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	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
1	NCT03581136	Phase II Multi-center Trial Evaluating 5 Fraction Stereotactic Partial Breast Irradiation Using Gammapod Study Documents:	Title Acronym: Other Ids: STU 042018-083	Recruiting	Breast Cancer	Device: Dose Fractionation Patients will receive 5 fractions of radiation. These should not be on consecutive days. At least 40 hours between each fraction and a maximum of 21 days to complete, i.e.: Tuesday, Thursday, Monday, Wednesday, Friday.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: Health-Related Quality of Life (HRQOL) Analysis [Time Frame: 5 years] The quality of life questionnaire will be used as a standardized instrument to measure the health outcome.Its provides a simple descriptive profile and a single index value for health status. The US version of the EQ-5D will be used, to enable mapping of general HR-QOL scores from EQ-5D scores into health state utility scores (ranging from 0 to 100) for the US population.Analyses will be performed for all subjects having received at least one fraction of radiation.The study will use the CTCAE version 4.0 for reporting of acute and late adverse events related to breast will be reported by the physician through exam/assessment during research visit, encompassing events since last research visit. Research will collect and log breast related events for up to 5 years. Secondary Outcome Measures: Evaluation of Cosmesis [Time Frame: 3Years] Photographs of both breasts will be taken and cosmesis will be graded by the patient, and the radiation oncologist using the EORTC scale at baseline, and twelve months from the start of therapy and at yearly intervals thereafter up to 3 years after treatment. Digital Photographs will be evaluated using the BCCT.core proprietary software developed by INESC Porto Breast Research Group (50-51) and an independent panel. Cosmesis forms using the EORTC scale will be completed by both physician and patient	Actual Enrollment: Estimated Enrollment: 74 Original Estimated Enrollment: 40 Age: 18 Years to 99 Years (Adult, Older Adult) Sex: Female	Study Sponsors: University of Texas Southwestern Medical Center Collaborators: Not Provided	Study Start: April 22, 2019 Primary Completion: May 25, 2028 (Final data collection date for primary outcome measure) Study Completion: June 28, 2030 First Posted: July 10, 2018 Results First Posted: Last Update Posted: May 13, 2021
2	NCT00837499	Breast Cancers: Risk Factors Among Mexican Women in Mexico, Mexican-American and African-American Women in the U.S. Study Documents:	Title Acronym: Other Ids: 2006-0551 S1 (U.S. NIH Grant/Contract)" onClick="openNewWindow('https://projectreporter.nih.gov/reporterapi.cfm?PROJECTNUM=3P50CA116199-02S1&Fy=all'); return false">3P50CA116199-02S1 (U.S. NIH Grant/Contract)	Completed	Breast Cancer	Behavioral: Questionnaire Interview and survey during visit or by phone, 30 - 40 minutes. Other Name: Survey	Study Type: Observational Phase: Study Design: Observational Model: Case-Control Time Perspective: Prospective Primary Outcome Measures: To find out if various risk factors and certain markers that help predict increased occurrence and prognosis of breast cancer differ among Mexican, Mexican-American, and African-American women. [Time Frame: 5 years] Secondary Outcome Measures: Not Provided	Actual Enrollment: 938 Estimated Enrollment: Original Estimated Enrollment: 1825 Age: 18 Years and older (Adult, Older Adult) Sex: Female	Study Sponsors: M.D. Anderson Cancer Center Collaborators: National Cancer Institute (NCI)	Study Start: January 1, 2007 Primary Completion: May 10, 2021 (Final data collection date for primary outcome measure) Study Completion: May 10, 2021 First Posted: February 5, 2009 Results First Posted: Last Update Posted: May 14, 2021

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3	NCT03762733	Tissue Acquisition and Genomics Analysis of Breast Cancer and Other Gynecologic Malignancies Study Documents:	Title Acronym: Other Ids: 190025 19-C-0025	Not yet recruiting	• Breast Cancer • Ovarian Cancer • Uterine Cancer	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 500 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: National Cancer Institute (NCI) Collaborators: Not Provided	Study Start: May 20, 2021 Primary Completion: December 29, 2023 (Final data collection date for primary outcome measure) Study Completion: December 29, 2023 First Posted: December 4, 2018 Results First Posted: Last Update Posted: May 17, 2021
4	NCT02390427	Phase Ib Dose-escalation Trial of Taselisib (GDC-0032) in Combination With Anti-HER2 Therapies in Participants With Advanced HER2+ Breast Cancer Study Documents:	Title Acronym: Other Ids: 15-024	Active, not recruiting	• Metastatic Breast Cancer • Recurrent Breast Cancer	• Drug: Taselisib Other Name: GCD-0032 • Drug: Trastuzumab emtansine Other Names: ○ T-DM1 ○ Kadcyla • Drug: Pertuzumab Other Name: Perjeta • Drug: Trastuzumab Other Name: Herceptin • Drug: Paclitaxel Other Names: ○ Taxol ○ Onxal	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: 68 Estimated Enrollment: Original Estimated Enrollment: 76 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Dana-Farber Cancer Institute Collaborators: Genentech, Inc.	Study Start: April 2015 Primary Completion: December 2020 (Final data collection date for primary outcome measure) Study Completion: December 2021 First Posted: March 17, 2015 Results First Posted: Last Update Posted: May 17, 2021

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
5	NCT03723928	S1703 Serum Tumor Marker Directed Disease Monitoring in Patients With Hormone Receptor Positive Her2 Negative Metastatic Breast Cancer Study Documents:	Title Acronym: Other Ids: S1703 NCI-2018-00090 (Registry Identifier: CTRP (Clinical Trial Reporting Program)) S1703 (Other Identifier: SWOG) SWOG-S1703 (Other Identifier: DCP) S1703 (Other Identifier: CTEP) UG1CA189974 (U.S. NIH Grant/Contract)	Recruiting	• Anatomic Stage IV Breast Cancer AJCC v8 • Estrogen Receptor Positive • HER2/Neu Negative • Progesterone Receptor Positive • Prognostic Stage IV Breast Cancer AJCC v8 • Elevated CA15-3 or CEA or CA27-29	• Other: Usual care disease monitoring Imaging and serum tumor markers are at the discretion of the treating physician (however imaging must be performed at least every 12 weeks). • Other: Serum Tumor Marker directed disease monitoring Serum tumor markers every 4-8 weeks without imaging Other Name: STMDDM • Other: Quality-of-Life Assessment Ancillary studies Other Name: Quality of Life Assessment • Other: Anxiety Questionnaire Administration Ancillary studies	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Health Services Research Primary Outcome Measures: Overall survival [Time Frame: Up to 312 weeks after randomization] The assessment of whether patients monitored with STMDDM have non-inferior overall survival compared with patients monitored with usual care will be based on multivariable Cox regression, adjusting for intervention assignment (intention-to-treat) and the stratification factor (bone only versus visceral disease). If at the time of final analysis the study shows notably fewer events than anticipated, extended follow-up will be examined for its potential to allow examination of the primary endpoint with full power. Secondary Outcome Measures: • Cumulative direct healthcare costs by arm [Time Frame: Up to 48 weeks after randomization] The comparison of direct healthcare costs by arm will be based on a multivariable linear regression, adjusting for patient and tumor characteristics. • Assessment of anxiety by arm [Time Frame: Up to 102 weeks after randomization] Patient anxiety will be measured at baseline and at 12, 24, 36, 48, and 102 after randomization using the State-Trait Anxiety inventory Scale (STAI-S). Differences in anxiety by arm will be evaluated using a mixed-effects model for repeated measures controlling for the baseline score and stratification factor as covariates. No direction of effect will be assumed, implying two-sided testing. • Assessment of quality of life by arm [Time Frame: Up to 102 weeks after randomization] Patient quality of life (QOL) will be measured at baseline and at weeks 12, 24, 36, 48, and 102 after randomization using the PROMIS-29. Differences in QOL by arm will be evaluated using a mixed-effects model for repeated measures, controlling for the baseline score and stratification factor as covariates. No direction of effect will be assumed, implying two-sided testing.	Actual Enrollment: Estimated Enrollment: 1320 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Southwest Oncology Group Collaborators: National Cancer Institute (NCI)	Study Start: July 16, 2018 Primary Completion: December 1, 2028 (Final data collection date for primary outcome measure) Study Completion: December 1, 2031 First Posted: October 30, 2018 Results First Posted: Last Update Posted: May 13, 2021

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
6	NCT03418961	S1501 Carvedilol in Preventing Cardiac Toxicity in Patients With Metastatic HER-2-Positive Breast Cancer Study Documents:	Title Acronym: Other Ids: S1501 NCI-2016-01047 (Registry Identifier: CTRP (Clinical Trial Reporting Program)) S1501 (Other Identifier: SWOG) SWOG-S1501 (Other Identifier: DCP) UG1CA189974 (U.S. NIH Grant/Contract)	Recruiting	• Cardiotoxicity • HER2/Neu Positive • Metastatic Malignant Neoplasm in the Brain • Recurrent Breast Carcinoma • Stage IV Breast Cancer AJCC v6 and v7	• Drug: Carvedilol Given PO Other Name: Coreg • Other: Laboratory Biomarker Analysis Correlative studies • Other: Patient Observation Undergo observation Other Names: ○ Active Surveillance ○ deferred therapy ○ expectant management ○ observation ○ Watchful Waiting	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Single (Outcomes Assessor) Primary Purpose: Supportive Care Primary Outcome Measures: • Drug adherence [Time Frame: Up to 108 weeks] 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. • Rate of cardiac event [Time Frame: Up to 108 weeks] Real-time, blinded, central ECHO read as a decrease in the 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 events 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 • Rate of death [Time Frame: Up to 108 weeks] Will compare rate of death from competing causes between treatment arms via Cox regression to evaluate whether those rates impact the primary analysis comparison. • Rate of first interruption of trastuzumab [Time Frame: Up to 108 weeks] 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. • Time to the first identification of cardiac dysfunction [Time Frame: Up to 108 weeks] 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 Secondary Outcome Measures: Incidence of adverse events associated with beta blocker treatment [Time Frame: Up to 108 weeks] Adverse events associated with beta blocker treatment will be assessed.	Actual Enrollment: Estimated Enrollment: 817 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Southwest Oncology Group Collaborators: National Cancer Institute (NCI)	Study Start: September 15, 2017 Primary Completion: January 1, 2029 (Final data collection date for primary outcome measure) Study Completion: January 1, 2029 First Posted: February 1, 2018 Results First Posted: Last Update Posted: May 17, 2021

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7	NCT04636710	Refining Local-Regional Therapy for IBC Study Documents:	Title Acronym: Other Ids: 20-151	Recruiting	• Breast Cancer • Inflammatory Breast Cancer • Sentinel Lymph Node	Procedure: Lymphoscintigraphy An imaging procedure using an injected radioactive substance or dye to identify lymph drainage A doctor reviews the images to identify the sentinel lymph nodes based on where the dye goes to first. Other Name: Sentinel lymph node mapping	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Diagnostic Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 50 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: Female	Study Sponsors: Dana-Farber Cancer Institute Collaborators: Not Provided	Study Start: June 1, 2021 Primary Completion: December 1, 2023 (Final data collection date for primary outcome measure) Study Completion: December 1, 2027 First Posted: November 19, 2020 Results First Posted: Last Update Posted: May 11, 2021
8	NCT03685175	Effect of Cardiotoxic Anticancer Chemotherapy on the Metabolism of [1-13C]Pyruvate in Cardiac Mitochondria Study Documents:	Title Acronym: Other Ids: STU 072016-058	Recruiting	Breast Neoplasms	• Drug: Formal study using hyperpolarized 13C-pyruvate injection Administration at two visits: 1) baseline MRI before administration of doxorubicin and 2) within 2 weeks after completion of doxorubicin treatment Other Name: Cardiac MRI with injection of hyperpolarized 13C-pyruvate • Drug: Feasible study using hyperpolarized 13C-pyruvate injection Administration at two visits 1) after completion of doxorubicin treatment and 2) 1 to 6 months after the first scan following medical therapy, after standard of care medical therapy Other Name: Cardiac MRI with injection of hyperpolarized 13C-pyruvate	Study Type: Interventional Phase: Early Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Diagnostic Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 110 Original Estimated Enrollment: 100 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: University of Texas Southwestern Medical Center Collaborators: Not Provided	Study Start: July 1, 2018 Primary Completion: March 2022 (Final data collection date for primary outcome measure) Study Completion: March 2022 First Posted: September 26, 2018 Results First Posted: Last Update Posted: May 11, 2021

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
9	NCT04739696	Developing a Virtual Stress Management Intervention for Spousal/Partnered Caregivers of Solid Tumor Cancer Patients. Study Documents:	Title Acronym: Other Ids: 20-2458.cc 5R01CA231387-02 (U.S. NIH Grant/Contract)	Recruiting	• Breast Cancer • Lung Cancer • Colon Cancer • Solid Tumor, Adult	• Behavioral: PEPRR Briefly presented in the following order, sessions will include: 1) Overview and Introduction to Stress Management 2) Stress and the mind-body connection, 3) How our thoughts can lead to stress, 4) Coping with work and caregiver stress, 5) Strategies for maintaining energy and stamina with caregiver and work demands, 6) Coping with uncertainty and fear of unknown, 7) Managing changing relationships/communicating needs to employers and your loved ones, and 8) Getting the support they need including work accommodations and/or legal protections (e.g., Family Medical Leave Act, Americans with Disabilities Act) Other Names: ○ Virtual-PEPRR ○ PsychoEducation Paced Respiration and Relaxation • Behavioral: Pep-Pal Pep-Pal program consisted of 11 sessions: 1) Introduction to stress management, 2) Stress and the mind body connection, 3) How thoughts can lead to stress, 4) Coping with stress, 5) Strategies for maintaining energy and stamina, 6) Coping with uncertainty, 7) Managing changing relationships and communicating needs, 8) Getting the support they need; 9) Employment related challenges and resources for working caregivers; 10) Employment session one; 11) Employment session two	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Investigator, Outcomes Assessor) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 300 Original Estimated Enrollment: *Same as current* Age: 18 Years to 64 Years (Adult) Sex: All	Study Sponsors: University of Colorado, Denver Collaborators: National Cancer Institute (NCI)	Study Start: February 5, 2021 Primary Completion: September 2024 (Final data collection date for primary outcome measure) Study Completion: September 2024 First Posted: February 5, 2021 Results First Posted: Last Update Posted: May 14, 2021

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10	NCT04200482	Lifestyle Program (Scalable Nutrition and Physical Activity) for the Improvement of Nutrition and Physical Activity in Stage 0-III Breast Cancer Survivors Study Documents:	Title Acronym: Other Ids: RG1006427 NCI-2019-07643 (Registry Identifier: CTRP (Clinical Trial Reporting Program)) 10335 (Other Identifier: Fred Hutch/University of Washington Cancer Consortium) P30CA015704 (U.S. NIH Grant/Contract)	Active, not recruiting	• Anatomic Stage 0 Breast Cancer AJCC v8 • 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 • Prognostic Stage 0 Breast Cancer AJCC v8 • Prognostic Stage I Breast Cancer AJCC v8 • Prognostic Stage IA	• Behavioral: One Diet and Physical Activity Session Attend 1 remote diet and physical activity session Other Names: ◦ Behavior or Lifestyle Modifications ◦ behavior modification ◦ Behavior Conditioning Therapy ◦ Behavioral Interventions ◦ Behavioral Treatments • Other: Electronic (e) Health (eHealth) Communication Intervention Receive eHealth communication intervention • Behavioral: Twelve Diet and Physical Activity Group Sessions Attend 12 remote diet and physical activity sessions in 6 months Other Names: ◦ Behavior or Lifestyle Modifications ◦ behavior modification ◦ Behavior Conditioning Therapy ◦ Behavioral Interventions ◦ Behavioral Treatments • Other: Questionnaire Administration Ancillary studies • Other: Quality-of-Life Assessment Ancillary studies Other Name: Quality of Life Assessment	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Supportive Care Primary Outcome Measures: • Accrual rate [Time Frame: At 6 months] Accrual rate will be measured by number of participants randomized during each month of study accrual. • Adherence: Class(es) Attendance [Time Frame: At 6 months] Adherence will be measured by number of class(es) attended per participant. • Adherence: Responsiveness to eHealth communication [Time Frame: At 6 months] Adherence will be measured by the number of responses to text messages per participant. • Biospecimen collection rate [Time Frame: At 6 months] Biospecimen collection rate will be assessed based on number of biospecimens collected. • Retention [Time Frame: At 6 months] Retention will be measured by the number of completed study assessments per participants. • Acceptability: Questions during exit interview [Time Frame: At 6 months] Acceptability will be measured by questions asking about trial acceptability in the exit questionnaire. Secondary Outcome Measures: *Same as current*	Actual Enrollment: 90 Estimated Enrollment: Original Estimated Enrollment: 60 Age: 18 Years and older (Adult, Older Adult) Sex: Female	Study Sponsors: Fred Hutchinson Cancer Research Center Collaborators: • National Cancer Institute (NCI) • Breast Cancer Research Foundation	Study Start: February 21, 2020 Primary Completion: July 31, 2021 (Final data collection date for primary outcome measure) Study Completion: July 31, 2021 First Posted: December 16, 2019 Results First Posted: Last Update Posted: May 10, 2021