follow-up will be terminated at onset of the GMC, death, emigration from Denmark, or December 31, 2016, whichever came first. Additionally for dyslipidemia, follow-up will be ended if a diagnosis of ischemic heart disease was received. A "wash-out" period will be employed in the five years before follow-up started (1995-1999), to identify and exclude prevalent cases from the analysis. Individuals with the GMC of interest before the observation period will be considered prevalent cases and excluded from the analyses (i.e. prevalent cases were "washed-out"). When estimating the risk of a specific GMC, the investigators will consider all individuals to be exposed or unexposed to the each mental disorder depending on whether a diagnosis is received before the end of follow-up. Persons will be considered unexposed to a mental disorder until the date of the first diagnosis, and exposed thereafter.
Study Results: NO
Conditions: Organic, Including Symptomatic, Mental Disorders|Substance Use|Schizophrenia|Mood [Affective] Disorders|Neurotic, Stress-related and Somatoform Disorders|Eating Disorder|Disorders of Adult Personality and Behavior|Mental Retardation|Disorder of Psychological Development|Behavioural Disorder|Hypertension|Dyslipidemias|Ischemic Heart Disease|Atrial Fibrillation|Heart Failure|Peripheral Occlusive Disease|Stroke|Diabetes Mellitus|Thyroid Disorder|Gout|Chronic Pulmonary Disease|Allergy|Chronic Gastritis|Chronic Liver Disease|Inflammatory Bowel Diseases|Diverticular Disease of Large Intestine|Chronic Kidney Diseases|Prostate Disorders|Connective Tissue Disorder|Osteoporosis|Pain|HIV/AIDS|Anemia|Cancer|Vision Disorders|Hearing Disorders|Migraine|Epilepsy|Parkinson Disease|Multiple Sclerosis|Neuropathy
Interventions: OTHER: Organic Disorders|OTHER: Substance Use Disorders|OTHER: Schizophrenia Disorders|OTHER: Mood disorders|OTHER: Neurotic disorders|OTHER: Eating Disorders|OTHER: Personality Disorders|OTHER: Intellectual Disorders|OTHER: Developmental Disorders|OTHER: Behavioral Disorders
Primary Outcome Measures: Risk of circulatory system general medical conditions, These will be ascertained using the following criteria:

Diagnosis in the Danish National Patient Register or death in the Cause of Death register, for at least one of the following diseases: hypertension, dyslipidemia, ischemic heart disease, atrial fibrillation, heart failure, peripheral arterial occlusive disease, stroke.

Records in the Danish National Prescription Register for at least one of the following types of medications: antihypertensives, lipid-lowering drugs, antianginal drugs (at least two prescriptions for a type of medication in one year).

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those with previous mental disorders, compared to those without. All persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000–2016), after at least 1 year of age|Risk of Endocrine System general medical conditions, These will be ascertained using the following criteria:

Diagnosis in the Danish National Patient Register or death in the Cause of Death register, for at least one of the following diseases: diabetes mellitus, thyroid disorders, gout.

Records in the Danish National Prescription Register for at least one of the following types of medications: antidiabetic, thyroid therapy drugs (at least two prescriptions for a type of medication in one year).

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those with previous mental disorders, compared to those without. All persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000–2016), after at least 1 year of age|Risk of Pulmonary System general medical conditions, These will be ascertained using the following criteria:

Diagnosis in the Danish National Patient Register or death in the Cause of Death register, for at least one of the following diseases: chronic pulmonary disease, allergy.

Records in the Danish National Prescription Register for at least one of the following types of medications: obstructive airway disease drugs, non-sedative antihistamines and/or nasal antiallergics (at least two prescriptions for a type of medication in one year).

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those with previous mental disorders, compared to those without. All

persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000-2016), after at least 1 year of age|Risk of Gastrointestinal System general medical conditions, These will be ascertained using the following criteria:

Diagnosis in the Danish National Patient Register or death in the Cause of Death register, for at least one of the following diseases: ulcer/chronic gastritis, chronic liver disease, inflammatory bowel disease, diverticular disease of intestine.

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those with previous mental disorders, compared to those without. All persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000-2016), after at least 1 year of age|Risk of Urogenital System general medical conditions, These will be ascertained using the following criteria:

Diagnosis in the Danish National Patient Register or death in the Cause of Death register, for at least one of the following diseases: chronic kidney disease, prostate disorders.

Records in the Danish National Prescription Register for at least one of the following types of medications: prostate hyperplasia therapy drugs (at least two prescriptions for a type of medication in one year).

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those with previous mental disorders, compared to those without. All persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000-2016), after at least 1 year of age|Musculoskeletal System general medical conditions, These will be ascertained using the following criteria:

Diagnosis in the Danish National Patient Register or death in the Cause of Death register, for at least one of the following diseases: connective tissue disorders, osteoporosis.

Records in the Danish National Prescription Register for at least one of the following types of medications: osteoporosis drugs (at least two prescriptions for a type of medication in one year) or repeated prescriptions for analgesics (at least four times in one year).

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those

with previous mental disorders, compared to those without. All persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000-2016), after at least 1 year of age|Risk of Neurological System general medical conditions, These will be ascertained using the following criteria:

Diagnosis in the Danish National Patient Register or death in the Cause of Death register, for at least one of the following diseases: vision problems, hearing problems, migraine, epilepsy*, Parkinson's Disease, multiple sclerosis, neuropathies.

Records in the Danish National Prescription Register for at least one of the following types of medications: specific anti-migraine drugs, antiepileptic drugs* (at least two prescriptions for a type of medication in one year)

*Both a diagnosis of epilepsy AND two prescriptions of an antiepileptic drug in one year are required.

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those with previous mental disorders, compared to those without. All persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000-2016), after at least 1 year of age|Risk of Hematological System general medical conditions, These will be ascertained using the following criteria:

Diagnosis in the Danish National Patient Register or death in the Cause of Death register, for at least one of the following diseases: HIV/AIDS, anemias.

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those with previous mental disorders, compared to those without. All persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000-2016), after at least 1 year of age|Risk of Cancers, These will be ascertained using the following criteria:

Cancer diagnosis in the Danish National Patient Register or death in the Cause of Death register.

Hazard ratios (HRs), with 95% confidence intervals, will be obtained to compare risk of diagnosis with a general medical condition in those with previous mental disorders, compared to those without. All

persons, sex-specific and lagged (accounting for time since mental disorder diagnosis) HRs will be obtained. Additionally absolute risks will be calculated., Diagnosed during the study period (2000-2016), after at least 1 year of age
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Aarhus
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 5940299
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: COMO-GMC
Start Date: 2000-01-01
Primary Completion Date: 2016-12-31
Completion Date: 2020-01-31
First Posted: 2019-02-20
Results First Posted:
Last Update Posted: 2020-05-22
Locations:
Study Documents:

NCT Number: NCT02571894
Study Title: The Cardio-Oncology Breast Cancer Study
Study URL: https://beta.clinicaltrials.gov/study/NCT02571894
Acronym: COBC
Study Status: UNKNOWN
Brief Summary: The main objective of this randomized controlled trial is to test the association between standard cardiac risk factors, biomarkers and parameters of echocardiography, electrocardiography, and cardiac magnetic resonance imaging, (predictors) and subsequent occurrence, frequency and severity of clinical or subclinical cardiotoxicity (outcome) within and between-groups, before start of chemotherapy, during treatment and at 1, 5, and 10 years after the completion of the chemotherapy among women with early breast cancer.
Study Results: NO
Conditions: Cardiotoxicity|Cardiomyopathies|Breast Cancer
Interventions: OTHER: Subclinical cardiotoxicity surveillance and treatment
Primary Outcome Measures: Event free survival, The cumulative incidence of clinical or subclinical cardiotoxicity, per randomized arm, in women with breast cancer at 1 year after treatment with neo- or adjuvant chemotherapy., 1 year after the completion of the chemotherapy.
Secondary Outcome Measures: Event free survival, 5 and 10 years after the completion of the chemotherapy.|Overall survival, 1, 5 and 10 years after the completion of the chemotherapy.|The levels of serum

biomarkers (hs-Troponin T (hs-TnT), B-type natriuretic peptide (BNP))., 1, 5 and 10 years after the completion of the chemotherapy.|Echocardiographic global longitudinal strain, 1, 5 and 10 years after the completion of the chemotherapy.|The quality of life, 1, 5 and 10 years after the completion of the chemotherapy.
Other Outcome Measures:
Sponsor: Karolinska University Hospital
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 320
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: COBC
Start Date: 2014-07
Primary Completion Date: 2020-02
Completion Date: 2020-02
First Posted: 2015-10-08
Results First Posted:
Last Update Posted: 2018-03-07
Locations: Karolinska University Hospital, Stockholm, 171 76, Sweden
Study Documents:

NCT Number: NCT02543294
Study Title: REcovery of Left Ventricular Dysfunction in CAncer Patients (RECAP Trial)
Study URL: https://beta.clinicaltrials.gov/study/NCT02543294
Acronym:
Study Status: COMPLETED
Brief Summary: The goal of this clinical trial is to learn if heart function remains normal after stopping heart failure medication in patients who have received chemotherapy.
Study Results: YES
Conditions: Heart Failure|Cancer Treatment Induced Left Ventricular Dysfunction
Interventions: DEVICE: Echocardiograms|DEVICE: Electrocardiogram|BEHAVIORAL: Symptom Questionnaire|BEHAVIORAL: Telephone Follow-Up
Primary Outcome Measures: Determine the Percentage of Cancer Survivors That Maintain Left Ventricular Ejection Fraction (LVEF) ≥50% After Discontinuing Cardiac Medications: Beta Blockers, Angiotensin Converting Enzyme Inhibitors (ACE-I), or Angiotensin Receptor Blockers (ARB)., A withdrawal failure is defined as a decrease in the LVEF when cardiac medications are discontinued as determined by echocardiogram to LVEF\<50% or a decrease by 10% from baseline measurement. Maintenance of LVEF is defined as LVEF≥50%. LVEF was assessed at Baseline, Months 2, 4, 6, 12, 18, \& 30., A total of 30 months from enrollment date of each participant;

Secondary Outcome Measures: Risk Factors to Predict Early Decline of Myocardial Function During the Weaning of HF (Heart Failure) Medications., To identify an increased troponin-I that can predict the possibility of HF medication withdrawal failure., A total of 30 months from enrollment date of each participant
Other Outcome Measures:
Sponsor: M.D. Anderson Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 20
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 2012-0379
Start Date: 2012-09-10
Primary Completion Date: 2017-09-10
Completion Date: 2017-09-10
First Posted: 2015-09-07
Results First Posted: 2018-05-01
Last Update Posted: 2020-02-05
Locations: University of Texas MD Anderson Cancer Center, Houston, Texas, 77030, United States
Study Documents: Study Protocol and Statistical Analysis Plan

NCT Number: NCT02859194
Study Title: The Effect of Lt to Rt Shunt Using Veno-veno-arterial Extracorporeal Membrane Oxygenation (ECMO) on Coronary Oxygenation in Lung Transplantation Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT02859194
Acronym:
Study Status: COMPLETED
Brief Summary: ECMO(Extracorporeal membrane oxygenation) is being essential for cardiopulmonary failure patients. There are two types of ECMO, which is veno-veno (V-V) that can be used in respiratory failure patients and veno-arterial (V-A) that can be used in cardiac failure patients. V-A ECMO can also be used during lung transplantation, substitution of cardiopulmonary bypass, which can show sufficient performance during operation and better postoperative outcome. However, regarding V-A ECMO circulating from femoral vein to femoral artery, there is a pro blem of differential hypoxia which might influence coronary artery and head vessels. In this prospective study, the investigators are planning to put another ECMO catheter into internal jugular vein which takes a role of left to right shunt, to mitigate the hypoxia of coronary artery.
Study Results: NO
Conditions: Interstitial Pulmonary Fibrosis ARDS|COPD (Chronic Obstructive Pulmonary Disease)|Bronchiectasis|

Lymphangioleiomyomatosis|Primary Pulmonary Hypertension|ARDS (Acute Respiratory Distress Syndrome)
Interventions: PROCEDURE: Veno-veno-arterial ECMO
Primary Outcome Measures: arterial blood oxygen partial pressure (PaO2), 5 min after jugular catheter flow 0ml/min|arterial blood oxygen partial pressure (PaO2), 5 min after jugular catheter flow 500 ml/min|arterial blood oxygen partial pressure (PaO2), 5 min after jugular catheter flow 1,000ml/min|arterial blood oxygen partial pressure (PaO2), 5 min after jugular catheter flow 1,500ml/min
Secondary Outcome Measures: venous blood oxygen partial pressure (PvO2), 5 min after jugular catheter flow 0ml/min|venous blood oxygen partial pressure (PvO2), 5 min after jugular catheter flow 500 ml/min|venous blood oxygen partial pressure (PvO2), 5 min after jugular catheter flow 1,000ml/min|venous blood oxygen partial pressure (PvO2), 5 min after jugular catheter flow 1,500ml/min
Other Outcome Measures:
Sponsor: Yonsei University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 10
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 4-2016-0124
Start Date: 2016-05-31
Primary Completion Date: 2016-10-14
Completion Date: 2016-10-14
First Posted: 2016-08-08
Results First Posted:
Last Update Posted: 2018-07-18
Locations: Department of Anesthesiology and Pain Medicine, Anesthesia and Pain Research Institue, Yonsei Universiy College of Medicine, Seoul, 120-752, Korea, Republic of
Study Documents:

NCT Number: NCT03577002
Study Title: Team-based Versus Primary Care Clinician-led Advance Care Planning in Practice-based Research Networks
Study URL: https://beta.clinicaltrials.gov/study/NCT03577002
Acronym:
Study Status: UNKNOWN
Brief Summary: This project compares two models of the Serious Illness Care Program (SICP) in primary care: clinician-focused SICP and team-based SICP. Discussion and planning for serious illness care can help patients identify what is most important to them and assure they receive care that best matches their goals and values, such as spending more time at home or not being in pain.

Study Results: NO
Conditions: Congestive Heart Failure|Cancer|Chronic Obstructive Pulmonary Disease|Cerebrovascular Accident|Frail Elderly Syndrome|Cardiovascular Diseases
Interventions: OTHER: Serious Illness Care Program (SICP)
Primary Outcome Measures: Global rating of goal-concordant care, patient-reported, Comparison between arms of whether care received corresponds to patient goals. This will be assessed at 12 months., 12 months after enrollment
Secondary Outcome Measures: Cumulative time spent at home, patient-reported questionnaires, Days at home will be reported over a 6-month range and will be compared between arms. Patients will report number of days spent in a hospital, nursing home or post-acute care home and number of trips to the emergency department during the last 6-month period. The number of days and ED trips reported will be combined then subtracted from the number of days in the 6-month reporting period to arrive a final number of days at home. This measure will be compared between both study arms., 12 months after enrollment|Generalized Anxiety Disorder (GAD-7), Participant assessment of anxiety using the Generalized Anxiety Disorder 7-item scale (GAD7) using 4-point scale for seven anxiety questions where low scores indicate less anxiety and high scores are higher levels of anxiety symptoms and a single composite score is calculated., Baseline, 6 months and 12 months after enrollment|Patient Health Questionnaire (PHQ-9) - Depression, Participant assessment of depression using the Patient Health Questionnaire depression test questionnaire (PHQ-9) scale using 4-point scale for nine depression questions where low scores indicate less depressive and high scores are higher levels of depressive symptoms and a single composite score is calculated., Baseline, 6 months and 12 months after enrollment|Patient-reported outcomes for individuals living with chronic conditions, Participant assessment of health, quality of life, mental health, satisfaction with social activities and roles, daily activities of living, anxiety/depression, sleep and pain using the PROMIS Global Health 10 short form, Baseline, 6 months and 12 months after enrollment|SICP acceptability, Participant assessment of the SICP conversation and program using and adapted SICP-developed Patient Acceptability Survey, Baseline, 6 months and 12 months after enrollment|SICP experience, Participant assessment of the SICP conversation and program using and adapted SICP-developed Patient Experience Survey, Baseline, 6 months and 12 months after enrollment|Quality of communication, Participant rating of the communication with the clinician or care team using a subset of questions from the Quality of Community questionnaire which uses an 11-point scale on 13 questions to rate care from the worst I could imagine (low score) to the very best I could imagine (high score), with a summed total score, Baseline, 6 months and 12 months after enrollment|Shared decision making for healthcare decisions, Measurement of shared decision-making using questionnaires to measure different aspects of making healthcare decisions, such as engagement, sureness, difficulty making a decision, and level of distress or

remorse after making a decision. Each of these shared decision-making subscales will be scored, Baseline, 6 months and 12 months after enrollment|Hospice use, Participant report of use of hospice or palliative care services, Baseline, 6 months and 12 months after enrollment|Detailed items on goal-concordant care, Patient reports on confidence in future care, trust in providers and family, and advance care planning processes responding to 10-point scale or yes/no questions., 6 months and 12 months after enrollment|Global rating of goal-concordant care, patient-reported, Comparison between arms of whether care received corresponds to patient goals. This will be assessed at 6 months., 6 months after enrollment
Other Outcome Measures:
Sponsor: Oregon Health and Science University
Collaborators: University of Wisconsin, Madison|University of Colorado, Denver|University of Iowa|Duke University|Laval University|University of Toronto
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 1120
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: OTHER
Other IDs: PLC-1609-36277
Start Date: 2019-02-28
Primary Completion Date: 2022-04-01
Completion Date: 2023-07-01
First Posted: 2018-07-05
Results First Posted:
Last Update Posted: 2021-05-06
Locations: State Networks of Colorado Ambulatory Practices and Partners, Aurora, Colorado, 80045, United States|Iowa Research Network, Iowa City, Iowa, 52242, United States|Duke Primary Care Research Consortium, Durham, North Carolina, 27705, United States|Oregon Rural Practice-based Research Network, Portland, Oregon, 97239, United States|Wisconsin Research and Education Network, Madison, Wisconsin, 53175, United States|University of Toronto Practice-based Research Network, Toronto, Ontario, Canada|Quebec Practice-based Research Network, Québec, Quebec, Canada
Study Documents:

NCT Number: NCT03155802
Study Title: Novel Biomarkers and Echocardiography for Subclinical Cardiac Toxicity in Breast Cancer Patients Receiving Anthracyclines
Study URL: https://beta.clinicaltrials.gov/study/NCT03155802
Acronym:
Study Status: UNKNOWN
Brief Summary: This is a pilot prospective cohort study, in adult female subjects 18-85 years old with a diagnosis of invasive breast

cancer who are planned for anthracycline-inclusive chemotherapy and followed up for a time period of 6 months post completion of anthracycline chemotherapy. They will participate in blood and imaging tests with a goal of determining the best method for predicting the occurrence of cardiotoxicity in this subpopulation.
Study Results: NO
Conditions: Cardiotoxicity|Heart Failure|Breast Cancer|Anthracycline Induced Cardiomyopathy|Biomarkers|Echocardiography
Interventions:
Primary Outcome Measures: Association of Heart Failure Biomarkers with Global Longitudinal strain rate, N Terminal-proBNP, hs troponin, ST2, galectin-3 with global longitudinal strain rate, up to 35 weeks
Secondary Outcome Measures: Prediction of initiation/change in cardiovascular medications based on serum biomarkers, NT-proBNP, up to 35 weeks|Prediction of initiation/change in cardiovascular medications based on serum biomarkers, ST2, up to 35 weeks|Prediction of initiation/change in cardiovascular medications based on serum biomarkers, hs-troponin, up to 35 weeks|Prediction of initiation/change in cardiovascular medications based on serum biomarkers, galectin-3, up to 35 weeks|Prediction of cardiotoxicity based on serum biomarkers, galectin-3, up to 35 weeks|Prediction of cardiotoxicity based on serum biomarkers, NT-proBNP, up to 35 weeks|Prediction of cardiotoxicity based on serum biomarkers, hs-troponin, up to 35 weeks|Prediction of cardiotoxicity based on serum biomarkers, ST2, up to 35 weeks
Other Outcome Measures: Association between modifications in chemotherapy with detection of subclinical cardiotoxicity, frequency of chemotherapy changes with subclinical cardiotoxicity, up to 10 weeks
Sponsor: Stony Brook University
Collaborators: Gilead Sciences
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 35
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 922042
Start Date: 2017-04-18
Primary Completion Date: 2020-12
Completion Date: 2020-12
First Posted: 2017-05-16
Results First Posted:
Last Update Posted: 2019-11-01
Locations: Stony Brook Medicine, Stony Brook, New York, 11738, United States
Study Documents:

NCT Number: NCT05521178

Study Title: Cardiotoxicities in Patients Receiving BTKi
Study URL: https://beta.clinicaltrials.gov/study/NCT05521178
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: This is a multicenter, prospective, observational cohort study to comprehensively and longitudinally evaluate and characterizes the cardiovascular events with CLL patients who are initiating treatment with a Bruton's tyrosine kinase (BTK) inhibitor ibrutinib or acalabrutinib.
Study Results: NO
Conditions: Chronic Lymphocytic Leukemia|Small Lymphocytic Lymphoma
Interventions: DIAGNOSTIC_TEST: Electrocardiogram|DIAGNOSTIC_TEST: Echocardiogram|DIAGNOSTIC_TEST: Cardiac magnetic resonance imaging|DEVICE: Mobile cardiac telemetry|DIAGNOSTIC_TEST: Blood pressure monitoring|DIAGNOSTIC_TEST: Blood draw
Primary Outcome Measures: Incidence of atrial arrhythmias, Any documented evidence of atrial arrhythmia including symptomatic and asymptomatic events captured by EKG, 28-day mini cardiac telemetry, or monitoring of cardiac rhythm during echocardiogram or cardiac MRI., During 6 months of BTK inhibitor therapy
Secondary Outcome Measures: Incidence of ventricular arrhythmias, Assessed by 28-day mobile telemetry, During 6 months of BTK inhibitor therapy|Severity of ventricular arrythmia, NCI Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, During 6 months of BTK inhibitor therapy
Other Outcome Measures:
Sponsor: Dana-Farber Cancer Institute
Collaborators: AstraZeneca
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 160
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 22-301
Start Date: 2024-01
Primary Completion Date: 2026-01-01
Completion Date: 2028-01-01
First Posted: 2022-08-30
Results First Posted:
Last Update Posted: 2023-06-27
Locations: Dana-Farber Cancer Institute, Boston, Massachusetts, 02215, United States
Study Documents:

NCT Number: NCT02666378
Study Title: Imaging Markers of Subclinical Cardiotoxicity in Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT02666378

Acronym:
Study Status: RECRUITING
Brief Summary: This research study is evaluating the use of Cardiac Magnetic Resonance Imaging (CMR) as a method of detecting early signs of damage to the heart that can be associated with anthracycline-based chemotherapy for the treatment of breast cancer.
Study Results: NO
Conditions: Breast Cancer
Interventions: OTHER: Cardiac Magnetic Resonance Imaging (CMR)|OTHER: Echocardiogram (ECHO)
Primary Outcome Measures: Cardiotoxicity, Cardiotoxicity as measured by changes in left ventricular ejection fraction within one-year of completion of treatment, 1 year after completion of treatment
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Beth Israel Deaconess Medical Center
Collaborators: American Heart Association|Dana-Farber Cancer Institute
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 190
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 15-017
Start Date: 2018-09-10
Primary Completion Date: 2024-07-10
Completion Date: 2024-07-10
First Posted: 2016-01-28
Results First Posted:
Last Update Posted: 2023-07-11
Locations: Beth Israel Deaconess Medical Center, Boston, Massachusetts, 02115, United States
Study Documents:

NCT Number: NCT00005494
Study Title: Prospective Study of Health in Runners and Walkers
Study URL: https://beta.clinicaltrials.gov/study/NCT00005494
Acronym:
Study Status: COMPLETED
Brief Summary: To compare rates of coronary heart disease (CHD), cancer, total mortality and exercise injuries in 68,000 runners and 68,000 walkers during four years of surveillance
Study Results: NO
Conditions: Coronary Disease|Cardiovascular Diseases|Heart Diseases|Coronary Heart Disease Risk Reduction|Breast Neoplasms|Neoplasms
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:

Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
Collaborators:
Sex: MALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment:
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 5011|R01HL058621
Start Date: 1998-06
Primary Completion Date:
Completion Date: 2004-05
First Posted: 2000-05-26
Results First Posted:
Last Update Posted: 2016-02-29
Locations:
Study Documents:

NCT Number: NCT03941184
Study Title: Spontaneous Coronary Artery Dissection (SCAD) and Autoimmunity
Study URL: https://beta.clinicaltrials.gov/study/NCT03941184
Acronym:
Study Status: COMPLETED
Brief Summary: This case control study aims to determine whether spontaneous coronary artery dissection (SCAD) is associated with autoimmune diseases and to update the incidence of SCAD in a population-based cohort.
Study Results: NO
Conditions: SCAD|Addison Disease|Ankylosing Spondylitis|Antiphospholipid Antibody Syndrome|Celiac Disease|Crohn Disease|Dermatomyositis|Polymyositis|Guillain-Barre Syndrome|Hepatitis, Autoimmune|Graves Disease|Hashimoto Thyroiditis|Multiple Sclerosis|Myasthenia Gravis|Pernicious Anemia|Polymyalgia Rheumatica|Primary Biliary Cirrhosis|Psoriasis|Rheumatoid Arthritis|Systemic Sclerosis|Sjögren Syndrome|Systemic Lupus Erythematosus|Takayasu Arteritis|Type 1 Diabetes Mellitus|Ulcerative Colitis|Uveitis|Vasculitis|Vitiligo|Raynaud
Interventions:
Primary Outcome Measures: Odds of autoimmune disease in SCAD cases compared to controls, Through study completion, or approximately 50 years (average age of study participants)|Incidence Rate of SCAD, Through study completion, or approximately 50 years (average age of study participants)
Secondary Outcome Measures: SCAD recurrence, Through study completion, or approximately 50 years (average age of study participants)
Other Outcome Measures: Odds of laboratory markers for autoimmune disease in SCAD cases compared to controls, Through study completion, or approximately 50 years (average age of study participants)|Odds of

validated rheumatoid arthritis in SCAD cases compared to controls, using the Rochester Epidemiology Project Rheumatoid Arthritis cohort, Through study completion, or approximately 50 years (average age of study participants)
Sponsor: Mayo Clinic
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 114
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 19-002489
Start Date: 1995-01-01
Primary Completion Date: 2020-11-10
Completion Date: 2020-11-10
First Posted: 2019-05-07
Results First Posted:
Last Update Posted: 2020-11-23
Locations: Mayo Clinic, Rochester, Minnesota, 55905, United States
Study Documents:

NCT Number: NCT05645653
Study Title: Nurse-led Medication Self-management Intervention in the Improvement of Medication Adherence
Study URL: https://beta.clinicaltrials.gov/study/NCT05645653
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: Back ground \& Aims Adult patients suffering from multimorbidity are at high risk of medication non-adherence. It has been well established that self-management support is an effective strategy to enhance medication adherence for patients with chronic conditions. However, little is known about the effect of the medication self-management intervention in Adult patients with multimorbidity. The aim of this study to evaluate the effectiveness of a nurse-led medication self-management intervention in improving medication adherence and health outcomes in adult patients with multimorbidity.

Methods This study is a single centre, single-blind, two-arm randomised controlled trial. Adult patients with multi-morbidity will be recruited from NCCCR Qatar. A total of 100 participants will be randomly allocated to receive standard care or standard care plus the medication self-management intervention. The intervention will be delivered by clinical nurse specialists. The 6-week intervention includes three face-to-face education sessions (2st week, 4rd week and 6th week) and two weekly (8th week and 10 week) follow-up phone calls. Participants in the control group continue to receive all respects of standard care offered by healthcare providers, including chronic

disease management, drug prescription, referral to hospital specialists, health education and consultations regarding patients' diseases and treatments during centre visits.

Outcome The primary outcome is medication adherence as measured by the 8-item Medication Adherence Report Scale. Secondary outcomes include medication self-management capacity (medication knowledge, medication beliefs, and medication self-efficacy), treatment experiences (medication treatment satisfaction and treatment burden). All outcomes will be measured at baseline, immediately post-intervention (7th week), and at 3-month post-intervention.
Study Results: NO
Conditions: Heart Diseases|CKD|Diabetes|Cancer|Asthma|Thyroid|Hypertension
Interventions: BEHAVIORAL: Motivational tteaching
Primary Outcome Measures: Medication Adherence, The Morisky-8 is a self-reporting measure of unintentional and intentional medication non-adherent behaviors with a yes and no response. The total score of the moresky-8 ranges from 0 to 8, with a higher score representing higher adherence to medication. Approx 50% percentage change in medication adherence after intervention from baseline to 3 months as compared to control, 3 months
Secondary Outcome Measures: Medication Knowledge, Change medication knowledge using The Patients' Perceived Knowledge in Medication Use Questionnaire (PKMUQ). The response scale ranges from 1 = strongly disagree to 5 = strongly agree, and the response scores of all 5 items will be summed. Higher scores indicate a higher level of medication knowledge. the score will vary from 5 to 25., 3 months|Medication beliefs, using the Beliefs about Medication Questionnaire (BMQ 18-item)self-reported questionnaire we will assess the medication beliefs from baseline to 3 months.

A 5-point Likert scale ranging from 1 = strongly disagree to 5 = strongly agree is used. A higher score indicates stronger beliefs about the corresponding concepts in each subscale. the score range would be 5 to 90., 3 months|Medication self-efficacy, Change in Self efficacy will be assess using the SEAMS 13 items of questionnaire. Each item has a 3-point scale ranging from 1 = not confident to 3 = very confident. The score of scale ranges from 13 to 39, with a higher medication self-efficacy by a higher score., 3 months|Treatment burden, The change in behavior and emotional burden using MTBQ questionnaire. Each item is scored on 6-point Likert scale, ranging from 0 = does not apply to 5 = most difficult. Scores are summed to derive a total score ranging from 0 to 50 with a higher score indicating a higher level of treatment burden., 3 months
Other Outcome Measures:
Sponsor: Hamad Medical Corporation
Collaborators: Medical Research Council
Sex: ALL
Age: ADULT, OLDER_ADULT

Phases: NA
Enrollment: 100
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 296
Start Date: 2022-12-01
Primary Completion Date: 2023-12-31
Completion Date: 2023-12-31
First Posted: 2022-12-09
Results First Posted:
Last Update Posted: 2022-12-09
Locations:
Study Documents: Study Protocol and Statistical Analysis Plan|Informed Consent Form

NCT Number: NCT01369953
Study Title: Informed Consent for Whole Genome Sequencing: Ideals and Norms Referenced by Early Participants
Study URL: https://beta.clinicaltrials.gov/study/NCT01369953
Acronym:
Study Status: COMPLETED
Brief Summary: Since 2007, the cost of sequencing a diploid human genome has fallen dramatically, from approximately $70 million to $20,000. As affordable sequencing platforms become more widely available, the advancement of biomedical science will draw increasingly on whole genome sequencing research requiring large cohorts of diverse populations. Key policy, ethical and legal implications of these developments will need to be understood in order to promote the efficacy and effectiveness of genomic research going forward.

An overall aim of this project is to obtain feedback on the informed consent process from some of the earliest particpants in studies using whole genome sequencing. A more specific goal is to characterize the salient personal and public references accessed by participants around the time of the informed consent process. By highlighting trends in participants views about study participation around the time of the initial informed consent process, we aim to advance the development of an ethically and socially relevant vocabulary with which to negotiate future terms of use for personal sequence data in genomic research.

Participants will be asked to complete a one-time, semi-structured telephone interview lasting approximately 45 minutes in the period 2-8 weeks following their initial informed consent session at the NIH. They will be recruited from two NIH protocols employing whole genome sequencing for distinct purposes. They The ClinSeqTM Study is a large-scale medical sequencing project investigating the causal role of genetics in cardiovascular disease enrolling both symptomatic and

healthy individuals. The Whole Genome Medical Sequencing for Gene Discovery Study (WGMS) enrolls children and adults for full sequencing with the aim of discovering the genetic etiology of rare conditions.
Study Results: NO
Conditions: Coronary Artery Disease|Proteus Syndrome|Coffin - Sins Syndrome|Familial Isolated Hyperparathyroidism|Dubouitz Syndrome
Interventions:
Primary Outcome Measures: Qualitative Description
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Human Genome Research Institute (NHGRI)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 30
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 999911185|11-HG-N185
Start Date: 2011-05-29
Primary Completion Date:
Completion Date: 2014-01-31
First Posted: 2011-06-09
Results First Posted:
Last Update Posted: 2018-07-26
Locations: National Human Genome Research Institute (NHGRI), 9000 Rockville Pike, Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT05880160
Study Title: Safety of Withdrawal of Pharmacological Treatment for Recovered HER2 Targeted Therapy Related Cardiac Dysfunction
Study URL: https://beta.clinicaltrials.gov/study/NCT05880160
Acronym: HER-SAFE
Study Status: NOT_YET_RECRUITING
Brief Summary: Breast cancer is the most common cancer in the United Kingdom (UK), but improvements in treatment mean 3 in 4 people survive for more than 10 years. Many people receive treatments called human epidermal growth factor receptor 2 (HER2) targeted therapies for their breast cancer, however these can affect heart function. This 'cardiotoxicity' is generally temporary and mild, but patients receive drugs to help their heart recover. Currently it is not known how long patients should receive these treatments. Patients with other types of heart failure are treated lifelong, but this may not be necessary here as the damaging cancer drugs have stopped. Taking drugs for many years can have an impact on people's quality of life, particularly for young patients. It is therefore important to understand the best treatment length. The investigators will study people whose heart function has recovered after HER2 therapy heart problems and are not at high risk

for heart disease. The investigators will carefully stop their heart drugs whilst monitoring them closely with special heart scans and blood tests to detect problems early. The investigators will also study how patients are currently treated using national data. The results of this study will help doctors better guide breast cancer survivors about treatment of heart damage from HER2 cancer therapies.
Study Results: NO
Conditions: Cardiotoxicity|HER2-positive Breast Cancer|Heart Failure|Cancer, Therapy-Related
Interventions: OTHER: Phased withdrawal of heart failure medications
Primary Outcome Measures: Relapse in Cardiotoxicity, Number of participants with relapse in cardiotoxicity, defined based on International Cardio-Oncology Society 2021 Guidelines as (at least one of):

1. Asymptomatic left ventricular ejection fraction (LVEF) reduction by ≥10 percentage points to a LVEF of \<50%
2. Asymptomatic LVEF reduction by ≥5 percentage points to an LVEF of \<50% plus new relative decline in global longitudinal strain (GLS) by \>15% from baseline AND/OR new rise in cardiac biomarkers (\>2 fold increase in N-terminal pro B-type natriuretic peptide \[NTproBNP\] to \>400ng/L, or high sensitivity Troponin \>99th percentile)
3. Clinical heart failure (based on symptoms and clinical examination) with at least one of the following: fall in LVEF ≥5%, increase in cardiac biomarkers (as above), relative fall in GLS \> 15%, new arrhythmia (excluding ectopy), 12 months
Secondary Outcome Measures: Cardiac Biomarkers (N-terminal pro B-type natriuretic peptide [NT-proBNP]), Change from baseline at 6 and 12 months in the cardiac biomarker NT-proBNP (measured in pg/L), 12 months|Cardiac Biomarkers (Troponin T), Change from baseline at 6 and 12 months in the cardiac biomarkers Troponin T (measured in ng/L)., 12 months|Quality of life (Kansas City Cardiomyopathy Questionnaire), Change from baseline at 6 and 12 months in the quality of life questionnaire score - the Kansas City Cardiomyopathy Questionnaire (Minimum 0 - Maximum 100; 0 to 24: very poor to poor; 25 to 49: poor to fair; 50 to 74: fair to good; and 75 to 100: good to excellent)., 12 months|Quality of life (Minnesota Living with Heart Failure Questionnaire), Change from baseline at 6 and 12 months in quality of life questionnaire score - the Minnesota Living with Heart Failure Questionnaire (Minimum 0 - Maximum 105, Higher score indicates worse outcome)., 12 months|Heart rate, Change from baseline at 6 and 12 months in baseline resting heart rate (beats per minute), 12 months|Blood Pressure, Change from baseline at 6 and 12 months in blood pressure (Systolic and diastolic, mmHg), 12 months|Left Ventricular Volumes (By Cardiac MRI), Change from baseline at 6 and 12 months in CMR-derived left ventricular volumes (measured in ml and ml/m2), 12 months|Left Ventricular Ejection Fraction (By Cardiac MRI), Change from baseline at 6 and 12 months in CMR-derived left ventricular ejection fraction (measured in %), 12 months|Left Ventricular Strain (By Cardiac MRI), Change from baseline at 6 and 12 months in CMR-

derived left ventricular strain (measured in %), 12 months|T1 mapping (By Cardiac MRI), Change from baseline at 6 and 12 months in CMR-derived native T1 mapping (measured in ms), 12 months|Medication Disutility, Medication disutility is the inconvenience to the patient of taking a given medication. This will be assessed with a structured questionnaire with qualitative responses regarding medication side effects, cost (financial and personal) and the benefits required to offset this., 12 months
Other Outcome Measures:
Sponsor: University College, London
Collaborators: British Heart Foundation|Barts & The London NHS Trust|University College London Hospitals
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 90
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: 147133|FS/CRTF/22/24395|312432
Start Date: 2023-06
Primary Completion Date: 2025-09
Completion Date: 2025-09
First Posted: 2023-05-30
Results First Posted:
Last Update Posted: 2023-05-30
Locations: St Bartholemew's Hospital, London, EC1A 7BE, United Kingdom|University College London Hospital, London, NW1 2BU, United Kingdom
Study Documents:

NCT Number: NCT05366153
Study Title: Risk-guided Disease managEment Plan to prevEnt CAD in Patients Treated With Previous Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05366153
Acronym: REDEEM-CAD
Study Status: NOT_YET_RECRUITING
Brief Summary: REDEEM-CAD is a prospective multi-centre study of CAD risk evaluation and management in cancer survivors 40-70 years with chemotherapy or radiotherapy \>5 years ago.
Study Results: NO
Conditions: Coronary Artery Disease
Interventions: DIAGNOSTIC_TEST: Coronary CT
Primary Outcome Measures: Proportion of evaluated patients who should undergo CAD prevention, High clinical risk, or intermediate risk with CAC score \>0, 3 years
Secondary Outcome Measures: Proportion with critical CAD, Coronary stenosis \>70% by CT coronary angiogram, 3 years|Proportion at intermediate clinical risk, Intermediate clinical risk (0.8-2.0%

annualized risk by Pooled Cohort Equation), 3 years|Statin responsiveness, Change in plaque volume, 3 year follow-up
Other Outcome Measures:
Sponsor: Baker Heart and Diabetes Institute
Collaborators: Western Health, Australia|Northern Hospital, Australia|Menzies Institute for Medical Research|Peter MacCallum Cancer Centre, Australia|The Alfred
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 748
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 134-22
Start Date: 2023-02-06
Primary Completion Date: 2026-05-30
Completion Date: 2026-05-30
First Posted: 2022-05-09
Results First Posted:
Last Update Posted: 2023-02-02
Locations:
Study Documents:

NCT Number: NCT01173341
Study Title: Cardiotoxicity of Cancer Therapy (CCT)
Study URL: https://beta.clinicaltrials.gov/study/NCT01173341
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: The objective of this study is to define the clinical significance of mechanistic biomarkers (including Neuregulin-1Beta) and novel echocardiographic measures of cardiac function in predicting the incident risk of cancer therapy cardiotoxicity.
Study Results: NO
Conditions: Breast Cancer
Interventions: DIAGNOSTIC_TEST: Echocardiography|OTHER: Blood Collection|OTHER: Symptoms Questionnaire
Primary Outcome Measures: Cardiac dysfunction or signs or symptoms of heart failure, Cardiac dysfunction. as defined according to the Cardiac Review and Evaluation Committee (CREC) criteria as a decline in LVEF of 10% to less than 55% without signs or symptoms, 15 years
Secondary Outcome Measures: Change in quantitated Left Ventricular Ejection Fraction (LVEF), Change in LVEF over the course of chemotherapy; incident diastolic dysfunction by echocardiography; the combined endpoint of any incident adverse cardiovascular outcome (arrhythmia, heart failure, systolic dysfunction, or diastolic dysfunction by echo), 15 years
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:

Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 700
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 09110
Start Date: 2010-07
Primary Completion Date: 2037-04
Completion Date: 2037-04
First Posted: 2010-08-02
Results First Posted:
Last Update Posted: 2023-03-24
Locations: Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT00284336
Study Title: Caelyx Adjuvant in Elderly Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00284336
Acronym:
Study Status: COMPLETED
Brief Summary: This is an open label Phase II study in elderly patients (65y or older) with early breast cancer who are candidate for adjuvant chemotherapy. A scheme with liposomal doxorubicin (Caelyx) and cyclophosphamide (endoxan) will be used. The aim is to study the cardiac effects of liposomal doxorubicin with new non-invasive techniques, ie strain rate imaging, classical echocardiography, and special blood tests measuring troponin I and BNP.
Study Results: NO
Conditions: Breast Cancer|Elderly
Interventions: DRUG: Caelyx|DRUG: endoxan
Primary Outcome Measures: Investigate the effect on cardiac strain rate imaging (SRI) of Caelyx|The relation between cardiac SRI and classical ejection fraction measurement.|The relation between strain rate and blood markers such as troponin-I and BNP
Secondary Outcome Measures: To assess the tolerability of Caelyx containing regimens in elderly breast cancer patients.
Other Outcome Measures:
Sponsor: Universitaire Ziekenhuizen KU Leuven
Collaborators:
Sex: FEMALE
Age: OLDER_ADULT
Phases: PHASE2
Enrollment: 16
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT

Other IDs: 2005-002995-13|S28720 UZ KUL
Start Date: 2006-01
Primary Completion Date:
Completion Date: 2007-04
First Posted: 2006-01-31
Results First Posted:
Last Update Posted: 2014-12-09
Locations: UZ gent, Gent, 9000, Belgium|UH gasthuisberg, Leuven, 3000, Belgium
Study Documents:

NCT Number: NCT04037436
Study Title: Functional Exercise and Nutrition Education Program for Older Adults
Study URL: https://beta.clinicaltrials.gov/study/NCT04037436
Acronym: MoveStrong
Study Status: COMPLETED
Brief Summary: There is strong evidence that specific types of exercise can improve health and physical function in older adults. While community exercise classes exist, many older adults with chronic conditions may need guidance from credentialed exercise professionals to ensure sufficient dose and progression and to address fears or low exercise self-efficacy. Furthermore, low protein intake among older adults is common and initiating exercise when nutrition is inadequate may cause weight loss and limit gains in muscle strength. The primary goal is to determine the feasibility of implementing the MoveSTroNg program under real-world conditions, measured through referral and recruitment to the program and study retention and adherence rates.
Study Results: NO
Conditions: Chronic Disease|Frail|Diabetes Mellitus|Cancer|Chronic Lung Disease|Cardiovascular Diseases|Congestive Heart Failure|Hypertension|Osteoporosis, Osteopenia|Arthritis|Stroke|Kidney Diseases
Interventions: OTHER: Strength and Balance Training & Nutrition Education|OTHER: Usual Care
Primary Outcome Measures: Feasibility - Recruitment, Definition: Number recruited at end of rollout. The criterion for success is to recruit 10 participants at each of 4 sites., 1 month (August 1 to 31st, 2019)|Feasibility - Retention, Definition: Number retrained at post-rollout end. The criterion for success is 90% at rollout end., Start of the program to 9 weeks|Feasibility - Adherence, Definition: Percentage of individuals that attended exercise and nutrition sessions.

The criterion for success is 70% or higher., 18 weeks after the start of the program
Secondary Outcome Measures: Body weight, Fried Frailty Index Components: We will measure the change in body weight with a calibrated scale. A change of 5% (greater or lower) in 1 year is considered worse., Start of the program and 18 weeks after the start|10 Meter Walk Test, Fried Frailty Index Components: walking speed via

the 10-meter walk test protocol. A change of 0.05 m/s is considered as a small meaningful change, while 0.13m/s is considered a substantial change., Start of the program and every 6 weeks until the 18th week|Center for Epidemiological Study Depression Scale, Fried Frailty Index Components: fatigue/exhaustion via the Center for Epidemiologic Study Depression Scale-Fatigue Questions. The score ranges from 0-60 (higher scores reflect increased symptom severity), Start of the program and every 6 weeks until the 18th week|Physical Activity Scale, Fried Frailty Index Components: lower physical activity via the CHAMPS Physical Activity Questionnaire for older adults. No score, but the recommended physical activity levels are 150 minutes of moderate to vigorous activity and 2 days of strength training of major muscle groups., Start of the program and every 6 weeks until the 18th week|Grip Strength, Fried Frailty Index Components: weakness via the Jamar hand-held dynamometer, Start of the program and every 6 weeks until the 18th week|30 Second Chair Stand Test, We will use a chair with a straight back without arm rests (seat 17" high), and a stopwatch. This will assess leg strength and endurance. Scores range depending on age and sex (e.g., male 60 to 64, \< 14 chair stands is considered below average, while a male 65 to 69, \< 12 is below average)., Start of the program and every 6 weeks until the 18th week|4 Square Step Test, The Four Square Step Test is used to assess dynamic stability and the ability of the subject to step over low objects forward, sideways, and backward. For older adults \> 15 seconds indicates increased risk of falls, Start of the program and every 6 weeks until the 18th week|EuroQol 5 dimension version 5-level (EQ-5D-5L), The EuroQol 5 dimension version 5-level (EQ-5D-5L) measures quality of life using 5 dimensions, on a 5 point scale, where a higher point is considered better.

The EuroQol 5 dimension version 5-level (EQ-5D-5L) also records the respondent's self-rated health on a 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' (100) and 'the worst health you can imagine' (0). This information can be used as a quantitative measure of health as judged by the individual respondents. A higher score indicates better quality of life, Start of the program and every 6 weeks until the 18th week|Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool, We will use the Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool to conduct interviewer administered diet recalls for 2 weekdays and 1 weekend day. Nutrient analysis is automated and will be used to quantify and compare protein and energy intakes at baseline and follow-up only. There is no scale to this section, Start of the program and every 6 weeks until the 18th week|Participant and provider experience, We will use a semi-structured interview guide to conduct exit interviews with each participant and kinesiologist. Interviews and training sessions will be audio-recorded and transcribed verbatim. Two researchers will perform thematic analyses to describe participant and provider experience and satisfaction, adaptations, and learning needs. There is no scale to this section, 18 weeks after the start of

the program|Adverse events, We will ask participants to report adverse events and falls, using Health Canada definitions. We will report serious and non-serious adverse events (total and attributable to intervention). There is no scale to this section, every 6 weeks until the 18th week after the start of the program|Resource use, We will use the Productivity and Activity Index questionnaire to assess indirect resource use over the last 6 weeks of the program.There is no scale to this section, Start of the program and every 6 weeks until the 18th week|Resource use, We will use the Health Utility Form to assess direct medical resource use over the last 6 weeks of the program. Direct medical costs will be measured using a closed and open-ended survey about their personnel, hospitalization, medications, rehabilitation, and test costs. This questionnaire also evaluates out of pocket expenses and transportation.There is no scale to this section, Start of the program and every 6 weeks until the 18th week
Other Outcome Measures:
Sponsor: University of Waterloo
Collaborators: Canadian Institutes of Health Research (CIHR)|City of Lakes family Health Team|Schlegel Villages and Research Institute for Aging|YMCA|Kinnect to Wellness
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 44
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: OTHER
Other IDs: 20190401
Start Date: 2019-09-24
Primary Completion Date: 2020-03-14
Completion Date: 2020-09-01
First Posted: 2019-07-30
Results First Posted:
Last Update Posted: 2020-11-03
Locations: Chaplin Family YMCA, Cambridge, Ontario, Canada|The Village of Arbour Trails, Guelph, Ontario, N1G 0C9, Canada|Village of Winston Park, Kitchener, Ontario, N2E 3K1, Canada|A.R. Kaufman Family YMCA, Kitchener, Ontario, N2G 3C5, Canada|Your Family Health Team, Sudbury, Ontario, P3A 2T4, Canada
Study Documents: Study Protocol, Statistical Analysis Plan, and Informed Consent Form

NCT Number: NCT03000036
Study Title: Doxorubicin-associated Cardiac Remodeling Followed by CMR in Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT03000036
Acronym:
Study Status: COMPLETED
Brief Summary: Twenty-seven breast cancer women without heart failure,

underwent CMR imaging (3T-Achieva, Philips) before and 3 times serially after 4-cycles of adjuvant DOX (60mg/m2). CMR assessed left ventricular (LV) ejection fraction (EF), T1 mapping pre and post gadolinium and late gadolinium enhancement imaging. Biomarkers were obtained before and 72 hours after each DOX-cycle.
Study Results: NO
Conditions: Breast Cancer Female|Doxorubicin Induced Cardiomyopathy
Interventions: DRUG: Doxorubicin|DEVICE: Achieva, Philips Medical Systems (3T magnet)|DRUG: Gadoterate Meglumine
Primary Outcome Measures: Quantification of fibrosis index by Cardiac Magnetic Resonance, Estimate the extracellular volume fraction derived from gadolinium-DTPA partition Coefficient of the myocardium, two years|Intracellular lifetime of water (τic) by Cardiac Magnetic Resonance, This metric estimates the myocyte size using Cardiac Magnetic Resonance T1 mapping data, two years
Secondary Outcome Measures: Left ventricular mass by Cardiac Magnetic Resonance, Electrocardiographically gated cine imaging with steady state free-precession to assess left ventricular mass., two years|Left ventricular volumes by Cardiac Magnetic Resonance, Electrocardiographically gated cine imaging with steady state free-precession to assess left ventricular volume., two years|Left ventricular ejection fraction by Cardiac Magnetic Resonance, Electrocardiographically gated cine imaging with steady state free-precession to assess left ventricular ejection fraction., two years|Left ventricular myocardial edema fraction by Cardiac Magnetic Resonance, Using T2-weighted sequences to visualize myocardial edema, two years
Other Outcome Measures: Ultra-sensitive troponin, Cardiac troponin (ng/mL), two years
Sponsor: University of Campinas, Brazil
Collaborators: Fundação de Amparo à Pesquisa do Estado de São Paulo
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 27
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: DOX-0675014600011
Start Date: 2012-07
Primary Completion Date: 2015-01
Completion Date: 2016-07
First Posted: 2016-12-21
Results First Posted:
Last Update Posted: 2016-12-21
Locations: State University of Campinas, Campinas, São Paulo, 13083-887, Brazil
Study Documents:

NCT Number: NCT04116281
Study Title: Short and Long Term Effects of a Physical Therapy Program After Breast Cancer Surgery
Study URL: https://beta.clinicaltrials.gov/study/NCT04116281
Acronym:
Study Status: SUSPENDED
Brief Summary: Objectives: To evaluate the pressure pain threshold, shoulder biomechanics, cardiorespiratory function and the quality of life associated with the short and long-term physical therapy rehabilitation following breast cancer surgery. Methodology: The study presents three objectives and involves three groups of participants. Objective 1 is to develop a topographic map of pressure pain in the shoulder (using a digital pressure algometer), evaluate the biomechanics of the shoulder (using a digital inclinometer and load card), cardiorespiratory function (through frequency variability resting heart rate and distance traveled, through the six-minute walk test) and quality of life (through questionnaires of quality of life, anxiety, depression, sleep quality, upper limb functionality, fatigue and level of physical activity) between a group of women prior to the operation of breast cancer (experimental group, n = 36) and a group of asymptomatic controls for shoulder pain (control group, n = 18). Objective 2 is to evaluate the possible changes in the pain map over 24 weeks of supervised kinetic intervention (Supervised Physiotherapy experimental group, n = 18, will begin after drainage, frequency 3 times per week and duration of 60 minutes each session) compared to unsupervised kinetic intervention (Home Physiotherapy experimental group, n = 18, participants will receive an exercise booklet). Objective 3 is to evaluate the biomechanics of the shoulder, cardiorespiratory function and the quality of life with respect to the experimental group with and without kinesic supervision. To achieve objective 1, two baseline evaluations will be carried out in both experimental and control groups (considering the month prior to the surgery of the experimental group) and the average of the evaluations will be considered evaluation 1. To achieve objectives 2 and 3, evaluation 2 (after 4 weeks of intervention), 3 (after 12 weeks of intervention) and 4 (after 24 weeks of intervention) will be performed. The statistical analysis will include the examination of qualitative and quantitative variables. Statistical tests will be applied according to the normality of the data and a significance level of 5% will be adopted for all comparisons. Expected results: It is expected to identify sensory, biomechanical, cardiorespiratory and quality of life alterations in the experimental group, compared to the control group. In addition, after 24 weeks of intervention, the supervised experimental group will show improvement in all the aforementioned variables with respect to the unsupervised group.
Study Results: NO
Conditions: Breast Cancer
Interventions: OTHER: Rehabilitation after breast cancer surgery
Primary Outcome Measures: Pressure pain threshold over the shoulder of breast cancer patients after a physical therapy rehabilitation program

following the surgery., This outcome will involve data regarding to pressure pain threshold assessment over the shoulder at three and six monthes of treatment., Three months|Pressure pain threshold over the shoulder of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to pressure pain threshold assessment over the shoulder at three and six monthes of treatment., Six months|Strength grip of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to objective measurement that consist in to do a maximal strenth grip. The unity of measurement it is in kg., Three months|Strength grip of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to objective measurement that consist in to do a maximal strenth grip. The unity of measurement it is in kg., Six months

Secondary Outcome Measures: Upper limb functionality of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to a questionnaire of upper limb function during activity daily routine. The questionnaire has 33 questions and each one has 5 posible answers., Three months|Upper limb functionality of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to a questionnaire of upper limb function during activity daily routine. The questionnaire has 33 questions and each one has 5 posible answers., Six months|Fatigue of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to a questionnaire wich contains 9 preguntas and 10 differente posibilities of answers., Three months|Fatigue of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to a questionnaire wich contains 9 questions and 10 different posibilities of answers., Six months|Cardiopulmonary function of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to functional capacity performed wiht the walking test measured by the distance performed after a walking., Three months|Cardiopulmonary function of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to functional capacity performed wiht the walking test measured by the distance performed after a walking., Six months|Cardiopulmonary function of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to heart rate variability measured with a Polar and reloj in a supine and orthostatic posture, Three months|Cardiopulmonary function of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to heart rate variability measured with a Polar and reloj in a supine and orthostatic posture, Six months|Quality of life of breast cancer

patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to a questionnaire of quality of life regarding symptoms of chemotherapy that affects on quality of life perception. The questionnaire has 53 questions and each one has 4 posible answers., Three months|Quality of life of breast cancer patients after a physical therapy rehabilitation program following the surgery., This outcome will involve data regarding to a questionnaire of quality of life regarding symptoms of chemotherapy that affects on quality of life perception. The questionnaire has 53 questions and each one has 4 posible answers., Six months
Other Outcome Measures:
Sponsor: Universidade Federal de Sao Carlos
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 36
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: DOUBLE (PARTICIPANT, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: 154/2019
Start Date: 2019-12-02
Primary Completion Date: 2020-05-30
Completion Date: 2024-02-25
First Posted: 2019-10-04
Results First Posted:
Last Update Posted: 2022-07-12
Locations: Catholic University of Maule, Talca, Maule, 3600000, Chile
Study Documents:

NCT Number: NCT01944813
Study Title: Advance Care Planning: A Way to Improve End-of-life Care Life Care
Study URL: https://beta.clinicaltrials.gov/study/NCT01944813
Acronym:
Study Status: UNKNOWN
Brief Summary: Communication about end-of-life issues is often suboptimal. A way to improve the quality of end-of-life care is Advance Care Planning (ACP). ACP is a discussion between an incurable ill patient and the health professionals about preferences for end-of-life care. In Denmark, there is no tradition of systematic communication with patients about end-of-life care. The aim is to investigate how ACP can be beneficial among incurable ill patients treated in an outpatient context and if the concept is feasible in a Danish context. The study is designed as a prospective randomised controlled trial. Patients from relevant departments will be included and randomised in two groups: one receiving usual care and the other receiving usual care and ACP. Data will be collected from Electronic

Patient Files and from questionnaires. If ACP is effective, it will improve the quality of end-of-life care for patients and their families and reduce the psychological distress in the bereaved relatives.
Study Results: NO
Conditions: Heart Failure|Pulmonary Disease|Neoplasms
Interventions: BEHAVIORAL: ACp conversation
Primary Outcome Measures: The proportion of patients who had their preferences regarding place of care and place of death met, 1.7.2015
Secondary Outcome Measures: Number of re-admissions to hospital from time of inclusion until death, 1.7.2015
Other Outcome Measures: The proportion of bereaved relatives who experienced symptoms of stress, anxiety and depression after the death of the patient, measured three months after the death of the patient, 1.7.2015|The proportion of patients who died at home, 1.7.2015
Sponsor: University of Aarhus
Collaborators: TrygFonden, Denmark|Danish Cancer Society
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 360
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 050880
Start Date: 2013-11
Primary Completion Date: 2015-07
Completion Date: 2015-07
First Posted: 2013-09-18
Results First Posted:
Last Update Posted: 2014-12-23
Locations: Aarhus University, Aarhus, 8000, Denmark
Study Documents:

NCT Number: NCT05638269
Study Title: A Multicentre Study on Features of the Gut Microbiota of Patients With Critical Chronic Diseases in China
Study URL: https://beta.clinicaltrials.gov/study/NCT05638269
Acronym:
Study Status: RECRUITING
Brief Summary: The human gut microbiome has been associated with many health factors but variability between studies limits the exploration of effects between them. This study aims to systematically characterize the gut microbiota of various critical chronic diseases, compare the similarities and differences of the microbiome signatures linked to different regions and diseases, and further investigate their impacts on microbiota-based diagnostic models.
Study Results: NO
Conditions: Essential Hypertension|Liver Cancer|Nasopharyngeal Cancer|

Pancreatic Cancer|Lung Cancer|Chronic Kidney Diseases|Acute Coronary Syndrome|Epilepsy|Gastric Cancer|Primary Aldosteronism|Subclinical hypothyroïdism
Interventions: OTHER: no intervention
Primary Outcome Measures: microbiome, The microbial composition of the stool and saliva samples was determined by 16S rRNA (ribosomal ribonucleic acid) gene sequencing analysis and metagenomics. Comparison of microbial abundance and diversity of healthy volunteers and patients with various diseases., baseline
Secondary Outcome Measures: biochemistry, Comparison of serum markers of healthy volunteers and patients with various diseases., baseline|metabonomics, Comparison of metabolites of healthy volunteers and patients with various diseases., baseline|proteomics, Comparison of peptides of healthy volunteers and patients with various diseases using mass spectrometry., baseline
Other Outcome Measures:
Sponsor: Zhujiang Hospital
Collaborators: National Natural Science Foundation of China
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 12000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CALM2101
Start Date: 2022-03-01
Primary Completion Date: 2024-12
Completion Date: 2025-12
First Posted: 2022-12-06
Results First Posted:
Last Update Posted: 2022-12-21
Locations: Emergency General Hospital, Chaoyang, Beijing, 100028, China|The People's Hospital Of Nanchuan Chongqing, Nanchuan, Chongqing, 408400, China|YongChuan hospital of Chongqing Medical Univeristy, Yongchuan, Chongqing, 402177, China|Fujian Medical University Union Hospital, Fuzhou, Fujian, 350001, China|Fujian Provincial Hospital, Fuzhou, Fujian, 350001, China|Fujian Cancer Hospital, Fuzhou, Fujian, 350014, China|The First Hospital of Lanzhou University, Lanzhou, Gansu, 730000, China|Lanzhou University Second Hospital, Lanzhou, Gansu, 730030, China|The Sixth Affiliated Hospital of South China University of Technology (Foshan Nanhai District People's Hospital), Foshan, Guangdong, 528200, China|The First Affiliated Hospital of Jinan University (Guangzhou Overseas Chinese Hospital) , Guangzhou, Guangdong, 510600, China|The seventh Affiliated Hospital, Sun Yat-sen University, Shenzhen, Guangdong, 518107, China|Zhongshan City People's Hospital, Zhongshan, Guangdong, 564000, China|The Second Affiliated Hospital of Guangxi Medical University, Nanning, Guangxi, 530007, China|People's Hospital of Guangxi Zhuang Autonomous Region, Nanning, Guangxi, 530021, China|Wuzhou Red Cross Hospital,

Tongliao, Guangxi, 543002, China|The Affiliated Cancer Hospital of Guizhou Medical University, Guiyang, Guizhou, 550001, China|The Affiliated Hospital of Guizhou Medical University, Guiyang, Guizhou, 550004, China|Hainan Traditional Chinese Medicine Hospital, Haikou, Hainan, 570100, China|Daqing People's Hospital (The Fifth Affiliated Hospital of Harbin Medical University) , Daqing, Heilongjiang, 163316, China|The First Affiliated Hospital of Harbin Medical University, Harbin, Heilongjiang, 150007, China|The Sixth Affiliated Hospital of Harbin Medical University, Harbin, Heilongjiang, 150088, China|Jixi Ji Mine Hospital, Jixi, Heilongjiang, China|Qiqihar Hospital of Traditional Chinese Medicine, Qiqihar, Heilongjiang, 161005, China|Luoyang Maternal and Child Health Hospital, Luoyang, Henan, 471000, China|Cancer Hospital, The First Affiliated Hospital, College of Clinical Medicine,Medical College of Henan University of Science and Technology, Luoyang, Henan, 471003, China|Shangqiu First People's Hospital, Shangqiu, Henan, 476100, China|Wuhan Mental Health Center, Wuhan, Hubei, 430012, China|Xiangyang Central Hospital, Xiangyang, Hubei, 441021, China|Nanzhang People's Hospital, Xianyang, Hubei, 441599, China|Zhuzhou Central Hospital, Zhuzhou, Hunan, 412007, China|Affiliated Hospital of Inner Mongolia Minzu University, Wuzhou, Inner Mongolia Autonomous Region, 028000, China|Wuxi No.2 People's Hospital, Wuxi, Jiangsu, 214002, China|Affiliated Hospital of Jinggangshan University, Ji'an, Jiangxi, 343000, China|First Affiliated Hospital of Gannan Medical University, Ganzhou, Jiangx, 341000, China|The Second Affiliated Hospital of Nanchang University, Nanchang, Jiangx, 330000, China|Chang Zhi Yi Xue Yuan Fu Shu He Ji Yi Yuan, Changzhi, Shanxi, 046011, China|The Second Hospital of Shanxi Medical University, Taiyuan, Shanxi, 030001, China|The Hospital of Shanxi University of Chinese Medicine, Taiyuan, Shanxi, 030024, China|Xi'an People's Hospital (Xi'an Fourth Hospital), Xi'an, Shanxi, 710004, China|The First Affiliated Hospital of Xi'an Medical University, Xi'an, Shanxi, 710077, China|The General Hospital of Western Theater Command PLA, Chengdu, Sichuan, 610083, China|Guang'an People's Hospital, Guang'an, Sichuan, 638099, China|The People's Hospital of Leshan, Leshan, Sichuan, 614000, China|Tianjin Beichen Hospital, Beichen, Tianjin, 300400, China|Tianjin Binhai New Area Dagang Hospital, Binhai, Tianjin, 300270, China|Tianjing Medical University Cancer Institute & Hospital, Hexi, Tianjin, 300060, China|The First People's Hospital of Kashgar Prefecture, Kashgar, Xinjiang Uygur Autonomous Region, 844000, China|First Affiliated Hospital of Kunming Medical University, Kunming, Yunnan, 650032, China|Qunjing Hospital of Traditional Chinese Medicine, Qujing, Yunnan, 655000, China|Hwa Mei Hospital,University of Chinese Academy of Sciences, Ningbo, Zhejiang, 315010, China
Study Documents:

NCT Number: NCT00003070
Study Title: Enalapril in Treating Heart Damage Patients Who Received Anthracycline Chemotherapy for Childhood Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00003070
Acronym:

Study Status: COMPLETED
Brief Summary: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Chemoprotective drugs, such as enalapril, may protect normal cells from the toxic effects of chemotherapy. It is not known whether enalapril is more effective than a placebo in treating heart damage in patients who received anthracycline chemotherapy for childhood cancer.

PURPOSE: Randomized double-blinded phase III trial to compare the effectiveness of enalapril with a placebo in treating heart damage in patients who received anthracycline chemotherapy for childhood cancer.
Study Results: NO
Conditions: Cardiac Toxicity|Unspecified Childhood Solid Tumor, Protocol Specific
Interventions: DRUG: enalapril maleate|PROCEDURE: quality-of-life assessment
Primary Outcome Measures: Cardiac functional status and quality of life, Cardiac functional status (depressed fractional shortening) and quality-of-life, will be assessed at baseline, two and five years into the study., baseline, two and five years
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Children's Oncology Group
Collaborators: National Cancer Institute (NCI)
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 13
Funder Type: NETWORK
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: DOUBLE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: P9480|POG-9480|NCI-P97-0086|CDR0000065745
Start Date: 2000-09
Primary Completion Date: 2003-07
Completion Date: 2007-03
First Posted: 2004-03-01
Results First Posted:
Last Update Posted: 2014-08-05
Locations: University of Alabama at Birmingham Comprehensive Cancer Center, Birmingham, Alabama, 35294-3300, United States|MBCCOP - Gulf Coast, Mobile, Alabama, 36688, United States|University of Arkansas for Medical Sciences, Little Rock, Arkansas, 72205, United States|University of California San Diego Cancer Center, La Jolla, California, 92093-0658, United States|Lucile Packard Children's Hospital at Stanford, Palo Alto, California, 94304, United States|University of California Davis Medical Center, Sacramento, California, 95817, United States|Yale Comprehensive Cancer Center, New Haven, Connecticut, 06520-8028, United States|Walter Reed Army Medical Center, Washington, District of Columbia, 20307-5000, United States|

Shands Hospital and Clinics, University of Florida, Gainesville, Florida, 32610-100277, United States|Sylvester Cancer Center, University of Miami, Miami, Florida, 33136, United States|Miami Children's Hospital, Miami, Florida, 33155, United States|CCOP - Florida Pediatric, Tampa, Florida, 33682-7757, United States|Emory University Hospital - Atlanta, Atlanta, Georgia, 30322, United States|Cancer Research Center of Hawaii, Honolulu, Hawaii, 96813, United States|Children's Memorial Hospital, Chicago, Chicago, Illinois, 60614, United States|University of Kansas Medical Center, Kansas City, Kansas, 66160-7357, United States|CCOP - Wichita, Wichita, Kansas, 67214-3882, United States|MBCCOP - LSU Health Sciences Center, New Orleans, Louisiana, 70112, United States|CCOP - Ochsner, New Orleans, Louisiana, 70121, United States|Ochsner Clinic, New Orleans, Louisiana, 70121, United States|Marlene & Stewart Greenebaum Cancer Center, University of Maryland, Baltimore, Maryland, 21201, United States|Johns Hopkins Oncology Center, Baltimore, Maryland, 21231-2410, United States|Boston Floating Hospital Infants and Children, Boston, Massachusetts, 02111, United States|Dana-Farber Cancer Institute, Boston, Massachusetts, 02115, United States|University of Massachusetts Memorial Medical Center, Worcester, Massachusetts, 01655, United States|Children's Hospital of Michigan, Detroit, Michigan, 48201, United States|University of Mississippi Medical Center, Jackson, Mississippi, 39216-4505, United States|Cardinal Glennon Children's Hospital, Saint Louis, Missouri, 63104, United States|Washington University School of Medicine, Saint Louis, Missouri, 63110, United States|CCOP - Northern New Jersey, Hackensack, New Jersey, 07601, United States|Hackensack University Medical Center, Hackensack, New Jersey, 07601, United States|Roswell Park Cancer Institute, Buffalo, New York, 14263-0001, United States|Schneider Children's Hospital, New Hyde Park, New York, 11042, United States|Mount Sinai School of Medicine, New York, New York, 10029, United States|University of Rochester Cancer Center, Rochester, New York, 14642, United States|State University of New York - Upstate Medical University, Syracuse, New York, 13210, United States|Mission Saint Joseph's Health System, Asheville, North Carolina, 28801, United States|Carolinas Medical Center, Charlotte, North Carolina, 28232-2861, United States|Presbyterian Healthcare, Charlotte, North Carolina, 28233-3549, United States|Duke Comprehensive Cancer Center, Durham, North Carolina, 27710, United States|East Carolina University School of Medicine, Greenville, North Carolina, 27858-4354, United States|Comprehensive Cancer Center at Wake Forest University, Winston-Salem, North Carolina, 27157-1082, United States|Oklahoma Memorial Hospital, Oklahoma City, Oklahoma, 73126-0307, United States|CCOP - Columbia River Program, Portland, Oregon, 97213, United States|St. Christopher's Hospital for Children, Philadelphia, Pennsylvania, 19134-1095, United States|Medical University of South Carolina, Charleston, South Carolina, 29425-0721, United States|Children's Hospital of Greenville Hospital System, Greenville, South Carolina, 29605, United States|Saint Jude Children's Research Hospital, Memphis, Tennessee, 38105-2794, United States|Simmons Cancer Center - Dallas,

Dallas, Texas, 75235-9154, United States|Baylor College of Medicine, Houston, Texas, 77030, United States|MBCCOP - South Texas Pediatric, San Antonio, Texas, 78229-3900, United States|University of Texas Health Science Center at San Antonio, San Antonio, Texas, 78284-7811, United States|Naval Medical Center, Portsmouth, Portsmouth, Virginia, 23708-2197, United States|Massey Cancer Center, Richmond, Virginia, 23298-0037, United States|Midwest Children's Cancer Center, Milwaukee, Wisconsin, 53226, United States|Cross Cancer Institute, Edmonton, Alberta, T6G 1Z2, Canada|Children's Hospital, Hamilton, Ontario, L8N 3Z5, Canada|Hospital for Sick Children, Toronto, Ontario, M5G 1X8, Canada|Montreal Children's Hospital, Montreal, Quebec, H3H 1P3, Canada|Hopital Sainte Justine, Montreal, Quebec, H3T 1C5, Canada|Swiss Pediatric Oncology Group Bern, Bern, CH 3010, Switzerland
Study Documents:

NCT Number: NCT05913999
Study Title: Serial PET MPI in Patients Undergoing Cancer Treatment
Study URL: https://beta.clinicaltrials.gov/study/NCT05913999
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: This study aims to evaluate the effects of cardiotoxic cancer therapies on myocardial blood flow (MBF) and perfusion in a prospective sample of VA patients.
Study Results: NO
Conditions: Cancer|Chemotherapeutic Toxicity|Coronary Artery Disease|Coronary Microvascular Disease
Interventions:
Primary Outcome Measures: PET myocardial perfusion imaging (MPI)., Change from baseline in number of patients with perfusion defects measured as % total perfusion deficit (TPD) of the left ventricular myocardium by PET, Baseline (within 1 month prior to the initiation of cancer treatment), during cancer treatment (estimated at 1-6 months), and within 1 month post-cancer treatment completion (approximately 2-9 months)|PET myocardial blood flow (MBF) measurement., Change from baseline in number of patients with myocardial blood flow abnormalities measured as stress myocardial blood flow (SMBF) values \< 2 mL/min/g of left ventricular myocardium by PET, Baseline (within 1 month prior to the initiation of cancer treatment), during cancer treatment (estimated at 1-6 months), and within 1 month post-cancer treatment completion (approximately 2-9 months)
Secondary Outcome Measures: Transthoracic echocardiography (TTE) global left ventricular systolic function., Change from baseline in number of patients with global systolic dysfunction measured as % left ventricular ejection fraction by TTE., Baseline (within 1 month prior to the initiation of cancer treatment), during cancer treatment (estimated at 1-6 months), and within 1 month post-cancer treatment completion (approximately 2-9 months)|Transthoracic echocardiography (TTE) focal left ventricular systolic function., Change from baseline in number of patients with focal systolic dysfunction measured as % left ventricular global longitudinal strain by TTE., Baseline (within

1 month prior to the initiation of cancer treatment), during cancer treatment (estimated at 1-6 months), and within 1 month post-cancer treatment completion (approximately 2-9 months)|Transthoracic echocardiography (TTE) focal left atrial systolic function., Change from baseline in number of patients with focal systolic dysfunction measured as % left atrial strain by TTE., Baseline (within 1 month prior to the initiation of cancer treatment), during cancer treatment (estimated at 1-6 months), and within 1 month post-cancer treatment completion (approximately 2-9 months)|Electrocardiogram (ECG) findings., Change from baseline in number of patients with any of the following ECG changes:

* new T-wave inversions
* new ST-segment deviations \>/= 1mm
* new left bundle branch block, Baseline (within 1 month prior to the initiation of cancer treatment), during cancer treatment (estimated at 1-6 months), and within 1 month post-cancer treatment completion (approximately 2-9 months)|Metabolic or cardiac function abnormalities as determined by blood work findings, Change from baseline in number of patients with changes in the values of serological tests indicative of metabolic or cardiac function abnormalities including one or more of the following:

* high sensitivity troponin (ng/L)
* cardiac C-reactive protein (mg/L)
* brain-type natriuretic peptide (pg/mL)
* fasting lipid panel: total cholesterol (mg/dL), low-density lipoprotein cholesterol (mg/dL), high-density lipoprotein cholesterol (mg/dL), triglycerides (mg/dL)
* complete metabolic panel: total protein (g/dL), albumin (g/dL), total bilirubin (mg/dL), direct bilirubin (mg/dL), aspartate aminotransferase (IU/L), alanine transaminase (IU/L), alkaline phosphatase (IU/L), sodium (mmol/L), potassium (mmol/L), chloride (mmol/L), bicarbonate (mmol/L), blood urea nitrogen (mg/dL), creatinine (mg/dL), glucose (mg/dL)
* complete blood count: white blood cell count (k/uL), hemoglobin (g/dL), hematocrit (%), platelet (k/uL), Baseline (within 1 month prior to the initiation of cancer treatment), during cancer treatment (estimated at 1-6 months), and within 1 month post-cancer treatment completion (approximately 2-9 months)

Other Outcome Measures:
Sponsor: University of California, Los Angeles
Collaborators: VA Greater Los Angeles Healthcare System
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 60
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p

Other IDs: IRBNet 1668650-1
Start Date: 2023-06-01
Primary Completion Date: 2025-05-31
Completion Date: 2026-05-31
First Posted: 2023-06-22
Results First Posted:
Last Update Posted: 2023-06-22
Locations: West Los Angeles VA Medical Center, Los Angeles, California, 90073, United States
Study Documents:

NCT Number: NCT01080170
Study Title: The Effect of Aromatase Inhibitors on Cardiovascular Risk Factors in Women With Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01080170
Acronym: Silhouette
Study Status: COMPLETED
Brief Summary: This study explores how aromatase inhibitor therapy affects risk factors for heart disease in postmenopausal women with breast cancer.
Study Results: NO
Conditions: Breast Cancer
Interventions:
Primary Outcome Measures: Body Composition, 12 months
Secondary Outcome Measures: Lipids, 12 months
Other Outcome Measures:
Sponsor: University of Pittsburgh
Collaborators: National Center for Research Resources (NCRR)
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 20
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PRO09060055|KL2RR024154-04
Start Date: 2010-03
Primary Completion Date: 2013-06
Completion Date: 2013-06
First Posted: 2010-03-03
Results First Posted:
Last Update Posted: 2016-05-13
Locations: University of Pittsburgh, Department of Medicine., Pittsburgh, Pennsylvania, 15232, United States
Study Documents:

NCT Number: NCT02769299
Study Title: Cardiotoxicity of Radiation Therapy (CTRT)
Study URL: https://beta.clinicaltrials.gov/study/NCT02769299
Acronym:

Study Status: COMPLETED
Brief Summary: The overall objective of this proposal is to determine the utility of sensitive imaging and biomarker measures in detecting subclinical cardiotoxicity across a spectrum of radiation doses to the heart. We will focus specifically on patients receiving photon or proton chest radiotherapy. Our broad working hypothesis is that RT induces early, subclinical CV injury, as evidenced by cardiomyocyte inflammation and necrosis, and worsening CV function.
Study Results: NO
Conditions: Breast Cancer|Lung Cancer|Mediastinal Lymphomas
Interventions: RADIATION: Radiation Therapy
Primary Outcome Measures: Number of CV injury, 8 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 147
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 04115
Start Date: 2015-06-02
Primary Completion Date: 2018-11-26
Completion Date: 2018-11-26
First Posted: 2016-05-11
Results First Posted:
Last Update Posted: 2019-01-09
Locations: Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States
Study Documents:

NCT Number: NCT03534570
Study Title: Gated Radiotherapy in Left Sided Breast Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT03534570
Acronym: GATTUM
Study Status: UNKNOWN
Brief Summary: To assess the need of respiratory gated radiotherapy in left sided breast cancer patients.
Study Results: NO
Conditions: Breast Neoplasm Female|Radiotherapy Side Effect|Heart Diseases
Interventions:
Primary Outcome Measures: Measurement of distance from chestwall to the heart, Rigid and non-rigid measurement of distance from chestwall to the heart., 3 years|Measurement of distance from the heart to the mammary gland, Rigid and non-rigid measurement of distance from the heart to the mammary gland, 3 years

Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Technical University of Munich
Collaborators:
Sex: FEMALE
Age: ADULT
Phases:
Enrollment: 150
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: GATTUM -1
Start Date: 2018-05
Primary Completion Date: 2019-12
Completion Date: 2019-12
First Posted: 2018-05-23
Results First Posted:
Last Update Posted: 2018-05-23
Locations: Klinikum rechts der Isar; TUM, Munich, 81675, Germany
Study Documents:

NCT Number: NCT01415999
Study Title: Cardiovascular Function in Adult Survivors of Childhood Malignancies
Study URL: https://beta.clinicaltrials.gov/study/NCT01415999
Acronym:
Study Status: COMPLETED
Brief Summary: Anthracyclines have been used commonly to treat children with solid tumours and haematological malignancies and have led to their increased survival. Nonetheless, anthracycline has the side effect of cardiotoxicity. The purpose of this study is to assess the impact of anthracycline therapy on heart deformation and fibrosis, heart-vessel interaction, usefulness of circulating biomarkers in the assessment of heart function and potential genetic predisposition to heart failure in adult survivors of childhood cancers.
Study Results: NO
Conditions: Childhood Cancers
Interventions:
Primary Outcome Measures:
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: The University of Hong Kong
Collaborators:
Sex: ALL
Age: ADULT
Phases:
Enrollment: 142
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p

Other IDs: UW 11-289
Start Date: 2011-08
Primary Completion Date: 2012-07
Completion Date: 2012-07
First Posted: 2011-08-12
Results First Posted:
Last Update Posted: 2017-10-25
Locations: Queen Mary Hospital, Hong Kong, Hong Kong, China
Study Documents:

NCT Number: NCT01375699
Study Title: Doxorubicin With or Without Sildenafil, With Analysis of Cardiac Markers
Study URL: https://beta.clinicaltrials.gov/study/NCT01375699
Acronym:
Study Status: COMPLETED
Brief Summary: Sildenafil increases the therapeutic effect of doxorubicin used as treatment for cancers of solid tumors through both an increase in anti-tumor effects and protection from cardiac toxicity.
Study Results: NO
Conditions: Breast Cancer|Gastrointestinal Cancer|Genitourinary Cancer|Sarcoma|Gynecologic Cancer
Interventions: DRUG: Doxorubicin|DRUG: Sildenafil
Primary Outcome Measures: Safety of concurrent sildenafil with doxorubicin-based chemotherapy, Sildenafil will be administered at least 7 days prior to scheduled first dose of doxorubicin and continue daily dosing through 2 weeks after last doxorubicin dose. Multiple biomarkers as candidate early markers of anthracycline-induced cardiotoxicity will be tested., 25 months|The difference in left ventricular ejection fraction (LVEF) between arms, A repeated measures analysis of variance (ANOVA) will be used to compare the LVEF between Arm 1 and Arm 2 over all visits. A pooled t-test will also be performed to determine the change in LVEF between first and last visits., 4 years
Secondary Outcome Measures: Comparison of candidate early markers of cardiac injury, The fluctuation in the levels of biomarkers including novel ultra sensitive troponins and BNP, as well as tissue doppler imaging studies with echocardiography will analyzed., 37 months
Other Outcome Measures:
Sponsor: Virginia Commonwealth University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 26
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT

Other IDs: MCC-13419|NCI-2011-0098
Start Date: 2011-08-11
Primary Completion Date: 2017-08-04
Completion Date: 2018-01-19
First Posted: 2011-06-17
Results First Posted:
Last Update Posted: 2019-08-26
Locations: Virginia Commonwealth University/Massey Cancer Center, Richmond, Virginia, 23298-0037, United States
Study Documents:

NCT Number: NCT04877899
Study Title: Mazankowski Alberta Heart Institute (MAHI) EchoGo Discovery 1 Protocol
Study URL: https://beta.clinicaltrials.gov/study/NCT04877899
Acronym:
Study Status: ENROLLING_BY_INVITATION
Brief Summary: This study aims to compare conventionally acquired Left Ventricle Ejection Fraction (LVEF) and Global Longitudinal Strain (GLS) data to Artificial Intelligence (AI) driven automated processing of 2 dimensional contrast and 2 dimensional non-contrast resting transthoracic echocardiograms for application in the assessment of patients undergoing chemotherapy with cardiotoxic drugs. This is a single-centre retrospective study which utilizes echocardiographic DICOM image and meta-data datasets received from a Canadian site. Data processed using the AI driven automated processing will be compared to conventionally acquired LVEF and GLS measurements and results will be analysed to determine accuracy and precision.
Study Results: NO
Conditions: Cardiotoxicity|Cancer
Interventions: DEVICE: EchoGo
Primary Outcome Measures: Compare the performance of automated EF and GLS measurements in resting transthoracic echocardiograms against conventional measurement acquisition., Measurements shall be compared using bias and 95% confidence intervals on bias. Regression coefficients and comparative statistics will be employed for this objective., Baseline|Compare the performance of automated EF and GLS measurements in resting transthoracic echocardiograms against conventional measurement acquisition., Measurements shall be compared using bias and 95% confidence intervals on bias. Regression coefficients and comparative statistics will be employed for this objective., Follow up (up to 1 year)|Compare the performance of automated EF and GLS measurements in resting transthoracic echocardiograms with and without the application of contrast agents., Measurements will be assessed using bias and 95% confidence internals on bias. Regression coefficients, comparative statistics and equivalence testing might also be employed as a comparison measure for this objective., Baseline|Compare the performance of automated EF and GLS measurements in resting transthoracic echocardiograms with and without the application of contrast agents., Measurements will be

assessed using bias and 95% confidence internals on bias. Regression coefficients, comparative statistics and equivalence testing might also be employed as a comparison measure for this objective., Follow up (up to 1 year)
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Ultromics Ltd
Collaborators: Mazankowski Alberta Heart Institute
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 250
Funder Type: INDUSTRY
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: COL-04
Start Date: 2020-10-08
Primary Completion Date: 2021-03-31
Completion Date: 2021-11-30
First Posted: 2021-05-07
Results First Posted:
Last Update Posted: 2021-09-05
Locations: Mazankowski Alberta Heart Institute, Edmonton, Alberta, T6G 2J2, Canada
Study Documents:

NCT Number: NCT03818776
Study Title: Proton Based Cardiac Sparing Accelerated Fractionated RadioTherapy in Unresectable NSCLC
Study URL: https://beta.clinicaltrials.gov/study/NCT03818776
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to treat participants with the combination of durvalumab (the study drug) and proton beam therapy. Proton beam therapy is a type of radiotherapy (RT) with a unique characteristic where the proton stops at a specific depth according to its energy. This may be advantageous in treating lung cancer because it allows for a sufficient tumor dose that may improve local control and survival while sparing normal organs at risk, such as the heart, lung, and spinal cord.
Study Results: NO
Conditions: Non-Small Cell Lung Cancer
Interventions: DRUG: Durvalumab|RADIATION: Proton beam therapy RT
Primary Outcome Measures: Safety of intervention as defined by number of participants with Dose Limiting Toxicities (DLT) between first dose of Durvalumab and 30 days following completion of radiotherapy., Safety of intervention as defined by number of participants with DLT's between first dose of Durvalumab and 30 days following completion of radiotherapy. This is defined as 0 of 3 or 1 of 6 participants having no DLT of either Durvalumab or RT.

DLT for RT defined as:

1. Grade 4-5 non-hematologic serious adverse events (SAEs) considered by the Investigators to be probably or definitely related to protocol treatment.
2. Grade 3 or higher cardiac adverse events (e.g. severely symptomatic congestive heart failure (CHF), myocarditis, pericardial effusion, myocardial infarction, symptomatic arrhythmia) considered by the Investigators to be probably or definitely related to protocol treatment.
3. Grade 3 or higher pulmonary adverse events (e.g. dyspnea/ pneumonitis) considered by the Investigators to be probably or definitely related to protocol treatment and not responsive to steroids.
4. Failure to receive at least 54, Up to 30 days following end of treatment
Secondary Outcome Measures: Feasibility of intervention defined by number of participants receiving full course of RT treatment and minimum of two doses of Durvalumab, Feasibility of intervention is defined as a participant receiving the entire course of prescribed RT as well as having received a minimum of two doses of Durvalumab., Up to 30 days following end of treatment|Number of participants with Adverse Events according to CTCAE v5.0, All toxicities will be graded according to NCI CTCAE, Version 5.0. See Adverse Events section., Up to 30 days following end of treatment
Other Outcome Measures:
Sponsor: Case Comprehensive Cancer Center
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: EARLY_PHASE1
Enrollment: 7
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: SEQUENTIAL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CASE1518
Start Date: 2019-08-30
Primary Completion Date: 2022-01-27
Completion Date: 2022-01-27
First Posted: 2019-01-28
Results First Posted:
Last Update Posted: 2023-07-12
Locations: University Hospitals Cleveland Medical Center, Case Comprehensive Cancer Center, Cleveland, Ohio, 44106, United States
Study Documents:

NCT Number: NCT04696081
Study Title: Atrial Fibrillation in Active Cancer Patients

Study URL: https://beta.clinicaltrials.gov/study/NCT04696081
Acronym: AFIB-CANCER
Study Status: RECRUITING
Brief Summary: Atrial fibrillation is a common complication of both cancer and anticancer drugs but the consequences of such events remain poorly known and are not adressed in both phase III oncological trials and cardiological guidelines. The objective of this study is to create a prospective multicenter international registry of adult patients with an active cancer and experiencing atrial fibrillation to study major cardiovascular events occurrence during a 1 year follow-up.
Study Results: NO
Conditions: Cancer|Drug Toxicity|Atrial Fibrillation|Cardiovascular Complication
Interventions: OTHER: occurence of atrial fibrillation
Primary Outcome Measures: Occurrence of major cardiovascular events and death of any cause at 1 year, Occurrence of death of any cause, cardiovascular death, heart failure, stroke, myocardial infarction in active cancer patients with atrial fibrillation., from inclusion in the registry to 1 year of follow-up
Secondary Outcome Measures: Occurrence of major cardiovascular events and death of any cause at 1 year in prevalent and incident AF patients, Occurrence of death of any cause, cardiovascular death, heart failure, stroke, myocardial infarction in active cancer patients according to the AF type (prevalent or incident)., from inclusion in the registry to 1 year of follow-up|Description of the population of active cancer patients experiencing atrial fibrillation (in both prevalent and incidence AF patients)., Description of the population of active cancer patients experiencing atrial fibrillation. Active cancers will be defined according Agnelli et al. (NEJM 2020; 382:1599-1607)., at the inclusion in the registry|Description of the management of atrial fibrillation in cancer patients (in both prevalent and incidence AF patients)., Description of the management (anticoagulants, rhythm or rate control) of atrial fibrillation in cancer patients, from inclusion in the registry to 1 year of follow-up|Description of the population of active cancer patients having a major cardiovascular event, Description of the population of patients having a major cardiovascular event among cancer patients experiencing atrial fibrillation, from inclusion in the registry to 1 year of follow-up|Identifying risk factors associated with major cardiovascular events and all cause mortality occurrence, Identifying risk factors (clinical, EKG, biological, echocardiography) of major cardiovascular events and all cause mortality in cancer patients experiencing atrial fibrillation, from inclusion in the registry to 1 year of follow-up|Identifying factors associated with atrial fibrillation recurrence, Identifying factors (clinical, EKG, biological, echocardiography) of atrial fibrillation recurrence in cancer patients, from inclusion in the registry to 1 year of follow-up|Occurrence of major and clinically relevant non-major bleedings (2005 ISTH definition), Occurrence of major and clinically relevant non-major bleedings in active cancer patients experiencing atrial

fibrillation., from inclusion in the registry to 1 year of follow-up| Identifying risk factors associated with major and clinically relevant non-major bleedings (2005 ISTH definition), Identifying risk factors (clinical, EKG, biological, echocardiography) of major and clinically relevant non-major bleedings in active cancer patients experiencing atrial fibrillation, from inclusion in the registry to 1 year of follow-up
Other Outcome Measures:
Sponsor: University Hospital, Caen
Collaborators: Groupe Hospitalier Pitie-Salpetriere|University Hospital, Marseille, France|Hospices Civils de Lyon, France|University of Pennsylvania, USA|Centre Francois Baclesse, Caen, France|Saint Antoine University Hospital, Paris, France|Vanderbilt University Medical Center, USA|University Hospital of Saint-Etienne, France|Hôpital Lariboisière Fernand Widal, Paris, France|University Hospital, Rennes, France|Hospital Universitario La Paz, Spain|Institut de Cancérologie de l'Ouest Nantes, France|Fundacion Cardio Onco, Santiago, Chile|Hunter New England Area Health Service, University of Newcastle, Australia|Cardiology Division, University of Modena and Reggio Emilia, Policlinico di Modena, Italy|Heidelberg University
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 1000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Pharmaco122020
Start Date: 2021-09-01
Primary Completion Date: 2023-09-01
Completion Date: 2024-01-01
First Posted: 2021-01-06
Results First Posted:
Last Update Posted: 2022-10-03
Locations: Alexandre, Caen, Normandy, 14000, France
Study Documents:

NCT Number: NCT00126581
Study Title: Erlotinib Hydrochloride With or Without Carboplatin and Paclitaxel in Treating Patients With Stage III-IV Non-small Cell Lung Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00126581
Acronym:
Study Status: COMPLETED
Brief Summary: This randomized phase II trial studies how well erlotinib hydrochloride with or without carboplatin and paclitaxel works in treating patients with stage III-IV non-small cell lung cancer. Erlotinib hydrochloride may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Drugs used in chemotherapy, such as carboplatin and paclitaxel, work in different

ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving erlotinib hydrochloride together with carboplatin and paclitaxel may kill more tumor cells than giving either drug alone.
Study Results: YES
Conditions: Lung Adenocarcinoma|Lung Adenosquamous Carcinoma|Malignant Pericardial Effusion|Malignant Pleural Effusion|Minimally Invasive Lung Adenocarcinoma|Stage IIIB Lung Non-Small Cell Cancer AJCC v7|Stage IV Lung Non-Small Cell Cancer AJCC v7
Interventions: DRUG: Carboplatin|DRUG: Erlotinib|DRUG: Erlotinib Hydrochloride|DRUG: Paclitaxel
Primary Outcome Measures: 18 Weeks Progression Free Survival (PFS) Rate, The product limit estimator developed by Kaplan Meier will be used to graphically describe progression free survival for patients randomized to each study arm.

The 18 week progression-free survival rate was defined as the proportion of patients that were alive progression-free 18 weeks after registration into the study. Disease progression was assessed per modified RECIST criteria, and defined as at least a 20% increase in the sum of the longest diameters of target lesions, in either primary or nodal lesions, taking as reference the smallest sum longest diameter recorded since the baseline measurements, or the appearance of new lesions. Kaplan-Meier estimate of 18-week progression-free survival was calculated., At 18 weeks
Secondary Outcome Measures: Overall Response Rate, The proportion of patients who respond (completely or partially) to each combination regimen will be estimated. An exact binomial confidence interval will be computed for these estimates.

Response was defined using Response Evaluation Criteria In Solid Tumors (RECIST) criteria:

Complete Response (CR): disappearance of all target lesions; Partial Response (PR) 30% decrease in sum of longest diameter of target lesions, Duration of Study (up to 3 years)|Number of Participants With Grade 3, 4 or 5 Adverse Event at Least Possibly Related to Treatment., The National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 3.

Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life Threatening; Grade 5: Death., Duration of study (up to 3 years)
Other Outcome Measures: Overall Survival, Overall survival (OS) is defined as the time from patient randomization (arm assignment) to death from any cause. The median OS with 95% CI was estimated using the Kaplan-Meier method., Time from randomization to death (up to 3 years)|Progression Free Survival (PFS) by Epidermal Growth Factor Receptor (EGFR) Mutation Status, PFS was defined as the time from registration until disease progression or death, whichever occurs first. The median PFS with 95% CI was estimated using the Kaplan-Meier

method. Progression is defined as in the primary outcome measure.

EGFR mutations were performed at the Dana-Farber Cancer Institute using a sensitive heteroduplex method coupled with enzymatic digestion as previously reported (Janne PA, et al: A rapid and sensitive enzymatic method for epidermal growth factor receptor mutation screening. Clin Cancer Res 12:751-758, 2006). All positive findings were independently verified and subjected to sequencing. The mutation analyses were blinded to the participants' clinical outcome., Duration of treatment (up to 3 years)|Overall Response Rate by EGFR Mutation Status, Response and EGFR mutation status are defined in previous outcome measures., Duration of study (up to 3 years)|Progression Free Survival With KRAS Mutation Status, Progression free survival is defined in previous outcome measures. GIven the small number of KRAS mutant participants, the analysis combines data from both arms., Duration of study (up to 3 years)|Overall Response Rate With KRAS Mutational Status, Overall response is defined in previous outcome measures. GIven the small number of KRAS mutant participants in each treatment arm, the analysis combines data from both arms., Duration of study (up to 3 years)
Sponsor: National Cancer Institute (NCI)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE2
Enrollment: 188
Funder Type: NIH
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: NCI-2009-00464|NCI-2009-00464|CDR0000437097|CALGB-30406|CALGB-30406|U10CA180821|U10CA031946
Start Date: 2005-08-15
Primary Completion Date: 2010-06-30
Completion Date: 2017-11-28
First Posted: 2005-08-04
Results First Posted: 2013-10-07
Last Update Posted: 2019-08-07
Locations: East Bay Radiation Oncology Center, Castro Valley, California, 94546, United States|Eden Hospital Medical Center, Castro Valley, California, 94546, United States|Valley Medical Oncology Consultants-Castro Valley, Castro Valley, California, 94546, United States|Bay Area Breast Surgeons Inc, Emeryville, California, 94608, United States|Valley Medical Oncology Consultants-Fremont, Fremont, California, 94538, United States|Saint Rose Hospital, Hayward, California, 94545, United States|Contra Costa Regional Medical Center, Martinez, California, 94553-3156, United States|El Camino Hospital, Mountain View, California, 94040, United States|Highland General Hospital, Oakland, California, 94602, United States|Alta Bates Summit Medical Center - Summit Campus, Oakland, California, 94609, United

States|Bay Area Tumor Institute, Oakland, California, 94609, United States|Hematology and Oncology Associates-Oakland, Oakland, California, 94609, United States|Tom K Lee Inc, Oakland, California, 94609, United States|Valley Care Health System - Pleasanton, Pleasanton, California, 94588, United States|Valley Medical Oncology Consultants, Pleasanton, California, 94588, United States|University of California San Diego, San Diego, California, 92103, United States|Kaiser Permanente-San Diego Mission, San Diego, California, 92108, United States|Veterans Administration-San Diego Medical Center, San Diego, California, 92161, United States|UCSF Medical Center-Mount Zion, San Francisco, California, 94115, United States|Doctors Medical Center- JC Robinson Regional Cancer Center, San Pablo, California, 94806, United States|Middlesex Hospital, Middletown, Connecticut, 06457, United States|Beebe Medical Center, Lewes, Delaware, 19958, United States|Christiana Care Health System-Christiana Hospital, Newark, Delaware, 19718, United States|MedStar Georgetown University Hospital, Washington, District of Columbia, 20007, United States|MedStar Washington Hospital Center, Washington, District of Columbia, 20010, United States|Holy Cross Hospital, Fort Lauderdale, Florida, 33308, United States|Jupiter Medical Center, Jupiter, Florida, 33458, United States|Mount Sinai Medical Center, Miami Beach, Florida, 33140, United States|Memorial Health University Medical Center, Savannah, Georgia, 31404, United States|University of Chicago Comprehensive Cancer Center, Chicago, Illinois, 60637, United States|AMITA Health Adventist Medical Center, La Grange, Illinois, 60525, United States|Elkhart General Hospital, Elkhart, Indiana, 46515, United States|Community Howard Regional Health, Kokomo, Indiana, 46904, United States|IU Health La Porte Hospital, La Porte, Indiana, 46350, United States|Saint Joseph Regional Medical Center-Mishawaka, Mishawaka, Indiana, 46545, United States|Memorial Hospital of South Bend, South Bend, Indiana, 46601, United States|Northern Indiana Cancer Research Consortium, South Bend, Indiana, 46628, United States|University of Iowa/Holden Comprehensive Cancer Center, Iowa City, Iowa, 52242, United States|University of Maryland/Greenebaum Cancer Center, Baltimore, Maryland, 21201, United States|MedStar Franklin Square Medical Center/Weinberg Cancer Institute, Baltimore, Maryland, 21237, United States|Union Hospital of Cecil County, Elkton, Maryland, 21921, United States|Massachusetts General Hospital Cancer Center, Boston, Massachusetts, 02114, United States|Brigham and Women's Hospital, Boston, Massachusetts, 02115, United States|Dana-Farber Cancer Institute, Boston, Massachusetts, 02215, United States|Mass General/North Shore Cancer Center, Danvers, Massachusetts, 01923, United States|Cape Cod Hospital, Hyannis, Massachusetts, 02601, United States|Lowell General Hospital, Lowell, Massachusetts, 01854, United States|South Shore Hospital, South Weymouth, Massachusetts, 02190, United States|Lakeland Medical Center Saint Joseph, Saint Joseph, Michigan, 49085, United States|University of Minnesota/Masonic Cancer Center, Minneapolis, Minnesota, 55455, United States|Missouri Cancer Associates, Columbia, Missouri, 65201, United States|Veterans Administration, Columbia, Missouri, 65201, United States|University of

Missouri – Ellis Fischel, Columbia, Missouri, 65212, United States| Capital Region Medical Center, Jefferson City, Missouri, 65101, United States|Washington University School of Medicine, Saint Louis, Missouri, 63110, United States|Missouri Baptist Medical Center, Saint Louis, Missouri, 63131, United States|Center for Cancer Care and Research, Saint Louis, Missouri, 63141, United States|CHI Health Saint Francis, Grand Island, Nebraska, 68803, United States|Great Plains Health Callahan Cancer Center, North Platte, Nebraska, 69101, United States|University of Nebraska Medical Center, Omaha, Nebraska, 68198, United States|University Medical Center of Southern Nevada, Las Vegas, Nevada, 89102, United States|Saint Joseph Hospital, Nashua, New Hampshire, 03060, United States|Cooper Hospital University Medical Center, Camden, New Jersey, 08103, United States|Rutgers Cancer Institute of New Jersey, New Brunswick, New Jersey, 08903, United States|Roswell Park Cancer Institute, Buffalo, New York, 14263, United States|Hematology Oncology Associates of Central New York–East Syracuse, East Syracuse, New York, 13057, United States|Northwell Health NCORP, Lake Success, New York, 11042, United States|North Shore University Hospital, Manhasset, New York, 11030, United States|Long Island Jewish Medical Center, New Hyde Park, New York, 11040, United States|Ralph Lauren Center for Cancer Care and Prevention, New York, New York, 10035, United States|Memorial Sloan Kettering Cancer Center, New York, New York, 10065, United States|Saint Joseph's Hospital Health Center, Syracuse, New York, 13203, United States|State University of New York Upstate Medical University, Syracuse, New York, 13210, United States|UNC Lineberger Comprehensive Cancer Center, Chapel Hill, North Carolina, 27599, United States|Novant Health Presbyterian Medical Center, Charlotte, North Carolina, 28204, United States|Duke University Medical Center, Durham, North Carolina, 27710, United States|Wayne Memorial Hospital, Goldsboro, North Carolina, 27534, United States|Wayne Radiation Oncology, Goldsboro, North Carolina, 27534, United States|Margaret R Pardee Memorial Hospital, Hendersonville, North Carolina, 28791, United States|Vidant Oncology-Kinston, Kinston, North Carolina, 28501, United States|Wilson Medical Center, Wilson, North Carolina, 27893, United States|Ohio State University Comprehensive Cancer Center, Columbus, Ohio, 43210, United States|University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, 73104, United States|Cancer Care Associates, Oklahoma City, Oklahoma, 73120, United States|Memorial Hospital of Rhode Island, Pawtucket, Rhode Island, 02860, United States|Rhode Island Hospital, Providence, Rhode Island, 02903, United States|Miriam Hospital, Providence, Rhode Island, 02906, United States|Roper Hospital, Charleston, South Carolina, 29401, United States|McLeod Regional Medical Center, Florence, South Carolina, 29506, United States|Saint Francis Hospital, Greenville, South Carolina, 29601, United States| Greenville Memorial Hospital, Greenville, South Carolina, 29605, United States|Greenville Health System Cancer Institute-Eastside, Greenville, South Carolina, 29615, United States|Central Vermont Medical Center/National Life Cancer Treatment, Berlin, Vermont, 05602, United States|University of Vermont and State Agricultural College,

Burlington, Vermont, 05405, United States|Rappahannock General Hospital, Kilmarnock, Virginia, 22482, United States|Virginia Commonwealth University/Massey Cancer Center, Richmond, Virginia, 23298, United States
Study Documents:

NCT Number: NCT04328181
Study Title: Comparison of Imaging Quality Between Spectral Photon Counting Computed Tomography (SPCCT) and Dual Energy Computed Tomography (DECT)
Study URL: https://beta.clinicaltrials.gov/study/NCT04328181
Acronym: SPEQUA
Study Status: RECRUITING
Brief Summary: This pilot study wants to determine to which extent SPCCT allows obtaining images with improved quality and diagnostic confidence when compared to standard Dual Energy CT (DECT), both with and without contrast agent injection.

Depending on the anatomical structures/organs to be visualized during CT examinations, different scanning protocols are performed with quite variable ionizing radiation doses. Therefore, in order to obtain the most extensive and representative results of the improvement in image quality between SPCCT and DECT that will be performed CT imaging on several body regions and structures, including diabetic foot, diabetic calcium coronary scoring, adrenal glands, coronary arteries, lung parenchyma, kidney stones, inner ear, brain and joints, earl/temporal bone, colorectal carcinosis.
Study Results: NO
Conditions: Diabetic Foot Ulcer|Coronary Artery Disease|Parenchymatous; Pneumonia|Kidney Stone|Inner Ear Disease|Brain Stroke|Joint Diseases|Diabetes|Adrenal Incidentaloma|Hyperaldosteronism|Macroadenoma|Interstitial Lung Disease|Intracranial Arteriovenous Malformations
Interventions: DEVICE: Spectral Photon Counting Computed Tomography (SPCCT)|DEVICE: DECT (Dual Energy CT)
Primary Outcome Measures: quality of the images, A single four-point scale will be used (1: unacceptable, 2: usable under limited conditions, 3: probably acceptable, 4: fully acceptable) based on the European guidelines on quality criteria for computed tomography, Day 8
Secondary Outcome Measures: Diagnostic confidence graded, The diagnostic confidence grade will be calculated on a four-point scale (1: insufficient, 2: poor, 3: average, 4: good)., Day 8|Subjective image quality graded, It will be calculated on a five-point scale (1: poor, 2: fair, 3: average, 4: good, 5: excellent) for each following criterion: noise, artifacts and sharpness., Day 8|CT Dose Index volumic (CTDIvol), To determine the radiation dose delivered to the patients during the DECT and SPCCT imaging procedures.

The CTDI is an estimation of the dose delivered to the organs for each acquired section that is based on acquisition parameters of a water

phantom with a 32 cm diameter. The value is expressed in milligray (mGy)., Day 8|Dose Length Product (DLP), To determine the radiation dose delivered to the patients during the DECT and SPCCT imaging procedures.

The DLP is obtained as follows: CTDI * length of body explored = value in mGy.cm., Day 8|Equivalent dose (mSv), To determine the radiation dose delivered to the patients during the DECT and SPCCT imaging procedures.

The equivalent dose is obtained by multiplying the DLP to the specific organ conversion factor., Day 8|Quantitatively image quality : Noise, The noise by selecting regions of interest (ROI) will calculated., Day 8|Quantitatively image quality : Density, The density (HU) by selecting regions of interest (ROI) will calculated., Day 8|Quantitatively image quality : contrast-to-noise ratio, The contrast-to-noise ratio (CNR) by selecting regions of interest (ROI) will calculated., Day 8|Depiction of anatomical structures of interest, Depiction of anatomical structures of interest will be graded on a four-point scale (1: visualization just possible, 2: unclear borders but different structures already visible, 3: very good visualization, well-defined anatomy, 4: perfect delineation of anatomy)., Day 8|Radiation dose, An average radiation dose delivered to the patients for each clinical application will be calculated., Day 8|Statistical comparison between SPCCT and DECT, Statistical comparison between SPCCT and DECT will be performed over all images and anatomical structures globally and also for each clinical application of interest., Day 8
Other Outcome Measures:
Sponsor: Hospices Civils de Lyon
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 316
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 69HCL19_0486|ID-RCB
Start Date: 2021-01-29
Primary Completion Date: 2024-01-29
Completion Date: 2024-01-29
First Posted: 2020-03-31
Results First Posted:
Last Update Posted: 2023-05-25
Locations: Hôpital Cardiologique Louis Pradel - Hospices Civils de Lyon, Bron, Avenue Doyen Lépine, 69500, France
Study Documents:

NCT Number: NCT01498276
Study Title: Family Genetics Health Education and Healthy Behaviors
Study URL: https://beta.clinicaltrials.gov/study/NCT01498276
Acronym:
Study Status: COMPLETED
Brief Summary: Background:

- Family-based approaches to reduce disease risk and promote healthy behaviors may be better than targeting individuals. Risk assessments based on family health history may help educate families on disease risks and encourage them to change physical activity and food choices. Specifically, researchers want to better understand the role of mothers in teaching healthy behaviors to their families.

Objectives:

* To determine mothers influence on diet and health-related behaviors.
* To study an intervention tool that connects family health history and disease risk.

Eligibility:

- 18 years of age who have at least one child living at home.

Design:

* Participants will complete a survey over the phone. The survey will take 30 to 40 minutes to complete. The survey will collect family health history on heart disease, diabetes, colorectal cancer, and breast cancer.
* Researchers will give participants a Family Health Package (FHP). The FHP will provide information on family health history and disease risk. It will also recommend behaviors that can reduce health risks.
* Two weeks after sending the FHP, participants will complete a phone survey about the FHP materials and their social networks.
* Some participants will be invited to focus groups. The focus groups will explore diet and health behavior. They will look at food purchasing and preparation and meal sharing. The groups will also discuss attitudes toward healthy eating and physical activity. Each focus group will last 1 to 2 hours.
* Participants will be asked to complete an electronic survey regarding participants health status, causal health beliefs, risk perceptions, and intentions to communicate health information.
* Then, participants will have the opportunity to use the electronic version of the FHP, which will assess family health history.
* After using the FHeP, participants will complete a short electronic survey to identify knowledge and understanding gained from the use of the application, changes in communication intentions, and suggestions for improvements to the application.
* Upon completion of the electronic portion of the study, a study team

member will conduct a semi-structured interview to allow the participants to qualitatively evaluate their user experience, including satisfaction and usefulness.
* This study process will take approximately 60-90 minutes.
Study Results: NO
Conditions: Diabetes|Cancer|Heart Disease
Interventions:
Primary Outcome Measures: Participants' comprehension of an intervention tool, Participants' comprehension of intervention tool outlining family health history and risk assessment of etiologically complex health conditions (heart disease, diabetes, breast and colorectal cancer), interim and end-point|Intergenerational transfer of diet-related behaviors, Intergenerational transfer of diet-related behaviors, interim and end-point
Secondary Outcome Measures: Efficacy of utilizing mothers to educate family members of disease risk and motivate healthy behaviors., Efficacy of utilizing mothers to educate family members of disease risk and motivate healthy behaviors., interim and end-point
Other Outcome Measures:
Sponsor: National Human Genome Research Institute (NHGRI)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 310
Funder Type: NIH
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 120023|12-HG-0023
Start Date: 2012-01-03
Primary Completion Date:
Completion Date:
First Posted: 2011-12-23
Results First Posted:
Last Update Posted: 2023-06-26
Locations: National Institutes of Health Clinical Center, Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT00677781
Study Title: Impact of Microparticles on Postoperative Complications in Surgical Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT00677781
Acronym:
Study Status: COMPLETED
Brief Summary: Microparticles are cellular fragments which are released actively or passively under conditions of inflammation and stress. The impact of surgical operations on quantity and quality of microparticles remains unknown. In this observatory study we investigate quantitative and qualitative aspects of microparticles

during cardiac and abdominal operations.
Study Results: NO
Conditions: Neoplasm, Hepatic|Pancreatic Neoplasms|Colorectal Neoplasms
Interventions:
Primary Outcome Measures: Postoperative morbidity, 30 days
Secondary Outcome Measures: Hospital stay, 30 days|Mortality, 30 days
Other Outcome Measures:
Sponsor: University of Bern
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 108
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: KEK251_07
Start Date: 2008-02
Primary Completion Date: 2008-12
Completion Date: 2010-01
First Posted: 2008-05-15
Results First Posted:
Last Update Posted: 2011-09-07
Locations: Department of visceral and transplant surgery, Bern University Hospital, Bern, 3010, Switzerland
Study Documents:

NCT Number: NCT04706481
Study Title: Archival of Human Biological Samples in CU-Med Biobank
Study URL: https://beta.clinicaltrials.gov/study/NCT04706481
Acronym:
Study Status: RECRUITING
Brief Summary: CU-Med Biobank collaborates with different researchers for collecting and distributing human biospecimens and clinical data for assisting scientific research.
Study Results: NO
Conditions: Healthy|Cancer|Heart Diseases|Neurological Diseases or Conditions|Kidney Diseases|Diabetes|Other Disease
Interventions: PROCEDURE: Specimen Collection
Primary Outcome Measures: To distribute human biospecimens for clinical research, By using the biological samples from CU-Med Biobank, translational studies can be done., 99 years|To discover the pathological mechanism of different acute and chronic diseases such as cancer, stroke, heart disease, dementia & diabetes, The relationship between different genome/proteome/bacteriome/virome and various diseases can be revealed, thus leading to a better prognostic and diagnostic outcome., 99 years
Secondary Outcome Measures:
Other Outcome Measures:

Sponsor: Chinese University of Hong Kong
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 10000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: CREC 2019.152
Start Date: 2020-01-01
Primary Completion Date: 2050-12-01
Completion Date: 2050-12-01
First Posted: 2021-01-12
Results First Posted:
Last Update Posted: 2022-03-09
Locations: CU-Med Biobank, Hong Kong, Hong Kong
Study Documents:

NCT Number: NCT05615376
Study Title: Beat to Beat A Study in Paediatric, Adolescent and Young Adult Patients Who Are Undergoing or Have Undergone Cancer Therapy to Evaluate the Agreement Between QTc Measured Using 12 Lead Electrocardiogram (ECG) and a Wearable Device ECG
Study URL: https://beta.clinicaltrials.gov/study/NCT05615376
Acronym:
Study Status: RECRUITING
Brief Summary: A prospective study in paediatric, adolescent and young adult patients aged 7 to 18 years to evaluate the agreement between QTc measured using 12 lead electrocardiogram (ECG) and the wearable device ECG.
Study Results: NO
Conditions: Neoplasms|Cardiac Arrhythmia
Interventions: DEVICE: ECG application|DEVICE: 12 lead ECG
Primary Outcome Measures: Recording of a 12 lead ECG and wearable device ECG, 12 lead ECG and wearable device ECG recordings will be taken at the time point of care. The wearable device ECG will be placed on the left wrist to record a V1 (lead I) ECG and on the left ankle to record a V2 (lead II) ECG reading from which the QT interval can be calculated., Day 1 of inpatient stay|Recording of a 12 lead ECG and wearable device ECG, 12 lead ECG and wearable device ECG recordings will be taken at the time point of care. The wearable device ECG will be placed on the left wrist to record a V1 (lead I) ECG and on the left ankle to record a V2 (lead II) ECG reading from which the QT interval can be calculated., Day 4 of inpatient stay| Calculation of QT interval by two blinded health professionals, The wearable device ECG and 12 lead ECG will be de-identified and given appropriate study numbers. This data will be listed separately for each patient. The QT interval for each recording will be calculated. This is the time corresponding to beginning of depolarization to

repolarization of the ventricles. It is calculated using a standardised approach (Fridericia's formula:QTcF = QT divided by cube root of RR)., Day 1 of inpatient stay|Calculation of QT interval by two blinded health professionals, The wearable device ECG and 12 lead ECG will be de-identified and given appropriate study numbers. This data will be listed separately for each patient. The QT interval for each recording will be calculated. This is the time corresponding to beginning of depolarization to repolarization of the ventricles. It is calculated using a standardised approach (Fridericia's formula:QTcF = QT divided by cube root of RR)., Day 4 of inpatient stay
Secondary Outcome Measures: Number of Participants with Abnormal QTc that is greater than 0.48mm on 12 lead ECG and wearable device ECG, From the analysis of QT measurements from Outcome 2, prolonged or abnormal QTc measurement will be noted. An abnormal QTc is greater than 0.48mm. This data will be collected separately for each patient., Day 1 inpatient stay|Number of Participants with Abnormal QTc that is greater than 0.48mm on 12 lead ECG and wearable device ECG, From the analysis of QT measurements from Outcome 2, prolonged or abnormal QTc measurement will be noted. An abnormal QTc is greater than 0.48mm. This data will be collected separately for each patient., Day 4 inpatient stay|Sensitivity calculations of wearable device vs 12 Lead ECG, Sensitivity is calculated only in the participants who are declared to have QTc prolongation (abnormal QTc) and is calculated as the proportion patients with QTc prolongation on the wearable device among those with QTc prolongation on the 12-lead ECG., Day 1 inpatient stay|Sensitivity calculations of wearable device vs 12 Lead ECG, Sensitivity is calculated only in the participants who are declared to have QTc prolongation (abnormal QTc) and is calculated as the proportion patients with QTc prolongation on the wearable device among those with QTc prolongation on the 12-lead ECG., Day 4 inpatient stay|Specificity calculations of wearable device vs 12 Lead ECG, Specificity is calculated only in participants who do not have QTc prolongation and is calculated as the proportion patients who do not have QTc prolongation on the wearable device among those who do not have QTc prolongation on the 12-lead ECG., Day 1 inpatient stay|Specificity calculations of wearable device vs 12 Lead ECG, Specificity is calculated only in participants who do not have QTc prolongation and is calculated as the proportion patients who do not have QTc prolongation on the wearable device among those who do not have QTc prolongation on the 12-lead ECG., Day 4 inpatient stay|To calculate the interobserver variability between the two health care professional readings of QTc., The corrected QT interval will be calculated on both the wearable device ECG and the 12 lead ECG for each patient and measured by a health professional. QT interval will be calculated by the health professional by using the QT and RR interval from the ECGs using Frederichia's interval (QTcF = QT divided by cube root of RR). This data will be collected separately for each patient. The standard deviation of the difference in QTc interval between the two observers will be reported., Day 1 inpatient stay|To calculate the interobserver variability between the two health care

professional readings of QTc., The corrected QT interval will be calculated on both the wearable device ECG and the 12 lead ECG for each patient and measured by a health professional. QT interval will be calculated by the health professional by using the QT and RR interval from the ECGs using Frederichia's interval (QTcF = QT divided by cube root of RR). This data will be collected separately for each patient for each patient The standard deviation of the difference in QTc interval between the two observers will be reported., Day 4 inpatient stay
Other Outcome Measures:
Sponsor: Murdoch Childrens Research Institute
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: NA
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 88476
Start Date: 2023-02-07
Primary Completion Date: 2023-07-01
Completion Date: 2024-02-01
First Posted: 2022-11-14
Results First Posted:
Last Update Posted: 2023-02-23
Locations: The Royal Children's Hospital, Parkville, Victoria, 3052, Australia
Study Documents:

NCT Number: NCT01708798
Study Title: Study of the Effect of Eplerenone on Heart Function in Women Receiving Anthracycline Chemotherapy for Breast Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT01708798
Acronym:
Study Status: TERMINATED
Brief Summary: Doxorubicin and other anthracyclines are commonly used to treat breast cancer and other types of cancer. Unfortunately, they can cause heart muscle damage, resulting in scarring, abnormal contraction and relaxation, and heart failure symptoms. This side effect occurs more frequently at higher doses, and limits the total dose that can be given to cancer patients. Eplerenone is an oral medication that prevents or reverses heart damage in other disease states, and is commonly used to treat heart failure. This study will investigate the use of eplerenone to protect the heart from these harmful side effects of doxorubicin.

Few therapies have been shown to prevent heart damage in patients receiving anthracyclines. Small studies have suggested that other

heart failure medications (ACE inhibitors, beta-blockers) may reduce the incidence of cardiac toxicity, but eplerenone and other drugs in its class (aldosterone antagonists) have not previously been studied. Eplerenone inhibits enzyme pathways that cause scarring of the heart, and animal studies suggest that anthracyclines cause damage through these same pathways.

This study aims to investigate whether eplerenone protects the heart from the harmful effects of doxorubicin chemotherapy. Specifically, it will measure the effect that eplerenone has on heart muscle relaxation. It will randomly assign women undergoing chemotherapy with doxorubicin to one of two groups: one group will receive eplerenone, and the other group will receive placebo (sugar) pills. The subjects will not know which type of pills they are taking. Heart muscle relaxation will be measured at baseline, after completion of chemotherapy (8-12 weeks), and after 6 months. There will also be various blood tests measured in the study subjects, to determine whether there might be certain blood tests that identify patients at particularly high risk of heart toxicity after doxorubicin therapy.
Study Results: NO
Conditions: Breast Cancer
Interventions: DRUG: Eplerenone|DRUG: Placebo
Primary Outcome Measures: Change in average E' (averaged septal E' and lateral E'), The average early diastolic tissue velocity of the mitral valve annulus measured by tissue Doppler echocardiography (averaged velocities of the mitral annulus measured at the lateral edge and the septal edge), 6 months
Secondary Outcome Measures: Development of worsening diastolic function, Development of worsening diastolic function, defined as a decline by at least one American Society of Echocardiography gradation of diastolic dysfunction, 6 months|Development of worsening systolic function, Development of worsening systolic function, defined as a decline in LVEF of ≥10% to ≤50%, 6 months|Change in septal E', Change in early diastolic tissue velocity of the septal mitral annulus (E', measured by tissue Doppler echocardiography), 6 months|Change in lateral E', Change in early diastolic tissue velocity of the lateral mitral annulus (E', measured by tissue Doppler echocardiography), 6 months|Change in E/E', Change in the ratio of early diastolic mitral inflow velocity (E, measured by pulse wave Doppler echocardiography) to the average early diastolic tissue velocity of the mitral annulus (E', measured by tissue Doppler echocardiography), 6 months|Change in E/A, Change in the ratio of peak early diastolic mitral inflow velocity (E) to peak mitral inflow velocity during atrial systole (A), both measured by pulse wave Doppler echocardiography, 6 months|Change in left atrial volume index, Change in the left atrial volume index, defined as the left atrial volume measured on the 2D echocardiogram indexed to body surface area, 6 months|Change in left ventricular ejection fraction (LVEF), Change in LVEF, measured by echocardiogram using Simpson's method, 6 months|Biomarkers, Change in biomarkers of myocardial injury, inflammation, and collagen turnover as predictors

of cardiotoxicity, Baseline, 1 week, 2 weeks, 4 weeks, 6 months
Other Outcome Measures: Incidence of hyperkalemia, Incidence of hyperkalemia defined as serum potassium \>5.5 mmol/L, 6 months|Incidence of adverse events leading to discontinuation of study drug, Incidence of adverse events leading to discontinuation of study drug, including hypotension, dizziness, hyperkalemia, or renal failure, 6 months|Signal-averaged ECG (SAECG) changes, Change in late potentials measured on SAECG, Baseline, 8-12 weeks, 6 months|Exercise stress test, Change in QT/RR interval slope, exercise capacity, peak heart rate, heart rate recovery, ventricular arrhythmias during exercise, ventricular arrhythmias during recovery, presence of ischemia, Baseline, 6 months|Genetic predictors of cardiotoxicity and of response to eplerenone, Genetic predictors of cardiotoxicity and of response to eplerenone, 6 months|ECG changes, Change in QT interval, arrhythmias, Pre- and post-chemotherapy infusions (over 8-12 weeks)|Global longitudinal strain (GLS), Change in GLS from baseline to 6 months, 6 months
Sponsor: University of British Columbia
Collaborators: Canadian Cancer Society (CCS)|Pfizer
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases: PHASE2|PHASE3
Enrollment: 44
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: TRIPLE (PARTICIPANT, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: H12-00185
Start Date: 2014-05
Primary Completion Date: 2016-11
Completion Date: 2016-11
First Posted: 2012-10-17
Results First Posted:
Last Update Posted: 2017-01-05
Locations: British Columbia Cancer Agency, Vancouver Centre, Vancouver, British Columbia, V5Z 4E6, Canada
Study Documents:

NCT Number: NCT05746598
Study Title: Effect of Genetic and Epigenetic Factors on the Clinical Response and Toxicity to Cisplatin Among Egyptian Non-small Cell Lung Cancer Patients
Study URL: https://beta.clinicaltrials.gov/study/NCT05746598
Acronym:
Study Status: RECRUITING
Brief Summary: Lung cancer is the leading cause of death worldwide, with non-small-cell lung cancer (NSCLC) being the most common histotype according to the global cancer observatory 2022. A variety of therapeutic options for advanced/metastatic non-oncogene-addicted

NSCLC have recently been approved based on their impact on patient outcomes in terms of survival and safety profile. Current guidelines advocate for personalized treatment options based on molecular and immunologic characteristics, which drives the physician's decision toward tailored oncology.

In the last two to three decades, hundreds of cancer biological prognostic markers for non-small cell lung cancer have been proposed. Although they have shown a potential in this field, validation studies are still required and, to date, there is in sufficient evidence to recommend the routine clinical use of any of these putative biomarkers. Therefore, the discovery of robust prognostic and/or predictive biomarkers in patients with non-small cell lung cancer is imperative for advancing treatment strategies for the disease and improving patient care.
Study Results: NO
Conditions: Non Small Cell Lung Cancer|Nephropathy|Cardiotoxicity
Interventions: DRUG: Cisplatin injection
Primary Outcome Measures: Nephrotoxicity, Change in Creatinine Clearance, 6 months
Secondary Outcome Measures: Blood urea nitrogen, Change in Blood urea nitrogen, 6 months|Serum creatinine, change in Serum creatinine, 6 month|Cardiotoxicity, Change in ejection fraction, 6 months
Other Outcome Measures:
Sponsor: Ain Shams University
Collaborators: Misr International University
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 178
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: NSCLC-Genetics
Start Date: 2020-07-01
Primary Completion Date: 2023-03-01
Completion Date: 2023-04-01
First Posted: 2023-02-28
Results First Posted:
Last Update Posted: 2023-02-28
Locations: Ain Shams University, Cairo, 11315, Egypt
Study Documents:

NCT Number: NCT05209776
Study Title: Local Inflammation in Arrhythmogenic Right Ventricular Cardiomyopathy
Study URL: https://beta.clinicaltrials.gov/study/NCT05209776
Acronym: LI-ARVC
Study Status: RECRUITING
Brief Summary: The understanding of ARVC pathophysiology remains

incomplete. Several clues indicate that disease progression is mediated through inflammation. The present study aim to document the feasibility of detecting the potential presence of intracardiac local inflammatory components in patients with ARVC.
Study Results: NO
Conditions: Arrhythmogenic Right Ventricular Dysplasia
Interventions: BIOLOGICAL: Peripheral immunological assessment on venous blood|BIOLOGICAL: Immunological assessment carried out on intracardiac material
Primary Outcome Measures: Identify the inflammatory components by C-reactive protein, Rate of C-reactive protein in the blood, 24 months|Identify the inflammatory components by interleukine1, Rate of interleukin 1 beta in the blood, 24 months|Identify the inflammatory components by onterleukine6, Rate of interleukin 6 in the blood, 24 months|Identify the inflammatory components by interleukine10, Rate of interleukin 10 in the blood, 24 months|Identify the inflammatory components by Tumor Necrosis Factor, Rate of Tumor Necrosis Factor alpha in the blood, 24 months|Identify the inflammatory components by Transforming Growth Factor, Rate of Transforming Growth Factor beta in the blood, 24 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University Hospital, Toulouse
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 80
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NON_RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: RC31/21/0026
Start Date: 2022-02-01
Primary Completion Date: 2024-02-01
Completion Date: 2024-02-01
First Posted: 2022-01-27
Results First Posted:
Last Update Posted: 2022-08-18
Locations: Toulouse University Hospital Center, Toulouse, France
Study Documents:

NCT Number: NCT00039481
Study Title: Oblimersen Plus Combination Chemotherapy and Dexrazoxane in Treating Children and Adolescents With Relapsed or Refractory Solid Tumors
Study URL: https://beta.clinicaltrials.gov/study/NCT00039481
Acronym:
Study Status: COMPLETED
Brief Summary: Phase I trial to study the effectiveness of oblimersen

plus combination chemotherapy and dexrazoxane in treating children and adolescents who have relapsed or refractory solid tumors. Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Oblimersen may increase the effectiveness of doxorubicin and cyclophosphamide by making the tumor cells more sensitive to the drug. Chemoprotective drugs such as dexrazoxane may protect normal cells from the side effects of chemotherapy
Study Results: NO
Conditions: Cardiac Toxicity|Unspecified Childhood Solid Tumor, Protocol Specific
Interventions: BIOLOGICAL: oblimersen sodium|DRUG: dexrazoxane hydrochloride|DRUG: doxorubicin hydrochloride|DRUG: cyclophosphamide|BIOLOGICAL: filgrastim|OTHER: laboratory biomarker analysis|OTHER: pharmacological study
Primary Outcome Measures: Dose-limiting toxic effects and recommended phase II dose, graded according to the National Cancer Institute Common Toxicity Criteria (NCI CTC) v2.0, Up to day 21|Change in pharmacokinetic behavior of this regimen, Days 1 (pre-infusion), 5, 6, and 8 (end of infusion)|Antitumor activity, Up to day 21|Biologic activity of oblimersen in mononuclear cells and tumor tissues, in terms of B-cell lymphoma 2 (bcl-2) and related protein expression, Up to day 21
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Cancer Institute (NCI)
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases: PHASE1
Enrollment: 15
Funder Type: NIH
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: NCI-2012-01872|ADVL0211|U01CA097452|CDR0000069387
Start Date: 2002-11
Primary Completion Date: 2005-10
Completion Date:
First Posted: 2003-01-27
Results First Posted:
Last Update Posted: 2013-01-17
Locations: Children's Oncology Group, Arcadia, California, 91006-3776, United States
Study Documents:

NCT Number: NCT04891081
Study Title: Plasma Metanephrines in Patients With Cyanotic and Acyanotic Congenital Heart Disease
Study URL: https://beta.clinicaltrials.gov/study/NCT04891081
Acronym:

Study Status: UNKNOWN
Brief Summary: The aim of our study is to compare plasma metanephrines in patients with cyanotic and acyanotic congenital heart disease and possible association with chronic hypoxic stress.
Study Results: NO
Conditions: Acyanotic Congenital Heart Disease|Cyanotic Congenital Heart Disease|Pheochromocytoma|Paraganglioma
Interventions:
Primary Outcome Measures: Plasma metanephrine level, Level of plasma metanephrine, baseline, one point of time in a cross-sectional study|Plasma normetanephrine level, Level of plasma normetanephrine, baseline, one point of time in a cross-sectional study
Secondary Outcome Measures: Hypoxemia, Length of hypoxemia presence in years, baseline, one point of time in a cross-sectional study
Other Outcome Measures:
Sponsor: University Medical Centre Ljubljana
Collaborators: University of Ljubljana, Faculty of Medicine|University Rehabilitation Institute, Republic of Slovenia
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 50
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 0000
Start Date: 2019-11-01
Primary Completion Date: 2021-05-31
Completion Date: 2021-06-09
First Posted: 2021-05-18
Results First Posted:
Last Update Posted: 2021-05-18
Locations: Department of Internal Medicine, Faculty of Medicine, University of Ljubljana, Ljubljana, Slovenia, Ljubljana, 1000, Slovenia
Study Documents:

NCT Number: NCT05636774
Study Title: Empower the Heart of Patients With Terminal Cancer Using Cardiac Medicines Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT05636774
Acronym: EMPATICC
Study Status: NOT_YET_RECRUITING
Brief Summary: The pathophysiological implications of various cancer diseases and anti-cancer therapies is the occurrence of a cardiac disease-like phenotype with cardiac dysfunction, cardiac wasting, and cardiac homeostasis changes (incl. fibrosis and apoptosis) in end-stage cancer patients, causing heart failure like syndrome with development of congestion, dyspnoea and severely reduced physical functioning. The present trial aims to evaluate, if a heart failure

medication improves the self-care ability and self-reported health care status of patients with pre-terminal cancer in palliative care.
Study Results: NO
Conditions: Pre-terminal Cancer
Interventions: DRUG: Heart failure medication|DRUG: Placebo
Primary Outcome Measures: Days alive and able to wash themselves, patient performed act of washing by him/her-selves without interference of staff (regardless of whether as shower or bath, on a sink, or using a "sponge bath" in the bed), since baseline during 30 days of follow-up
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University Hospital, Essen
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 72
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT
Other IDs: 22-10545-AF
Start Date: 2022-11-28
Primary Completion Date: 2024-05-31
Completion Date: 2024-10-31
First Posted: 2022-12-05
Results First Posted:
Last Update Posted: 2022-12-07
Locations:
Study Documents:

NCT Number: NCT05687474
Study Title: Baby Detect : Genomic Newborn Screening
Study URL: https://beta.clinicaltrials.gov/study/NCT05687474
Acronym:
Study Status: RECRUITING
Brief Summary: Newborn screening (NBS) is a global initiative of systematic testing at birth to identify babies with pre-defined severe but treatable conditions. With a simple blood test, rare genetic conditions can be easily detected, and the early start of transformative treatment will help avoid severe disabilities and increase the quality of life.

Baby Detect Project is an innovative NBS program using a panel of target sequencing that aims to identify 126 treatable severe early onset genetic diseases at birth caused by 361 genes. The list of diseases has been established in close collaboration with the Paediatricians of the University Hospital in Liege. The investigators

use dedicated dried blood spots collected between the first day and 28 days of life of babies, after a consent sign by parents.
Study Results: NO
Conditions: Congenital Adrenal Hyperplasia|Familial Hyperinsulinemic Hypoglycemia 1|Phosphoglucomutase 1 Deficiency|Maturity Onset Diabetes of the Young|Cystic Fibrosis|Hypophosphatasia, Infantile|Congenital Hypothyroidism|DAVID|Pituitary Hormone Deficiency, Combined|Diamond Blackfan Anemia|Wiskott-Aldrich Syndrome|Fanconi Anemia|Hemophilia A|Hemophilia B|Glucose 6 Phosphate Dehydrogenase Deficiency|Alpha-Thalassemia|Sickle Cell Disease|Shwachman-Diamond Syndrome|Alpha 1-Antitrypsin Deficiency|Inflammatory Bowel Disease 25, Autosomal Recessive|Wilson Disease|Progressive Familial Intrahepatic Cholestasis|Crigler-Najjar Syndrome|DIAR4|Familial Chylomicronemia|Lysosomal Acid Lipase Deficiency|Familial Hemophagocytic Lymphocytosis|Griscelli Syndrome|Chediak-Higashi Syndrome|Severe Congenital Neutropenia|SCID|Chronic Granulomatous Disease|Menkes Disease|X-ALD|Smith-Lemli-Opitz Syndrome|Ataxia With Vitamin E Deficiency|THMD5|THMD4|Thiamine-Responsive Megaloblastic Anemia|Thiamine Metabolism Dysfunction Syndrome 2|GOT2 DEFICIENCY|Cerebral Folate Transport Deficiency|Segawa Syndrome, Autosomal Recessive|Congenital Myasthenic Syndrome|Metachromatic Leukodystrophy|Sepiapterin Reductase Deficiency|Dopamine Beta Hydroxylase Deficiency|Glut1 Deficiency Syndrome|Late-Infantile Neuronal Ceroid Lipofuscinosis|Aromatic L-amino Acid Decarboxylase Deficiency|Charcot-Marie-Tooth Disease, Type 6C|Hereditary Hyperekplexia|Brain Dopamine-Serotonin Vesicular Transport Disease|Very Long Chain Hydroxy Acyl Dehydrogenase Deficiency|Tyrosinemia, Type I|Disaccharide Intolerance I|Beta Ketothiolase Deficiency|Phosphoglycerate Dehydrogenase Deficiency|Succinyl-Coa 3-Oxoacid Transferase Deficiency|Pyridoxine-5'-Phosphate Oxidase Deficiency|Pyridoxine-Dependent Epilepsy|Propionic Acidemia|Pompe Disease|Phenylalanine Hydroxylase Deficiency|Ornithine Transcarbamylase Deficiency|N Acetyl Glutamate Synthethase Deficiency|Riboflavin Deficiency|Maple Syrup Urine Disease|Medium Chain Acyl CoA Dehydrogenase Deficiency|Malonic Acidemia|Long-chain 3-hydroxyacyl-CoA Dehydrogenase Deficiency|Isovaleric Acidemia|Phosphoserine Aminotransferase Deficiency|Phosphoserine Phosphatase Deficiency|Spatccm|Hyperornithinemia-Hyperammonemia-Homocitrullinuria|MRT8, FORMERLY|S-Adenosylhomocysteine Hydrolase Deficiency|Mucopolysaccharidosis VII|Mucopolysaccharidosis VI|Mucopolysaccharidosis IV A|Mucopolysaccharidosis II|Mucopolysaccharidosis I|Transcobalamin Deficiency|Isolated Methylmalonic Acidemia|Cobalamin Deficiency|Homocystinuria|Holocarboxylase Synthetase Deficiency|Fanconi Bickel Syndrome|Glycogen Storage Disease|Glycine Encephalopathy|Glutaric Acidemia I|Glucose Galactose Malabsorption|Gaucher Disease, Type 1|Galactosemias|Fructosemia|Fructose-1,6-Diphosphatase Deficiency|Carbamoyl Phosphate Synthase 1 Deficiency|Citrullinemia Type II|Citrullinemia 1|Creatine Deficiency Syndrome|Systemic Primary Carnitine Deficiency|Carnitine Palmitoyltransferase Deficiency 2|Carnitine Palmitoyltransferase Deficiency 1|Carnitine Acylcarnitine Translocase Deficiency|Riboflavin

Transporter Deficiency|Branched-Chain Keto Acid Dehydrogenase Kinase Deficiency|Andersen Tawil Syndrome|Timothy Syndrome|Jervell-Lange Nielsen Syndrome|Catecholaminergic Polymorphic Ventricular Tachycardia|Familial Hypertrophic Cardiomyopathy Type 4| Pseudohypoaldosteronism, Type II|Pseudohypoaldosteronism Type 1| Primary Hyperoxaluria|X Linked Hypophosphatemia|Hereditary Nephrogenic Diabetes Insipidus|Cystinosis|Congenital Nephrotic Syndrome, Finnish Type|Alport Syndrome|Hereditary Retinoblastoma|Biotinidase Deficiency| Aciduria, Argininosuccinic|Arginemia|ACAD9 Deficiency|3-Hydroxy 3-Methyl Glutaric Aciduria|3-Hydroxy-3-Methylglutaryl-CoA Synthase 2 Deficiency
Interventions:
Primary Outcome Measures: Acceptability, The percentage of parents accepting the proposed screening in comparison with the number of mothers approached for consent, through study completion, an average of 1 year|Feasability - timing, The Turn-around time for the different mutations that are screened, through study completion, an average of 1 year|Feasabilty - reliability, The percentage of false positives and the predicted value for each test The estimation of the false negatives through collaboration with physicians treating the different diseases., through study completion, an average of 1 year
Secondary Outcome Measures: Consequence of NBS on early treatment access - timing, The time passed between the birth of diagnostic-positive newborns to the initiation of their treatment, through study completion, an average of 1 year|Consequence of NBS on early treatment access - frequency, The number of patients offered early treatment, through study completion, an average of 1 year|To improve the detection technique for disease related mutations that are not detected in classical screening by improving the classification of unspecified variants., The number of new mutations implemented yearly in the NBS., through study completion, an average of 1 year
Other Outcome Measures:
Sponsor: Laurent Servais
Collaborators: Centre Hospitalier Universitaire de Liege|University of Liege
Sex: ALL
Age: CHILD
Phases:
Enrollment: 40000
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2021-239
Start Date: 2022-09-01
Primary Completion Date: 2023-08-31
Completion Date: 2025-08-31
First Posted: 2023-01-18
Results First Posted:
Last Update Posted: 2023-01-26
Locations: CRMN, Hôpital La Citadelle, Liege, Wallonia, 4000, Belgium

Study Documents:

NCT Number: NCT05025774
Study Title: Fitness and Lung Function Among Survivors of Heart Transplant, Leukemia and Infant BPD Through Exercise
Study URL: https://beta.clinicaltrials.gov/study/NCT05025774
Acronym: FLASHLITE
Study Status: NOT_YET_RECRUITING
Brief Summary: This study aims to more accurately assess cardiac function, ventilation and exercise capacity in a non-invasive fashion, and to better characterize exercise intolerance in the setting of three populations of individuals with chronic diseases of childhood (acute lymphoblastic leukemia (ALL), chronic lung disease (CLD) of prematurity, and post-heart transplant (HT))
Study Results: NO
Conditions: Chronic Lung Disease|Chronic Obstructive Pulmonary Disease|Acute Lymphoblastic Leukemia|Heart Transplant
Interventions: OTHER: Physical activity
Primary Outcome Measures: Measure of Peak O2 intake during test exercise, Maximal cardiopulmonary exercise testing (CPX) will be completed on cycle ergometer to determine peak oxygen uptake, a measure of cardiorespiratory fitness, 3-4 hours during the onetime study visit day|Measure of Cardiac output during test exercise, Cardiac output is measured using C2H2 open-circuit breathing technique: a mass spectrometer medical gas analyzer will measure gas concentration continuously, yielding serial Stroke Volume measurements during incremental exercise. Cardiac output is the product of heart rate and stroke volume, 3-4 hours during the onetime study visit day
Secondary Outcome Measures: The proportion of expiratory flow limitation (EFL), The proportion of expiratory flow limitation (EFL) during exercise while tracking dyspnea and perceived exertion, 3-4 hours during the onetime study visit day|Association between cardiac function and patient reported outcomes of perceived fitness, Logistic regression will be used to understand associations between cardiac function and patient reported outcomes of perceived fitness, 3-4 hours during the onetime study visit day
Other Outcome Measures:
Sponsor: Masonic Cancer Center, University of Minnesota
Collaborators:
Sex: ALL
Age: CHILD, ADULT
Phases:
Enrollment: 90
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: PEDS-2021-29482
Start Date: 2023-10-01
Primary Completion Date: 2024-08-01
Completion Date: 2024-08-01

First Posted: 2021-08-27
Results First Posted:
Last Update Posted: 2023-07-10
Locations:
Study Documents:

NCT Number: NCT00636844
Study Title: Detection of Chemotherapy Induced Cardiotoxicity
Study URL: https://beta.clinicaltrials.gov/study/NCT00636844
Acronym:
Study Status: COMPLETED
Brief Summary: To identify patients that are at risk of heart damage after receiving chemotherapy (adriamycin).
Study Results: NO
Conditions: Cancer
Interventions:
Primary Outcome Measures: The genetic profile of patients with anthracycline-induced elevation of troponin-I, one year
Secondary Outcome Measures: Assess the genetic profile of patient with anthracycline-induced left ventricular systolic and diastolic dysfunction, one year|Assess the relationship of quantitative increases of pro-oxidant stress and a specific genetic profile, one year
Other Outcome Measures:
Sponsor: George Washington University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 36
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: JL-001
Start Date: 2008-01
Primary Completion Date: 2011-12
Completion Date: 2012-06
First Posted: 2008-03-17
Results First Posted:
Last Update Posted: 2013-03-13
Locations: George Washington University, Washington, District of Columbia, 20037, United States
Study Documents:

NCT Number: NCT03313544
Study Title: Evolution of the Heart Function When Monitoring Immunotherapies Anti-cancerous Inhibiting PD-1
Study URL: https://beta.clinicaltrials.gov/study/NCT03313544
Acronym:
Study Status: RECRUITING

Brief Summary: Prospective, monocentric clinical study. Patients selected for nivolumab therapy in AP-HM for melanoma and non-small cell lung cancer will be eligible. Do not include patients with conditions that do not allow MRI, prior cardiovascular disease with LVEF\<50%, cardiomyopathy, history of cardiac arrhythmia, history of cardiovascular toxicity under anticancer therapy, coronary artery disease or stroke less than 3 months Therapeutic management will not be modified and treatment will be administrated as usual.

Cardiovascular follow up will be identical to that recommended and realized in current care in the Cardio-Oncology unit of AP-HM. It will include clinical, biological (BNP and troponin) and trans-thoracic echocardiography (TTE) at baseline and then at 1, 3 and 6 months. Auto-antibodies against troponin I assay will be performed to avoid false negatives of normal blood level of troponin I at baseline and then at 6 months. Cardiac MRI will be performed as well at baseline and at the end of the study (6 months). MRI is the gold standard for ventricular function evaluation.

Primary endpoint will be left ventricular function evolution evaluated by global longitudinal strain (GLS, 2D speckles tracking) in TTE. Secondary endpoints will be left and right ventricular function parameters: LEVF by TTE and MRI, left ventricular indexed volumes by TTE and MRI, right ejection ventricular function and indexed volumes by TTE and MRI, systolic pulmonary arterial pressure by TTE, serum troponin I and BNP, arrhythmias and conduction disorders on the electrocardiogram (ECG).

Number of required subjects: GLS is recommended for following up left ventricular function under anticancer treatments. Based on the hypothesis of a significant GLS decrease (15%) in 20% of cases with alpha risk of 0.05 and accuracy of 0.12 which means expected confidence interval of 0.08-0.32, then the number of required subjects is 50 patients.

The inclusion period will be 18 months with a follow up if 6 months, ie a total duration of the study of 24 months.
Study Results: NO
Conditions: Melanoma|Non-small Cell|Lung Cancer
Interventions: DRUG: Nivolumab|DEVICE: MRI|BIOLOGICAL: BLOOD SAMPLES|DEVICE: trans-thoracic echocardiography
Primary Outcome Measures: systolic pulmonary arterial pressure, trans-thoracic echocardiography, 6 months
Secondary Outcome Measures: ventricular function evaluation., MRI, 6 MONTHS|serum troponin I, BLOOD SAMPLES, 1,3, 6 months|Brain natriuretic peptide (BNP), BLOOD SAMPLES, 1,3, 6 months
Other Outcome Measures:
Sponsor: Assistance Publique Hopitaux De Marseille
Collaborators:
Sex: ALL

Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 50
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: 2017-01|2017-001197-42
Start Date: 2018-04-09
Primary Completion Date: 2024-10
Completion Date: 2025-03
First Posted: 2017-10-18
Results First Posted:
Last Update Posted: 2023-04-21
Locations: Assistance Publique Hopitaux de Marseille, Marseille, 13354, France
Study Documents:

NCT Number: NCT00004074
Study Title: Interleukin-12 and Trastuzumab in Treating Patients With Cancer That Has High Levels of HER2/Neu
Study URL: https://beta.clinicaltrials.gov/study/NCT00004074
Acronym:
Study Status: COMPLETED
Brief Summary: Interleukin-12 may kill tumor cells by stopping blood flow to the tumor and by stimulating a person's white blood cells to kill cancer cells. Monoclonal antibodies such as trastuzumab can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Phase I trial to study the effectiveness of interleukin-12 and trastuzumab in treating patients who have cancer that has high levels of HER2/neu and has not responded to previous therapy
Study Results: NO
Conditions: Advanced Adult Primary Liver Cancer|Anaplastic Thyroid Cancer|Bone Metastases|Carcinoma of the Appendix|Distal Urethral Cancer|Fallopian Tube Cancer|Gastrinoma|Glucagonoma|Inflammatory Breast Cancer|Insulinoma|Liver Metastases|Localized Unresectable Adult Primary Liver Cancer|Lung Metastases|Male Breast Cancer|Malignant Pericardial Effusion|Malignant Pleural Effusion|Metastatic Gastrointestinal Carcinoid Tumor|Metastatic Parathyroid Cancer|Metastatic Transitional Cell Cancer of the Renal Pelvis and Ureter|Newly Diagnosed Carcinoma of Unknown Primary|Occult Non-small Cell Lung Cancer|Pancreatic Polypeptide Tumor|Primary Peritoneal Cavity Cancer|Proximal Urethral Cancer|Pulmonary Carcinoid Tumor|Recurrent Adenoid Cystic Carcinoma of the Oral Cavity|Recurrent Adrenocortical Carcinoma|Recurrent Adult Primary Liver Cancer|Recurrent Anal Cancer|Recurrent Bladder Cancer|Recurrent Breast Cancer|Recurrent Carcinoma of Unknown Primary|Recurrent Cervical Cancer|Recurrent Colon Cancer|Recurrent Endometrial Carcinoma|Recurrent Esophageal Cancer|Recurrent Extrahepatic Bile Duct Cancer|Recurrent Gallbladder Cancer|Recurrent

Gastric Cancer|Recurrent Gastrointestinal Carcinoid Tumor|Recurrent Islet Cell Carcinoma|Recurrent Malignant Testicular Germ Cell Tumor|Recurrent Mucoepidermoid Carcinoma of the Oral Cavity|Recurrent Non-small Cell Lung Cancer|Recurrent Ovarian Epithelial Cancer|Recurrent Pancreatic Cancer|Recurrent Parathyroid Cancer|Recurrent Prostate Cancer|Recurrent Rectal Cancer|Recurrent Renal Cell Cancer|Recurrent Salivary Gland Cancer|Recurrent Small Intestine Cancer|Recurrent Squamous Cell Carcinoma of the Larynx|Recurrent Squamous Cell Carcinoma of the Lip and Oral Cavity|Recurrent Squamous Cell Carcinoma of the Nasopharynx|Recurrent Squamous Cell Carcinoma of the Oropharynx|Recurrent Thyroid Cancer|Recurrent Transitional Cell Cancer of the Renal Pelvis and Ureter|Recurrent Urethral Cancer|Recurrent Vaginal Cancer|Recurrent Vulvar Cancer|Skin Metastases|Small Intestine Adenocarcinoma|Somatostatinoma|Stage III Adenoid Cystic Carcinoma of the Oral Cavity|Stage III Adrenocortical Carcinoma|Stage III Bladder Cancer|Stage III Cervical Cancer|Stage III Colon Cancer|Stage III Endometrial Carcinoma|Stage III Esophageal Cancer|Stage III Follicular Thyroid Cancer|Stage III Gastric Cancer|Stage III Malignant Testicular Germ Cell Tumor|Stage III Mucoepidermoid Carcinoma of the Oral Cavity|Stage III Ovarian Epithelial Cancer|Stage III Pancreatic Cancer|Stage III Papillary Thyroid Cancer|Stage III Prostate Cancer|Stage III Rectal Cancer|Stage III Renal Cell Cancer|Stage III Salivary Gland Cancer|Stage III Squamous Cell Carcinoma of the Larynx|Stage III Squamous Cell Carcinoma of the Lip and Oral Cavity|Stage III Squamous Cell Carcinoma of the Nasopharynx|Stage III Squamous Cell Carcinoma of the Oropharynx|Stage III Vaginal Cancer|Stage III Vulvar Cancer|Stage IIIA Anal Cancer|Stage IIIA Breast Cancer|Stage IIIA Non-small Cell Lung Cancer|Stage IIIB Anal Cancer|Stage IIIB Breast Cancer|Stage IIIB Non-small Cell Lung Cancer|Stage IV Adenoid Cystic Carcinoma of the Oral Cavity|Stage IV Adrenocortical Carcinoma|Stage IV Anal Cancer|Stage IV Bladder Cancer|Stage IV Breast Cancer|Stage IV Colon Cancer|Stage IV Endometrial Carcinoma|Stage IV Esophageal Cancer|Stage IV Follicular Thyroid Cancer|Stage IV Gastric Cancer|Stage IV Mucoepidermoid Carcinoma of the Oral Cavity|Stage IV Non-small Cell Lung Cancer|Stage IV Ovarian Epithelial Cancer|Stage IV Pancreatic Cancer|Stage IV Papillary Thyroid Cancer|Stage IV Prostate Cancer|Stage IV Rectal Cancer|Stage IV Renal Cell Cancer|Stage IV Salivary Gland Cancer|Stage IV Squamous Cell Carcinoma of the Larynx|Stage IV Squamous Cell Carcinoma of the Lip and Oral Cavity|Stage IV Squamous Cell Carcinoma of the Nasopharynx|Stage IV Squamous Cell Carcinoma of the Oropharynx|Stage IVA Cervical Cancer|Stage IVA Vaginal Cancer|Stage IVB Cervical Cancer|Stage IVB Vaginal Cancer|Stage IVB Vulvar Cancer|Thyroid Gland Medullary Carcinoma|Unresectable Extrahepatic Bile Duct Cancer|Unresectable Gallbladder Cancer|Urethral Cancer Associated With Invasive Bladder Cancer|WDHA Syndrome
Interventions: BIOLOGICAL: recombinant interleukin-12|BIOLOGICAL: ABI-007/carboplatin/trastuzumab
Primary Outcome Measures: Maximum tolerated dose (MTD) determined according to dose-limiting toxicities (DLTs) graded using Common Terminology Criteria for Adverse Events version 2.0 (CTCAE v2.0), Up

to 52 weeks
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: National Cancer Institute (NCI)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1
Enrollment: 15
Funder Type: NIH
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: NCI-2012-01398|99H0185|U01CA076576|CDR0000067282
Start Date: 1999-08
Primary Completion Date: 2009-02
Completion Date:
First Posted: 2003-10-29
Results First Posted:
Last Update Posted: 2013-02-28
Locations: Ohio State University Medical Center, Columbus, Ohio, 43210, United States
Study Documents:

NCT Number: NCT03265574
Study Title: PROACT: Can we Prevent Chemotherapy-related Heart Damage in Patients With Breast Cancer and Lymphoma?
Study URL: https://beta.clinicaltrials.gov/study/NCT03265574
Acronym: PROACT
Study Status: RECRUITING
Brief Summary: PROACT will establish the effectiveness of the angiotensin-converting enzyme inhibitor (ACEI) enalapril maleate (enalapril) in preventing cardiotoxicity in patients with breast cancer and non-Hodgkin lymphoma undergoing adjuvant epirubicin-based chemotherapy.
Study Results: NO
Conditions: Breast Cancer|Non Hodgkin Lymphoma
Interventions: DRUG: Enalapril
Primary Outcome Measures: Cardiac troponin T release, Cardiac troponin T release during anthracycline treatment, One month after last dose of anthracycline
Secondary Outcome Measures: Cardiac function, Cardiac function assessed by echocardiogram, One month after last dose of anthracycline|Adherence to enalapril, Ability of participant to adhere to enalapril, One month after last dose of anthracycline|Adverse Events / Reactions, Number and severity of Adverse Events and Reactions, One month after last dose of anthracycline|Anxiety or distress related to trial participation, Anxiety or distress related to trial participation, One month after last dose of anthracycline|Cancer and chemotherapy outcomes, Cancer and chemotherapy outcomes in

the population under study, One month after last dose of anthracycline|Cardiac troponin I release, cardiac troponin I release during anthracyline treatment, One month after last dose of anthracycline
Other Outcome Measures:
Sponsor: South Tees Hospitals NHS Foundation Trust
Collaborators: Newcastle University|University of Durham|Newcastle-upon-Tyne Hospitals NHS Trust
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 128
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 2016152
Start Date: 2017-10-04
Primary Completion Date: 2022-12-31
Completion Date: 2023-05-31
First Posted: 2017-08-29
Results First Posted:
Last Update Posted: 2022-10-24
Locations: South Tees Hospitals NHS FT, Middlesbrough, Teesside, TS4 3BW, United Kingdom
Study Documents:

NCT Number: NCT00679874
Study Title: Assessment of Cardiotoxicity After Chemotherapy for Breast Cancer by Cardio-vascular Magnetic Resonance (MR)
Study URL: https://beta.clinicaltrials.gov/study/NCT00679874
Acronym: Cardiotox
Study Status: TERMINATED
Brief Summary: Consecutive patients with a first diagnosis of breast cancer will be identified at the Tom Baker Cancer Centre (TBCC) and included into the study, if they are going to receive chemotherapy with anthracyclines and / or Trastuzumab and do not have contra-indications for the CMR study. Besides the usual clinical care for these patients (e.g. blood samples before each cycle of chemotherapy; MUGA scans to follow cardiac size and function), the patients will undergo serial contrast-enhanced CMR studies (before, during and 9-12 months after completion of the chemotherapy); patients will be seen at an outpatient clinic in the Dept. of Cardiac Sciences / Heart Function Clinic for a clinical assessment (including ECG, additional blood test like Troponin-T, BNP, 6-minute-walk-test) and recommendations will be made to medical treatment in patients with evidence for heart failure.

Time points for the CMR and clinic assessments will be co-coordinated with regularly scheduled test by the TBCC to avoid unnecessary burden for the patients. The oncologists at the TBCC will be blinded to the

results of the CMR studies and to laboratory results, unless the participating cardiologists identify a clinical need for communication.

Standardized CMR protocols will be employed and all interpretations will be blinded to the time course of the chemotherapy and cardiotoxic side effects.

We will test the hypothesis, whether CMR can be useful in patients with potentially cardiotoxic chemotherapy to:

* Identify patients at risk for the development of grade 2-4 cardiotoxic side effects as classified by the NCI guidelines (common toxicity criteria, 2001, 1-12)
* Identify imaging parameters to predict early or late Cardiotoxicity
* Provide additional clinical information to optimize medical treatment for heart failure

Study Results: NO
Conditions: Breast Cancer
Interventions: OTHER: Cardio-vascular MRI
Primary Outcome Measures: Drop in ejection fraction of 10% as compared to baseline, 12 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: University of Calgary
Collaborators:
Sex: FEMALE
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 66
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: Cardiotox_001
Start Date: 2008-05
Primary Completion Date: 2011-09
Completion Date: 2011-09
First Posted: 2008-05-19
Results First Posted:
Last Update Posted: 2011-10-04
Locations: University of Calgary, Dept. of Cardiac Sciences and Tom Baker Cancer Centre, Calgary, Alberta, T2N 2T9, Canada
Study Documents:

NCT Number: NCT00724581
Study Title: Amiodarone Prophylaxis for Atrial Fibrillation in Patients Undergoing Surgery for Lung Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT00724581
Acronym: PASCART
Study Status: UNKNOWN

Brief Summary: Patients undergoing lung resection due to pulmonary cancer can be compromised in their postoperative period due to atrial fibrillation.

A retrospective analysis performed at our institution indicates that 30 % of the population develope atrial fibrillation in the postoperative period.

Amiodarone is known to diminish the occurence of postoperative atrial fibrillation after heart surgery, why this drug is chosen as a prophylactic agent for the mentioned population.

Amiodarone is administrated twice a day for 5 days at a dose of 600 mg oral treatment after an initial loading bolus og 300 mg intravenously.
Study Results: NO
Conditions: Atrial Fibrillation
Interventions: DRUG: Amiodarone
Primary Outcome Measures: Free of atrial fibrillation, 31082009
Secondary Outcome Measures: Cost-benefit analysis of amiodarone prophylactic, 31082009
Other Outcome Measures:
Sponsor: Aarhus University Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 275
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: PREVENTION
Other IDs: 2612-3681
Start Date: 2008-08
Primary Completion Date: 2009-08
Completion Date: 2009-12
First Posted: 2008-07-29
Results First Posted:
Last Update Posted: 2008-07-29
Locations: Aarhus University Hospital, Skejby, Aarhus, DK-8200, Denmark
Study Documents:

NCT Number: NCT03166813
Study Title: Remote Ischaemic Preconditioning in Childhood Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT03166813
Acronym:
Study Status: COMPLETED
Brief Summary: Survival rates of children with cancers have improved significantly in the recent few decades. Nonetheless, the side effect

of this class of drugs on heart function remains to be an issue of concern. Exploration of new strategies to protect the heart in the long term is therefore of paramount importance in children undergoing treatment of cancers. Previous cardioprotective interventions hav focused on changing the formulation or rate of administration of anthracyclines but with no observable benefits. While dexrazoxane, an iron chelator, has shown to reduce cardiotoxic outcomes, there remains worries of an association between dexrazoxane use and an increased risk of developing secondary malignancies. Recently, the clinical application of remote ischaemic preconditioning (RIPC) as a non-invasive and an easily applicable non-pharmacological myocardial protective intervention has gained increasing interest. Remote ischaemic preconditioning is the phenomenon in which brief episodes of reversible ischaemia and reperfusion applied to one vascular bed render resistance to ischaemia reperfusion injury of tissues and organs distant away. It can be achieved by repeated 5-minute cycles of inflation and deflation of blood pressure cuff placed over the arm or leg to induce limb ischaemia and reperfusion injury. It is noteworthy that anthracycline cardiotoxicity and myocardial reperfusion injury occur through similar pathways. Hence, the investigators hypothesize that RIPC may reduce myocardial injury in children receiving anthracycline chemotherapy for childhood malignancies. The proposed study aims to conduct a parallel-group blinded randomized controlled trial study to investigate whether RIPC may reduce heart damage in childhood cancer patients undergoing anthracycline-based treatment, and to determine the effect of RIPC on the changes in levels of cardiac troponin T, and on the occurrence of clinical cardiovascular events and echocardiographic indices.
Study Results: NO
Conditions: Cardiotoxicity
Interventions: PROCEDURE: Remote Ischaemic Preconditioning|OTHER: Control
Primary Outcome Measures: High sensitivity cardiac troponin T (hs-cTnT), Biomarker of myocardial injury, hs-cTnT will be measured at baseline, and at 3 months after completion of all anthracycline. The change from baseline hs-cTnT to at 3 months after completion of all anthracycline will be measured.
Secondary Outcome Measures: Occurrence of clinical cardiovascular events, Clinical cardiovascular events include development of clinical congestive heart failure, occurrence of cardiac arrhythmias, the need to institute cardiac medications, and cardiac death, at baseline, within 1 week and at 3 months after completion of all anthracycline treatment.|Echocardiographic assessment of left ventricular function, left ventricular systolic and diastolic function, Echocardiographic assessment will be performed at baseline, and within 1 week and at 3 months after completion of all anthracycline treatment.
Other Outcome Measures:
Sponsor: The University of Hong Kong
Collaborators:
Sex: ALL

Age: CHILD, ADULT
Phases: NA
Enrollment: 68
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: TRIPLE (CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|
Primary Purpose: PREVENTION
Other IDs: UW17-143
Start Date: 2017-07-01
Primary Completion Date: 2022-06-01
Completion Date: 2022-06-01
First Posted: 2017-05-25
Results First Posted:
Last Update Posted: 2022-06-08
Locations: Hong Kong Children's Hospital, Hong Kong, Hong Kong
Study Documents:

NCT Number: NCT00132613
Study Title: Trial of Drainage With or Without Bleomycin Instillation for Malignant Pericardial Effusion
Study URL: https://beta.clinicaltrials.gov/study/NCT00132613
Acronym:
Study Status: COMPLETED
Brief Summary: The purpose of this study is to evaluate the efficacy of pericardial instillation of bleomycin as a sclerosing agent after pericardial drainage for lung cancer-associated malignant pericardial effusion.
Study Results: NO
Conditions: Malignant Pericardial Effusion
Interventions: PROCEDURE: Observation alone after pericardial drainage|DRUG: Pericardial instillation of bleomycin after drainage
Primary Outcome Measures: Survival without pericardial effusion at 2 months
Secondary Outcome Measures: Successful extubation of pericardial drainage tube|time to extubation|survival without pericardial effusion at 1, 2, 4, 6, 12 months|symptom palliation|complication|long-term (> 6 months) effect on cardiac function
Other Outcome Measures:
Sponsor: Japan Clinical Oncology Group
Collaborators: Ministry of Health, Labour and Welfare, Japan
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 80
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: NONE|Primary Purpose: TREATMENT
Other IDs: JCOG9811|C000000030

Start Date: 1999-08
Primary Completion Date: 2006-11
Completion Date: 2006-11
First Posted: 2005-08-22
Results First Posted:
Last Update Posted: 2016-09-22
Locations: Aichi Cancer Center Hospital, Nagoya,Chikusa-ku,Kanokoden,1-1, Aichi, 464-8681, Japan|Aichi Cancer Center,Aichi Hospital, Okazaki,Kake-machi,Kuriyado,18, Aichi, 444-0011, Japan|National Cancer Center Hospital East, Kashiwa,Kashiwanoha,6-5-1, Chiba, 277-8577, Japan|National Hospital Organization Shikoku Cancer Center, Matsuyama,Horinouchi,13, Ehime, 790-0007, Japan|Kyushu University Hospital, Fukuoka,Higashi-ku,Maidashi,3-1-1, Fukuoka, 812-8582, Japan|Gifu Municipal Hospital, Gifu,Kashima-cho,7-1, Gifu, 500-8323, Japan|Gunma Prefectural Cancer Center, Ota,Takabayashi-nishi-cho,617-1, Gunma, 373-8550, Japan|National Nishigunma Hospital, Shibukawa,Kanai,2854, Gunma, 377-8511, Japan|National Hospital Organization, Dohoku National Hospital, Asahikawa,Hanasaki,7-4048, Hokkaido, 070-8644, Japan|National Hospital Organization Hokkaido Cancer Center, Sapporo,Shiroishi-ku,Kikusui,4-2-3-54, Hokkaido, 003-0804, Japan|Kobe City General Hospital, Kobe,Chuo-ku,Minatojimanakamachi,4-6, Hyogo, 650-0046, Japan|Hyogo College of Medicine, Nishinomiya,Mukogawa-cho,1-1, Hyogo, 663-8501, Japan|Ibaraki Kenritsu Chuo Hospital & Cancer Center, Nishi-ibarakigun,Tomobemachi,Koibuchi,6528, Ibaraki, 309-1793, Japan|Kanagawa Cancer Center, Yokohama,Asahi-ku,Nakao,1-1-2, Kanagawa, 241-0815, Japan|Yokohama Mucipical Citizen's Hospital, Yokohama,Hodogaya-ku,Okazawa-cho,56, Kanagawa, 240-8555, Japan|Kumamoto Regional Medical Center Hospital, Kumamoto,Honjo,5-16-10, Kumamoto, 860-0811, Japan|Tohoku University Hospital, Sendai,Aoba-ku,Seiryo-machi,1-1, Miyagi, 980-8574, Japan|Niigata Cancer Center Hospital, Niigata,Kawagishi-cho,2-15-3, Niigata, 951-8566, Japan|Osaka Prefectural Medical Center for Respiratory and Allergic Disease, Habikino,Habikino,3-7-1, Osaka, 583-8588, Japan|Rinku General Medical Center, Izumisano,rinku-ohrai-kita,2-23, Osaka, 598-0048, Japan|Graduate School of Medicine, Osaka City University, Osaka,Abeno-ku,Asahi-machi,1-5-7, Osaka, 545-0051, Japan|Osaka Medical Center for Cancer and Cardiovascular Diseases, Osaka,Higashinari-ku,Nakamichi,1-3-3, Osaka, 537-8511, Japan|Kinki University School of Medicine, Osaka-Sayama,Ohno-higashi,377-2, Osaka, 589-8511, Japan|National Hospital Organization Kinki-Chuo Chest Medical Center, Sakai,Nagasone,1180, Osaka, 591-8555, Japan|National Hospital Organization Toneyama National Hospital, Toyonaka,Toneyama,5-1-1, Osaka, 560-8552, Japan|Saitama Cancer Center, Kita-adachi,Ina,Komuro,818, Saitama, 362-0806, Japan|Tochigi Cancer Center, Utsunomiya,Yohnan,4-9-13, Tochigi, 320-0834, Japan|National Cancer Center Hospital, Chuo-ku,Tsukiji, 5-1-1, Tokyo, 104-0045, Japan|Cancer Institute Hospital, Koto-ku,Ariake,3-10-6, Tokyo, 135-8550, Japan|International Medical Center of Japan, Shinjuku-ku,Toyama,1-21-1, Tokyo, 162-8655, Japan|Yamagata Prefectural Central Hospital,

Yamagata,Aoyagi,1800, Yamagata, 990-2292, Japan
Study Documents:

NCT Number: NCT01913769
Study Title: Monitoring Radiobiological Effects in Thoracic Malignancy by Using Myocardial Perfusion Scan
Study URL: https://beta.clinicaltrials.gov/study/NCT01913769
Acronym:
Study Status: UNKNOWN
Brief Summary: Background:

Chemoradiation is an important treatment strategy of locally advanced inoperable or unresectable disease. Radiation dose is an independent predictor of a pathological response. In addition, chemotherapy has further impact on the aspect of outcome. Improvements in local treatment delivery are needed to facilitate dose escalation and to minimize toxicity. There have been sequential improvements in tumor localization, radiation planning and delivery over the years. Helical tomotherapy nowadays provides the most precise data on radiotherapy (RT) dose delivered to thoracic malignancies, and allows greater sparing of the heart from doses associated with increased complications. However, heart disease shows a wide spectrum of pathologies, and multiple risk factors related. The damage of the myocytes may lead to not only myocardial perfusion defects, but also in functional deterioration, or even in biomarkers.

Since the impact of radiation-induced heart injury in patients with thoracic malignancies (including esophageal cancer, lung cancer, et al) is poorly documented, we try to delineate of RT-related cardiac effects and clinical impacts.

Objective:

This study aims to investigate the correlation of post-tomotherapy cardiovascular effects with myocardial perfusion and cardiac functional studies.

Methods:

The study plans to enroll thoracic cancer patients who will undergo local RT after complete staging. Patients will receive global risk scoring assessment (Framingham Risk Score, FRS), blood sampling for basic biochemistry, inflammatory biomarker, and myocardial perfusion image (MPI) at the time points of before and after RT. The results of MPI will be analyzed in qualitative visual interpretation of perfusion patterns, and functional quantitative data for cardiac functional parameters as well. The patients will be regular followed-up in CV OPD, following clinical judgement and guideline. The association between baseline and follow-up MPI, biomarker and clinical presentation will be further investigated.

Expected results:

We will obtain myocardial perfusion visual qualitative data in patients who received locoregional RT, respectively. These results will help in the understanding of pathophysiology, clinical management and follow-up of suspected RT-related heart disease.
Study Results: NO
Conditions: Thoracic Neoplasms|Late Effect of Radiation
Interventions: RADIATION: Thallium-201 Myocardial Perfusion Study
Primary Outcome Measures: To investigate the correlation of post-RT cardiovascular effects with myocardial Tl-201 myocardial perfusion images, By literature reviewing, cardiovascular functional status in patients received helical tomography has not been fully investigated yet. And the post-therapeutic heart disease tends to show a wide spectrum of pathologies and multiple risk factors. We will monitor risk factors of underlying disease, family history, metabolism, biomarkers, myocardial perfusion defect patterns, and cardiac functional parameters, in order to delineation of RT-related effects and clinical prognosis., July, 2014 (after 12 months of baseline study).
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Far Eastern Memorial Hospital
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: FEMH-IRB-102032-F
Start Date: 2013-07
Primary Completion Date: 2014-07
Completion Date: 2016-07
First Posted: 2013-08-01
Results First Posted:
Last Update Posted: 2013-08-01
Locations: Far Eastern Memorial Hospital, New Taipei City, 220, Taiwan
Study Documents:

NCT Number: NCT02220569
Study Title: PhysioFlow to Detect Cardiotoxicity in Chemo
Study URL: https://beta.clinicaltrials.gov/study/NCT02220569
Acronym: PULSE-ECCho
Study Status: UNKNOWN
Brief Summary: PULSE-ECCho will focus on trying to detect cardiotoxicity in cancer patients receiving chemotherapy early on in order to avoid irreversible damage. In addition to that, we will test

if the PhysioFlow is non-inferior to the conventional MUGA scan.
Study Results: NO
Conditions: Chemotherapy, Cancer, Cardiotoxicity, Physioflow
Interventions:
Primary Outcome Measures: comparing the change in ejection fraction measured by physioflow and MUGA scan, at initial diagnosis and after 3 month
Secondary Outcome Measures: acceptance score on the five-point Likert Scale to measure tolerability, At the end of physioflow and or MUGA scan, a questionnaire to assess acceptance was proposed to all patients. The following aspects were evaluated: preparation and information before the imaging examination, degree of preceding concern, comfort, helplessness during the examination, pain experienced, degree of overall satisfaction. Evaluation was performed with a five-point qualitative Likert scale: very low, low, moderate, high, very high, up to 24 hrs
Other Outcome Measures:
Sponsor: McGill University Health Centre/Research Institute of the McGill University Health Centre
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 100
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 4073
Start Date: 2014-10
Primary Completion Date: 2016-07
Completion Date: 2016-07
First Posted: 2014-08-20
Results First Posted:
Last Update Posted: 2015-09-23
Locations: McGill university health center, Royal Victoria hospital, Montreal, Quebec, h3a 1a1, Canada|Royal Victoria Hospital, Montreal, Quebec, h4a 1v3, Canada
Study Documents:

NCT Number: NCT05804669
Study Title: A Study to Evaluate the Safety and PK of CRN04894 for the Treatment of Cushing's Syndrome
Study URL: https://beta.clinicaltrials.gov/study/NCT05804669
Acronym:
Study Status: RECRUITING
Brief Summary: A Phase 1b/2a, first-in-disease, open-label, multiple-ascending dose exploratory study to evaluate safety, tolerability, pharmacokinetics (PK), and pharmacodynamic biomarker responses associated with CRN04894 (an adrenocorticotropic hormone \[ACTH\] receptor antagonist) in participants with ACTH-dependent Cushing's

syndrome (Cushing's disease or Ectopic ACTH Syndrome \[EAS\])
Study Results: NO
Conditions: Cushing Syndrome|Cushing Disease|Ectopic ACTH Syndrome
Interventions: DRUG: CRN04894
Primary Outcome Measures: Proportion of participants with treatment emergent adverse events (TEAEs), Up to Day 15|Proportion of participants with adrenal insufficiency, Up to Day 15|Proportion of participants with safety findings determined by laboratory testing, Up to Day 15|Assessment of the maximum observed plasma concentration of CRN04894, Up to Day 15|Assessment of the time to achieve maximum observed plasma concentration of CRN04894, Up to Day 15|Assessment of the plasma area under the curve of CRN04894, Up to Day 15
Secondary Outcome Measures: Change from baseline in early morning serum cortisol, Day 11
Other Outcome Measures:
Sponsor: Crinetics Pharmaceuticals Inc.
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1|PHASE2
Enrollment: 18
Funder Type: INDUSTRY
Study Type: INTERVENTIONAL
Study Design: Allocation: NA|Intervention Model: SEQUENTIAL|Masking: NONE|Primary Purpose: TREATMENT
Other IDs: CRN04894-04
Start Date: 2023-04
Primary Completion Date: 2026-04
Completion Date: 2026-04
First Posted: 2023-04-07
Results First Posted:
Last Update Posted: 2023-04-07
Locations: National Institutes of Health (NIH) - National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT05082311
Study Title: Cardiac and Vascular Changes in Pheochromocytoma and Paraganglioma
Study URL: https://beta.clinicaltrials.gov/study/NCT05082311
Acronym: PheoCard
Study Status: COMPLETED
Brief Summary: PHEOCHROMOCYTOMA (PCC)/ PARAGANGLIOMA are catecholamine secreting tumors with varied manifestations. Besides hypertension, PCC patients may have subclinical to overt cardiac and vascular dysfunction, which are important to recognize to minimize perioperative morbidity and mortality. Cardiovascular (CV) dysfunction can be in the form of hypertension, left ventricular (LV) hypertrophy, heart failure, cardiomyopathy, dysrhythmias, angina and Myocardial

infarction. Literature search revealed a few retrospective and a few prospective studies, including one prospective follow up study conducted at SGPGIMS to document CV changes in PCC. Our institutional study was the first to document the nature and extent of CV dysfunction and cardiomyopathy and their reversal after surgical cure. The studies revealed that PCC patients had significantly higher LV mass index, higher LV diastolic dysfunction, subclinical impaired LV systolic function. Earlier studies postulated apparent improvement in various cardiac indices even with selective α-blockade and continued after surgical cure, with near normalization at 3 -6 months postoperatively. Detailed cardiac and vascular evaluation in PCC patients can be of help in preoperative optimization of cardiac risk and may provide prognostic information The literature on PCC-mediated CV dysfunction and catecholamine cardiomyopathy is largely limited to case reports and retrospective studies, with few reports of their reversal after curative PCC operations. Whether the duration of disease influence the function of heart was not apparently addressed in earlier trials. Trials that established the differences in the degree of cardiac dysfunction between normotensive and hypertensive PCC patients involved smaller proportion of study subjects. Sub clinical changes in endomyocardium was presumed but not objectively assessed and hence its reversal after surgical cure is uncertain.

The aim of this research is to study the cardiac and vascular changes in Pheochromocytoma/ Paraganglioma patients and their reversal following curative surgery
Study Results: NO
Conditions: Pheochromocytoma|Paraganglioma|Cardiovascular Morbidity
Interventions: OTHER: Observational study
Primary Outcome Measures: Change of Systolic function indices measurement by 2D-Echocardiography from Baseline versus after alpha blockade and after surgery, Left ventricle end systolic and end diastolic diameter in millimeter, at baseline (Day 1), at Day 7- 10 after initiation of α-blockade, and 7 days, 3 and 6 months post adrenalectomy/ Paraganglioma excision|Change of Systolic function indices measurement by 2D-Echocardiography from baseline versus after alpha blockade and after surgery, Left ventricle end systolic and end diastolic volume dimensions in milliliter, at baseline (day 1), at Day 7- 10 after initiation of α-blockade, and 7 days, 3 and 6 months post adrenalectomy/ Paraganglioma excision|Change of Systolic function index measurement by 2D-Echocardiography from Baseline at after alpha blockade and at after surgery, Left ventricle Ejection fraction by Simpsons method in percentage, at baseline (Day1), at Day 7- 10 after initiation of α-blockade, and 7 days, 3 and 6 months post adrenalectomy/ Paraganglioma excision|Change of Diastolic function index measurement by pulsed wave doppler echocardiography from baseline versus after alpha blockade and after surgery, Peak velocities of the early (E) and Late phase (A) of the mitral valve inflow pattern and their ratio in centimeter per second, at baseline (Day 1), at Day 7- 10 after initiation of α-blockade, and 7 days, 3

and 6 months after adrenalectomy/ Paraganglioma excision|Change of Diastolic function indices measurement by pulsed wave doppler echocardiography from baseline versus after alpha blockade and after surgery, Flow rate across mitral valve in centimeter per second and deceleration time in millisecond, at baseline (day 1), at day 7- 10 after initiation of α-blockade, and 7 days, 3 and 6 months after adrenalectomy/ Paraganglioma excision|Change in Speckle tracking echocardiographic parameters at Baseline versus after alpha blockade and at after surgery, Left ventricle global longitudinal strain in percentage, at baseline (Day 1), at Day 7- 10 after initiation of α-blockade, and 7 days, 3 and 6 months post adrenalectomy/ Paraganglioma excision|Change in Speckle tracking echocardiographic parameters from Baseline in comparison to after alpha blockade and after surgery, Left ventricle global circumferential strain in percentage, at baseline (Day 1), at Day 7- 10 after initiation of α-blockade, and 7 days, 3 and 6 months post surgery|Change in Vascular Function indices by doppler Ultrasonography of the brachial artery from baseline at after alpha blockade and at after surgery, Flow mediated dilation of brachial artery diameter pre and post sublingual isosorbide dinitrate in millimeter, at baseline (Day 1), at Day 7- 10 after initiation of α-blockade, and 7 days, 3 and 6 months post adrenalectomy/ Paraganglioma excision
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Sanjay Gandhi Postgraduate Institute of Medical Sciences
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 55
Funder Type: OTHER_GOV
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2018-185-Mch-EXP-4
Start Date: 2019-01-19
Primary Completion Date: 2021-11-30
Completion Date: 2022-01-31
First Posted: 2021-10-18
Results First Posted:
Last Update Posted: 2022-02-10
Locations: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh, 226014, India
Study Documents:

NCT Number: NCT00325611
Study Title: Multidisciplinary Inpatient Palliative Care Intervention
Study URL: https://beta.clinicaltrials.gov/study/NCT00325611
Acronym:
Study Status: COMPLETED
Brief Summary: Palliative care is believed to improve care of patients

with life-limiting illnesses. This study evaluated the impact of a multi-center randomized trial of a palliative care team intervention on the quality and cost of care of hospitalized patients. Study subjects were randomized to intervention or usual care. At study end, patients receiving the palliative care intervention reported greater patient satisfaction with their care. Intervention patients also had significantly fewer ICU admissions and lower total costs for care 6 months past their hospitalization. Intervention patients completed more advance directives and had longer hospice stays.
Study Results: NO
Conditions: Cerebrovascular Accident|Cancer|Coronary Arteriosclerosis|Heart Failure, Congestive|Diabetes Mellitus|Acquired Immunodeficiency Syndrome|Failure to Thrive|Pulmonary Disease, Chronic Obstructive|Dementia|Kidney Failure, Chronic|Pneumonia|Liver Failure|Renal Failure|Respiratory Failure|Stroke
Interventions: BEHAVIORAL: Multidisciplinary palliative care team met with patient
Primary Outcome Measures: Quality and cost of care
Secondary Outcome Measures: Greater patient satisfaction|Lower ICU admissions|Lower total costs 6 months past hospitalization
Other Outcome Measures:
Sponsor: Kaiser Permanente
Collaborators: Garfield Memorial Fund
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 550
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: SINGLE_GROUP|Masking: NONE|Primary Purpose: PREVENTION
Other IDs: CO-02GGade-01 - H|NW-02RRich-01
Start Date: 2002-04
Primary Completion Date:
Completion Date: 2004-07
First Posted: 2006-05-15
Results First Posted:
Last Update Posted: 2006-05-15
Locations: Kaiser Permanente of Colorado, Aurora, Colorado, 80014, United States
Study Documents:

NCT Number: NCT05879211
Study Title: Goal Concordant Care Learning Laboratory
Study URL: https://beta.clinicaltrials.gov/study/NCT05879211
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: The goal-concordant care lab will develop and test strategies to optimize communication in advanced serious illness.
Study Results: NO

Conditions: Cancer|Heart Failure|Copd|Dementia
Interventions: BEHAVIORAL: Feedback
Primary Outcome Measures: Frequency of goals of care communication, Frequency of goals of care conversations in the last 6 months of life, 2 years|Timing of goals of care communication, Proximity of goals of care communication to death, 6 months
Secondary Outcome Measures:
Other Outcome Measures:
Sponsor: Duke University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 5000
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: Pro00106230
Start Date: 2023-06
Primary Completion Date: 2024-07
Completion Date: 2025-07
First Posted: 2023-05-30
Results First Posted:
Last Update Posted: 2023-05-30
Locations:
Study Documents:

NCT Number: NCT04467411
Study Title: Randomised Controlled Study of Physical Exercise Intervention in Breast Cancer Patients at Risk of Anthracycline-induced Cardiomyopathy: The EMBRACE Study
Study URL: https://beta.clinicaltrials.gov/study/NCT04467411
Acronym: EMBRACE
Study Status: RECRUITING
Brief Summary: Cardiomyopathy is a condition that affects the heart muscle, whereby it becomes enlarged, thick or rigid. When the heart muscle becomes involved, it affects the pumping action of the heart. This condition can affect as many as 10% of all patients after undergoing anthracycline cancer drug therapy and unfortunately carries the worst prognosis of all cardiomyopathies. To date, there is no effective intervention that will prevent a patient from developing this condition. The research conducted will look to see if an energy imbalance in the heart predates the onset of detrimental changes to the pumping function of the heart, if this is detected then we can act earlier to prevent the pumping function deteriorating.
Study Results: NO
Conditions: Breast Cancer
Interventions:
Primary Outcome Measures: Cardiac Energetics, Cardiac MRI and MRS, At

baseline|Cardiac Energetics, Cardiac MRI and MRS, Through study completion, up to sixteen weeks
Secondary Outcome Measures: Cardiac Imaging, Echocardiography, At baseline|Cardiac Imaging, Echocardiography, Through study completion, up to sixteen weeks|Blood Biomarkers, BNP and Troponins, At baseline|Blood Biomarkers, BNP and Troponins, Through study completion, up to sixteen weeks|Histology, Histology of skeletal muscle biopsies, At baseline|Histology, Histology of skeletal muscle biopsies, Through study completion, up to sixteen weeks
Other Outcome Measures:
Sponsor: University of Aberdeen
Collaborators:
Sex: FEMALE
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 12
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 2-049-18
Start Date: 2020-02-01
Primary Completion Date: 2030-08-30
Completion Date: 2030-08-30
First Posted: 2020-07-13
Results First Posted:
Last Update Posted: 2022-09-02
Locations: Cardiovascular Research Facility, Aberdeen, Aberdeenshire, AB25 2ZD, United Kingdom
Study Documents:

NCT Number: NCT00869011
Study Title: Exercise for Patients With Renal Cell Cancer Receiving Sunitinib
Study URL: https://beta.clinicaltrials.gov/study/NCT00869011
Acronym:
Study Status: UNKNOWN
Brief Summary: In this randomized, controlled trial the investigators evaluate the effects of an exercise program lasting for 12 weeks on the physical performance, the cardiovascular function (24h blood pressure, rest blood pressure and hear function) and the fatigue and mood of patients with renal cell carcinoma undergoing a therapy with Sunitinib.
Study Results: NO
Conditions: Renal Cell Carcinoma
Interventions: OTHER: Endurance exercise
Primary Outcome Measures: Fatigue, 12 weeks
Secondary Outcome Measures: VO2max, 12 weeks|Systolic and diastolic blood pressure (24 h), 12 weeks|Depression score, 12 weeks
Other Outcome Measures:
Sponsor: Charite University, Berlin, Germany

Collaborators: Pfizer
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE3
Enrollment: 70
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|
Masking: SINGLE (INVESTIGATOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: SUIR8687
Start Date: 2009-12
Primary Completion Date: 2011-06
Completion Date:
First Posted: 2009-03-25
Results First Posted:
Last Update Posted: 2009-12-23
Locations: Section Sports Medicine, Charité Universitätsmedizin Berlin, Hindenburgdamm 30, Berlin, 12200, Germany
Study Documents:

NCT Number: NCT03523611
Study Title: Right Ventricular Inflammation After Lung Resection
Study URL: https://beta.clinicaltrials.gov/study/NCT03523611
Acronym:
Study Status: UNKNOWN
Brief Summary: The purpose of this study is explore the impact of lung cancer surgery on inflammation and function of the right side of the heart.
Study Results: NO
Conditions: Lung Cancer|Ventricular Failure
Interventions: PROCEDURE: Lung Resection
Primary Outcome Measures: Can RV inflammation be assessed by T1 mapping CMR following lung resection by assessing the number of CMR studies which have an IQS>1?, The investigators will test and report inter- and intra-observer reproducibility of Region of Interest (ROI) definition in all datasets where Image Quality Score (IQS)\>1. The primary endpoint will be the number of MRI studies which have an IQS \>1., 2 months
Secondary Outcome Measures: Are T1 values at the ventricular insertion points increased following lung resection?, In all patients, the investigators willl measure T1 values at the ventricular insertion points using ROI tool to determine if T1 is increased following lung resection., 2 months|Association between RV inflammation and RV fibrosis following lung resection using measurement of extracellular volume?, Does the presence of RV inflammation ultimately lead to the development of RV fibrosis. In all patients, ECV will be assessed. An increase in ECV indicates development of fibrosis, 2 months|Is there any evidence of inflammation/fibrosis in the LV?, T1 values will be assessed in all patients at the LV free wall using ROI tool. ECV at the LV free wall will be measured to determine if there is fibrosis

present., 2 months
Other Outcome Measures:
Sponsor: University of Glasgow
Collaborators:
Sex: ALL
Age: CHILD, ADULT, OLDER_ADULT
Phases:
Enrollment: 15
Funder Type: OTHER
Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: 17/ANAES/06
Start Date: 2018-04-30
Primary Completion Date: 2019-04-19
Completion Date: 2019-08-01
First Posted: 2018-05-14
Results First Posted:
Last Update Posted: 2018-05-29
Locations: Golden Jubilee National Hospital, Glasgow, Strathclyde, G814HX, United Kingdom
Study Documents:

NCT Number: NCT04305613
Study Title: Cardiotoxicity in Locally Advanced Lung Cancer Patients Treated With Chemoradiation Therapy
Study URL: https://beta.clinicaltrials.gov/study/NCT04305613
Acronym: CLARITY
Study Status: ENROLLING_BY_INVITATION
Brief Summary: This observational cohort will evaluate the cardiovascular effects of chemoradiation used to treat locally advanced, non-small cell lung cancer. Patients will be enrolled prior to the start of therapy and followed during and for at least 2 years after therapy with echocardiograms, nuclear stress tests, blood sampling, and quality of life surveys.
Study Results: NO
Conditions: Cardiotoxicity|Lung Cancer Stage III|Lung Cancer Stage II|Radiation Toxicity
Interventions: OTHER: Chemoradiation
Primary Outcome Measures: High Sensitivity C-Reactive Protein, Change in hsCRP from baseline, up to 12 months|Growth Differentiation Factor 15, Change in GDF-15 from baseline, up to 12 months|Placental Growth Factor, Change in PIGF from baseline, up to 12 months|Left Ventricular Strain, Change in echo-derived measures of LV peak systolic strain (longitudinal) from baseline, up to 12 months|Ventricular Arterial Coupling, Change in echo-derived measures of ventricular-arterial coupling (Ea/Ees) from baseline, up to 12 months|Coronary Flow Reserve (CFR_, Change in PET/CT derived CFR from baseline, 6 months|Overall Survival (2 Year), All-cause mortality assessed by electronic medical record (EMR) review, 24 months|Cardiovascular Specific Mortality (2 Year), Cardiovascular specific mortality assessed by EMR review, 24

Months|Major Cardiovascular Events (2 Year), Incidence of MCE assessed by EMR review and patient interview, up to 24 months
Secondary Outcome Measures: High-Sensitivity Troponin T, Change in hsTnT from baseline, up to 12 months|N-type pro Brain Natriuretic Peptide, Change in NTproBNP from baseline, up to 12 months|Left Ventricular Ejection Fraction (2D), Change in echo-derived LVEF from baseline, up to 12 months|Right Ventricular Fractional Area Change (RAC), Change in echo-derived RAC from baseline, up to 12 months|Right Ventricular Longitudinal Strain, Change in echo-derived RV longitudinal strain from baseline, up to 12 months|Circumferential Strain, Change in echo-derived circumferential strain from baseline, up to 12 months|Diastolic Function, Change in echo-derived measures of diastolic function from baseline, up to 12 months|Valvular Disease, Change in echo-derived measures of valvular disease (degree of regurgitation or stenosis) from baseline, up to 12 months|Left Ventricular Ejection Fraction (3D), Change in 3D echocardiography derived LVEF from baseline, up to 12 months|Left Ventricular systolic strain (3D), Change in 3D echocardiography derived measures of LV systolic strain from baseline, up to 12 months|Left Ventricular Twist and Torsion, Change in 3D echocardiography derived measures of LV twist and torsion from baseline, up to 12 months|Global and Regional Myocardial Blood Flow at Rest, Change in PET/CT derived measures of global and regional myocardial blood flow at rest from baseline, up to 6 months|Global and Regional Myocardial Blood Flow at Stress, Change in PET/CT derived measures of global and regional myocardial blood flow at stress from baseline, up to 6 months|FACIT Fatigue Score, Change in FACIT Fatigue score from baseline. Score ranges from 0-52. Higher scores indicated less fatigue., up to 5 years|FACIT Dyspnea Score, Change in FACIT Dyspnea score from baseline. Score ranges from 0-30. Higher scores indicate more dyspnea., up to 5 years|Godin Leisure Time Exercise Score, Change in Godin Leisure Time Exercise Score from baseline. Higher scores indicate higher levels of physical activity., up to 5 years
Other Outcome Measures: Overall Survival (5 Year), All Cause Mortality assessed by National Death Index Search performed 5 years after the last patient is enrolled., 5-8 years|Cardiovascular Specific Mortality (5 Year), Cardiovascular Specific Mortality by National Death Index Search performed approximately 5 years after the final patient is enrolled., 5-8 Years|Major Cardiovascular Events (5 Year), Incidence of 5-Year MCE by EMR review and patient interview, 5 years|NCI Patient Reported Outcomes Common Terms and Criteria for Adverse Events (PRO-CTCAE), Incidence of symptomatic adverse events as assessed by NCI's PRO-CTCAE, 5 Years
Sponsor: Abramson Cancer Center at Penn Medicine
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases:
Enrollment: 221
Funder Type: OTHER

Study Type: OBSERVATIONAL
Study Design: Observational Model: |Time Perspective: p
Other IDs: UPCC 13519
Start Date: 2020-09-14
Primary Completion Date: 2025-09
Completion Date: 2028-09
First Posted: 2020-03-12
Results First Posted:
Last Update Posted: 2023-05-31
Locations: University of Alabama, Birmingham, Alabama, 35233, United States|The Brigham and Women's Hospital, Boston, Massachusetts, 02115, United States|Washington University School of Medicine, Saint Louis, Missouri, 63110, United States|Rutger's University / Cancer Institute of New Jersey, New Brunswick, New Jersey, 08901, United States|Montefiore Medical Center, Bronx, New York, 190467, United States|Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, 19104, United States|Chester County Hospital, West Chester, Pennsylvania, 19380, United States
Study Documents:

NCT Number: NCT05194111
Study Title: Treating Heart Dysfunction Related to Cancer Therapy With Sacubitril/Valsartan
Study URL: https://beta.clinicaltrials.gov/study/NCT05194111
Acronym: TREAT-HF
Study Status: RECRUITING
Brief Summary: To determine feasibility of recruitment and tolerability of treatment with sacubitril-valsartan among adult age survivors of cancer diagnosed at or before age 39 who have stage B heart failure.
Study Results: NO
Conditions: Heart Failure|Heart Dysfunction
Interventions: DRUG: Sacubitril-valsartan|DRUG: Valsartan
Primary Outcome Measures: Determine feasibility of recruitment to this pilot trial by evaluating the eligibility requirements among adult age survivors of cancer diagnosed at or before age 39 who have stage B heart failure., Number of participants screened for the clinical trial., 24 Months|Determine the feasibility of recruitment to this pilot trial by evaluating the eligibility requirements among adult age survivors of cancer diagnosed at or before age 39 who have stage B heart failure., Number of participants enrolled on the trial, 27 Months|Determine tolerability of treatment with sacubitril-valsartan among adult age survivors of cancer diagnosed at or before age 39 who have stage B heart failure., Number of participants that complete therapy, 27 Months
Secondary Outcome Measures: Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., Number of deaths while on study due to cardiac event, 27 Months|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of

cancer diagnosed at or before age 39., Number of deaths while on study due to non-cardiac events, 90 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By the number of Adverse events at 30 days, 30 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By the number of Adverse events at 60 days, 60 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By the number of Adverse events at 90 days, 90 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By determining number of participants with interval change utilizing a 6-minute walk test distance, 90 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By number of participants with cardiovascular magnetic resonance imaging assessment change in cardiac fibrosis burden., 90 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By number of participants with cardiovascular magnetic resonance imaging assessment change in microvascular perfusion., 90 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By number of participants with cardiovascular magnetic resonance imaging assessment change in arterial stiffness/4D flow., 90 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By number of participants with cardiovascular magnetic resonance imaging assessment change in left ventricular ejection fraction., 90 Days|Evaluate early efficacy of sacubitril-valsartan in the treatment of stage B heart failure among survivors of cancer diagnosed at or before age 39., By number of participants with cardiovascular magnetic resonance imaging assessment change in change in left ventricular strain., 90 Days
Other Outcome Measures:
Sponsor: Virginia Commonwealth University
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE1|PHASE2
Enrollment: 30
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: SINGLE (OUTCOMES_ASSESSOR)|Primary Purpose: SUPPORTIVE_CARE
Other IDs: MCC-21-18830|HM20023601
Start Date: 2022-03-09
Primary Completion Date: 2024-06-30
Completion Date: 2024-06-30

First Posted: 2022-01-18
Results First Posted:
Last Update Posted: 2023-05-10
Locations: Virginia Commonwealth University, Richmond, Virginia, 23298, United States
Study Documents:

NCT Number: NCT05361811
Study Title: Acceptance and Commitment Therapy for Caregivers of Children With a RASopathy: An Internal Pilot Feasibility Study and Follow-up Randomized Controlled Trial
Study URL: https://beta.clinicaltrials.gov/study/NCT05361811
Acronym:
Study Status: RECRUITING
Brief Summary: Background:

RASopathies are a group of genetic diseases that affect a child s development. They cause physical, cognitive, and behavioral symptoms. Caring for a child with a RASopathy can be stressful. Acceptance and Commitment Therapy (ACT) is a therapy that helps people become more aware and accepting of difficult thoughts and feelings. ACT has been found to be helpful for parents with high parenting stress.

Objective:

To find out if Acceptance and Commitment Therapy (ACT) can help caregivers of children with a RASopathy better cope with parenting stress.

Eligibility:

People aged 18 years or older who care for a child (younger than 18 years) with a RASopathy. The child must live with the caregiver at least 50% of the time.

Design:

The study is fully remote. Participants need a mobile device that can play audio and video and connect to the internet. They can borrow an iPod if needed.

Participants will download a free app called MetricWire. They will use this app to watch videos and answer questions.

The first 8 participants will be in a pilot study. They will receive the ACT intervention starting the first week after they begin the study.

After the pilot study, we will start a new phase called the randomized trial. In this phase, participants will have a 50-50 chance of being

in the group that will start the intervention right away or the group that will start the intervention after about 2 months.

Participants will fill out surveys on 5 random days each week. These surveys have 7 questions and take about 2 minutes. They will also fill out 3 longer questionnaires: once before ACT begins, once just after the 8-week study period, and once about 3 months later. Questions will cover topics including:

Parenting stress

Life satisfaction

Self-compassion

Uncomfortable feelings and thoughts

Mindfulness

Participants will take part in an 8-week ACT intervention. They will have one 75-minute session with an ACT coach in the first week.

Participants will watch 9- to 17-minute videos each week. The videos talk about how to practice ACT techniques to cope with parenting stress.

Participants will have 20- to 30-minute coaching sessions in weeks 3 and 6. The coach will help them practice exercises and work through any problems.
Study Results: NO
Conditions: Neurofibromatosis 1|Noonan Syndrome|Legius Syndrome|Cardiofaciocutaneous Syndrome|Costello Syndrome
Interventions: BEHAVIORAL: Waitlist|BEHAVIORAL: ACT Intervention
Primary Outcome Measures: Feasibility & Acceptability, Feasibility defined by compliance with viewing \>50% of the weekly videos (proposed target rate of 5 out of 8 videos watched; must watch at least 80% of each video), and 70% of participants attending both coaching sessions 2 and 3. Acceptability defined by descriptive data per caregiver reports of satisfaction on the Study Satisfaction survey (mean of questions 1-7 and 9)., 9 weeks|Changes in PSS, RCT: Mean scores on the Parental Stress Scale (PSS) will be compared from pre- to post-intervention (baseline to 8 weeks between the immediate intervention arm and the wait list control arm., 9 weeks
Secondary Outcome Measures: To examine the feasibility of ecological momentary assessment methods to assess patterns of parenting stress levels over time, Feasibility defined by compliance with daily surveys (target rate of 30 out of 40 surveys (75%) completed on average by each participant). Acceptability defined by post-intervention participant reports of satisfaction with completing daily EMA ratings on the Study Satisfaction survey., 21 weeks|To examine changes on

caregiver-completed measures of mindfulness, self-compassion, experiential avoidance, depression, and perceptions of child affect from pre- to post-intervention, We will examine pre- to post-intervention changes in scores on measures of mindfulness (MAAS), self-compassion (SCS-SF), experiential avoidance (BEAQ), depression (PROMIS Depression 8a) and child affect (PROMIS Positive Affect Scale)., 21 weeks|To determine whether psychological flexibility mediates the relationship between treatment group and parenting stress, We will look for a significant indirect association between treatment arm assignment and pre- to post-intervention PSS changes via psychological flexibility as measured by the BEAQ., 21 weeks
Other Outcome Measures:
Sponsor: National Cancer Institute (NCI)
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 70
Funder Type: NIH
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: 10000657|000657-C
Start Date: 2022-09-21
Primary Completion Date: 2024-07-01
Completion Date: 2024-10-01
First Posted: 2022-05-05
Results First Posted:
Last Update Posted: 2023-06-28
Locations: National Cancer Institute (NCI), Bethesda, Maryland, 20892, United States
Study Documents:

NCT Number: NCT05077111
Study Title: A Comparative Study Between Regional Anesthesia in Thoracoscopes and the Conventional General Anesthesia
Study URL: https://beta.clinicaltrials.gov/study/NCT05077111
Acronym: VATS
Study Status: ACTIVE_NOT_RECRUITING
Brief Summary: Video-assisted thoracic surgery (VATS) is usually performed with general anesthesia and single lung ventilation. However, performing thoracic surgery under awake regional anesthesia has several potential advantages including avoidance of airway trauma and ventilator dependence associated with endotracheal intubation, besides promoting enhanced recovery after surgery and shorter mean hospital stay.
Study Results: NO
Conditions: Pleural Effusion, Malignant|Pleural Mesothelioma|Pleural Empyema|Pulmonary Diseases or Conditions|Pleural Neoplasms|Pulmonary Atelectasis|Pleural Diseases|Pericardial Effusion|Mediastinal

Lymphadenopathy|Pneumothorax and Air Leak|Hemothorax|Pyopneumothorax
Interventions: PROCEDURE: Thoracic Epidural Anesthesia|PROCEDURE: General Anesthesia with One Lung Ventilation
Primary Outcome Measures: Perioperative changes in blood gases, Ratio of arterial oxygen tension to fraction of inspired oxygen (PaO2/FiO2), arterial carbon dioxide tension (PaCO2). Hypoxemia is defined as peripheral oxygen saturation (SpO2) \< 92% on room air with a need for oxygen supplementation., Imediately before operation, intraoperatively per hour, and postoperatively till 24 hours
Secondary Outcome Measures: Postoperative pain, The Visual Analogue Scale (VAS) consists of a 10 cm straight line with the endpoints defining extreme limits of "no pain at all" (0 cm) and "pain as bad as it could be" (10 cm). The patient is asked to mark his pain level on the line between the two endpoints. The distance between 0 and the mark then defines the subject pain score., Postoperatively at 3,12 and 24 hours|Postoperative opioid needs, Pethidine consumption, Postoperatively during the 24 hours after regaining sensation|Hospital stay, from day of operation to discharge; average, 5 days| Perioperative changes in heart rate, heart rate (HR) in beats per minute (bpm), Immediately before the operation, intraoperatively per hour, and postoperatively till 24 hours|The onset of ambulance., Rate of occurence of falling after ambulance will be recorded in each group., During the 24 hours after regaining of full motor power|Number of episodes of Post Operative Nausea and Vomiting (PONV), During the 24 hours postoperatively|Perioperative changes in mean arterial pressure, mean arterial pressure (MAP) in mmHg, Immediately before the operation, intraoperatively per hour, and postoperatively till 24 hours
Other Outcome Measures:
Sponsor: Mohamed Reda Ashour
Collaborators:
Sex: ALL
Age: ADULT, OLDER_ADULT
Phases: PHASE4
Enrollment: 40
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: SUPPORTIVE_CARE
Other IDs: FMASU M D 389/2019
Start Date: 2020-01-15
Primary Completion Date: 2021-09-15
Completion Date: 2021-10-15
First Posted: 2021-10-14
Results First Posted:
Last Update Posted: 2021-10-14
Locations: Ain Shams University, Cairo, 1156, Egypt
Study Documents: Study Protocol and Statistical Analysis Plan|Informed Consent Form

NCT Number: NCT05879913
Study Title: Coronary CT Angiography Scan in Prostate Cancer
Study URL: https://beta.clinicaltrials.gov/study/NCT05879913
Acronym:
Study Status: NOT_YET_RECRUITING
Brief Summary: This is a randomized pilot study of Coronary CT Angiography (CCTA) for coronary atherosclerosis vs. Usual Care in patients with prostate cancer who are either planning to begin, or are currently taking androgen deprivation therapy (ADT) .
Study Results: NO
Conditions: Prostate Cancer
Interventions: DEVICE: Coronary CT Angiography (CCTA)
Primary Outcome Measures: Proportion of Atherosclerosis in CCTA Arm, Proportion of prostate cancer patients without cardiac symptoms in the CCTA arm who are reclassified into a higher risk group using automated plaque assessment from CCTA that would otherwise be classed as low risk for ASCVD using the PCE, Baseline|Proportion of Subjects Eligible for Treatment Based on Automated Plaque Assessment from CCTA, Assessment of automated plaque from CCTA determining eligibility of lipid lowering treatment and aspirin, Baseline
Secondary Outcome Measures: Reduction in atherosclerotic cardiovascular disease (ASCVD) risk score, Changes in risk over time with intensive medical treatment tailored to plaque burden to test results in a reduction in cardiovascular risk factors including blood pressure, glucose and lipid levels, thus reducing the ASCVD risk score., Baseline, 6 months, and 12 months
Other Outcome Measures:
Sponsor: Indiana University
Collaborators: National Comprehensive Cancer Network|Pfizer|Myovant Sciences GmbH
Sex: MALE
Age: ADULT, OLDER_ADULT
Phases: NA
Enrollment: 100
Funder Type: OTHER
Study Type: INTERVENTIONAL
Study Design: Allocation: RANDOMIZED|Intervention Model: PARALLEL|Masking: NONE|Primary Purpose: DIAGNOSTIC
Other IDs: CTO-IUSCCC-0807
Start Date: 2023-08-01
Primary Completion Date: 2025-12-31
Completion Date: 2026-12-31
First Posted: 2023-05-30
Results First Posted:
Last Update Posted: 2023-06-29
Locations: Indiana University Melvin and Bren Simon Comprehensive Cancer Center, Indianapolis, Indiana, 46202, United States
Study Documents: