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	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
1	NCT05546229	Assessment of Methadone and Buprenorphine in Interstitial Fluid Study Documents:	Title Acronym: Other Ids: 1332356 5R44DA044905-03 (U.S. NIH Grant/Contract)	Recruiting	Opioid Use Disorder	Procedure: Microneedle based interstitial fluid collection Interstitial fluid will be collected from the skin using microneedles and suction.	Study Type: Observational Phase: Study Design: Observational Model: Case-Only Time Perspective: Prospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 22 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • National Institutes of Health (NIH) • National Institute on Drug Abuse (NIDA)	Study Start: September 14, 2022 Primary Completion: October 15, 2022 (Final data collection date for primary outcome measure) Study Completion: October 30, 2022 First Posted: September 19, 2022 Results First Posted: Last Update Posted: September 19, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
2	NCT05414084	Aggregate Metabolic Phenotypes for (Poly)Phenols: Development of an Oral (Poly)Phenol Challenge Test (OPCT) Study Documents:	Title Acronym: Other Ids: 1352/2020/SPER/UNIPR	Recruiting	• Individual Variability in (Poly)Phenol Metabolism • Cardiometabolic Health	Dietary Supplement: Oral (poly)phenol challenge test (OPCT) Nutritional challenge with standardized (poly)phenol-rich tablets	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Screening Primary Outcome Measures: *Same as current* Secondary Outcome Measures: • Assessing common cardiometabolic health biomarkers in blood samples [Time Frame: Baseline] Samples will be processed for the analysis of common biomarkers of cardiometabolic health: total cholesterol (mg/dL), HDL-cholesterol (mg/dL), triglycerides (mg/dL), glucose (mg/dL), insuline (uUI/mL). Analyses will follow standardised routine procedures. • Assessing risk prediction scores [Time Frame: Baseline] Risk prediction scores (i.e., Framingham General Cardiovascular Risk Score, Framingham Heart Study Primary Risk Functions for heart disease, stroke, diabetes, fatty liver disease, and hypertension, Atherosclerotic Cardiovascular Disease (ASCVD) Risk, QRISK3®, QDScore®, Finnish Diabetes Risk Score (FINDRISC)) will be assessed to understand their relationship with the aggregate phenolic metabotypes observed. The higher the scores, the worse the risk of developing the disease. • Evaluating trimethylamine N-oxide (TMAO) in urine and plasma samples [Time Frame: Baseline] TMAO will be quantified in baseline urine and fasting plasma samples by UHPLC-MS/MS. • Evaluating eicosanoids in urine samples [Time Frame: Baseline] Eicosanoids, including prostaglandins, thromboxanes, leukotrienes, isoprostanes and neuroprostanes will be evaluated in baseline urine samples (0-h) by UHPLC-QqQ-MS/MS. • Assessing DNA oxidation catabolites and branched fatty acyl esters of hydroxyl fatty acids (FAHFAs) in plasma samples [Time Frame: Baseline] DNA oxidation catabolites and FAHFAs will be measured in fasting plasma samples by UHPLC-QqQ-MS/MS. • Determining genetic differences among subjects [Time Frame: Baseline] Genotyping will be conducted using genome wide, SNP array approach untargeted methodology, using commercially available SNP arrays and a tSNP approach. This approach will involve the genotyping of approximately 300 SNPs. Genomic DNA will be prepared from PBMCs isolated from blood samples. • Assessing transcriptomic signatures in peripheral blood mononuclear cells (PBMCs). [Time Frame: Baseline] Specific patterns of gene expression related to each metabotype will be investigated in PBMCs by using a microarray-based approach. Analysis will be carried out in a subset of 10 samples for each metabotype. • Determining gut microbiota composition and functionality in fecal samples [Time Frame: Baseline] Microbial profiling will be assessed by shallow shotgun metagenomics. Full shotgun metagenomics analysis will be carried out to determine functional pathways. • Assessing dietary habits [Time Frame: Baseline]	Actual Enrollment: Estimated Enrollment: 300 Original Estimated Enrollment: *Same as current* Age: 18 Years to 74 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • Azienda Ospedaliero-Universitaria di Parma • University of Birmingham • Centro de Edafología y Biología Aplicada del Segura (CEBAS-CSIC)	Study Start: May 31, 2022 Primary Completion: April 2023 (Final data collection date for primary outcome measure) Study Completion: April 2023 First Posted: June 10, 2022 Results First Posted: Last Update Posted: September 16, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
3	NCT05547360	Analysis of Blood Metabolomics to Identify Potential Biomarkers of Gastrointestinal Bleeding Study Documents:	Title Acronym: Other Ids: S18	Recruiting	GastroIntestinal Bleeding	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Cross-Sectional Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 32 Original Estimated Enrollment: *Same as current* Age: 21 Years to 55 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: July 19, 2022 Primary Completion: December 31, 2022 (Final data collection date for primary outcome measure) Study Completion: December 31, 2022 First Posted: September 21, 2022 Results First Posted: Last Update Posted: September 21, 2022
4	NCT05537090	A Study to Assess Effect of BV100 on the Pharmacokinetics of Midazolam in Healthy Participants Study Documents:	Title Acronym: Other Ids: BV100-005	Recruiting	Healthy Volunteers	• Drug: BV100 Rifabutin for Infusion • Drug: Midazolam Syrup for oral administration	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Sequential Assignment Intervention Model Description: This is an open-label, 3 period fixed-sequence, Phase 1 clinical study to evalu-ate the effect of multiple doses of BV100 on the Pharmacokinetics on midazo-lam and its metabolite 1-hydroxymidazolam in healthy volunteers. Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 16 Original Estimated Enrollment: *Same as current* Age: 18 Years to 55 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: CRU Hungary Kft	Study Start: September 1, 2022 Primary Completion: October 30, 2022 (Final data collection date for primary outcome measure) Study Completion: December 30, 2022 First Posted: September 13, 2022 Results First Posted: Last Update Posted: September 15, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
5	NCT05230433	High-fat Meal Challenge in Pediatrics Study Documents:	Title Acronym: Other Ids: STUDY02001316	Active, not recruiting	• Pediatric Obesity • Insulin Resistance	Dietary Supplement: High-fat Challenge The shake will be composed of a mixture of BOOST Glucose Control(R) (Nestlé Products) supplemented with palm oil. Each participant will consume a volume of liquid equivalent to 25% of their estimated daily caloric needs, calculated by the USDA Dietary Reference Intakes using a moderate activity factor.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Basic Science Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 50 Original Estimated Enrollment: *Same as current* Age: 8 Years to 17 Years (Child) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: May 1, 2022 Primary Completion: September 19, 2022 (Final data collection date for primary outcome measure) Study Completion: December 31, 2023 First Posted: February 9, 2022 Results First Posted: Last Update Posted: September 21, 2022
6	NCT05041348	Metabonomic of Patients With Hepatitis B Cirrhosis Complicated With Sarcopenia. Study Documents:	Title Acronym: Other Ids: QYFYWZLL26461	Completed	Sarcopenia	Diagnostic Test: CT at the level of the third lumbar vertebra (L3) Muscle mass loss was defined as an skeletal muscle mass index (SMI) less than 46.96 cm²/m² for males and less than 32.46 cm²/m² for females	Study Type: Observational Phase: Study Design: Observational Model: Case-Control Time Perspective: Cross-Sectional Primary Outcome Measures: • amino acids [Time Frame: 2021.09.01-2022.08.01] Amino acids, especially BCCAs, is involved in muscle protein synthesis. So it is important for maintaining and increasing muscle mass . The concentration(μmol/L) of amino acids in the blood will be different in the three groups, especially amino acids associated with muscle metabolism. • myostatin [Time Frame: 2021.09.01-2022.08.01] increased myostatin levels contribute to muscle loss. So the concentration(pg/mL) of myostatin predicts to be higher in the sarcopenia patients. Secondary Outcome Measures: Not Provided	Actual Enrollment: 60 Estimated Enrollment: Original Estimated Enrollment: 90 Age: 18 Years to 60 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: August 17, 2021 Primary Completion: July 15, 2022 (Final data collection date for primary outcome measure) Study Completion: August 17, 2022 First Posted: September 13, 2021 Results First Posted: Last Update Posted: September 15, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
7	NCT05414409	The Gut Microbiome in Type 1 Diabetes and Mechanism of Metformin Action Study Documents:	Title Acronym: Other Ids: 15498	Not yet recruiting	• Type 1 Diabetes • Obesity	Drug: Metformin Metformin is an oral medication that improves insulin sensitivity.	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Non-Randomized Intervention Model: Sequential Assignment Intervention Model Description: The investigators will examine the differences in the gut microbiome between lean and obese youth with type 1 diabetes and then enroll the obese youth with type 1 diabetes into the clinical trial to receive metformin as an intervention. Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: • Differences in the gut microbiome in lean and obese youth with type 1 diabetes [Time Frame: 2 years] cross sectional comparison of stool microbiome using metagenomic sequencing data • Differences in the gut microbial metabolites in lean and obese youth with type 1 diabetes [Time Frame: 2 years] The investigators will measure and compare the stool and serum short chain fatty acids using mass spectrometry • Differences in the gut microbial metabolites in lean and obese youth with type 1 diabetes [Time Frame: 2 years] The investigators will measure and compare the stool and serum secondary bile acids using mass spectrometry • Changes in the gut microbiome in obese youth with type 1 diabetes in response to metformin [Time Frame: 3 years] longitudinal comparison before and after taking metformin for 6 months, stool samples will be collected monthly and sequenced for microbiome profile using metagenomic sequencing • Changes in the gut microbial metabolites in obese youth with type 1 in response to metformin [Time Frame: 3 years] The investigators will measure and compare the stool and serum metabolites (short chain fatty acids and secondary bile acids) before, during and after 6 months of daily metformin therapy using mass spectrometry Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 114 Original Estimated Enrollment: *Same as current* Age: 11 Years to 18 Years (Child, Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: October 2022 Primary Completion: August 2025 (Final data collection date for primary outcome measure) Study Completion: August 2026 First Posted: June 10, 2022 Results First Posted: Last Update Posted: September 19, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
8	NCT05543369	Study to Compare the Level of Elafibranor in Blood After Repeat Administration in Japanese and Non-Asian Healthy Participants Study Documents:	Title Acronym: Other Ids: CLIN-60190-450	Not yet recruiting	Healthy Volunteers	Drug: Elafibranor Oral Tablet Other Name: GFT505	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 48 Original Estimated Enrollment: *Same as current* Age: 18 Years to 55 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 15, 2022 Primary Completion: December 23, 2022 (Final data collection date for primary outcome measure) Study Completion: December 23, 2022 First Posted: September 16, 2022 Results First Posted: Last Update Posted: September 16, 2022
9	NCT05199610	An Open-Label, Single-Dose, Parallel-Group Study of the Pharmacokinetics and Safety of EQ143 Study Documents:	Title Acronym: Other Ids: EQ143-102	Recruiting	Severe Hepatic Impairment	Drug: aumolertinib A single dose of 55-mg EQ143 tablet will be administered in the morning on Day 1, and participants will remain for 5 days (4 nights) in the study center for collection of blood samples and safety monitoring. Participants will attend outpatient follow-up visits on Days 5, 6, 8, and 9 for additional blood sampling and safety assessments. Other Name: HS-10296	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 12 Original Estimated Enrollment: *Same as current* Age: 18 Years to 75 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: March 22, 2022 Primary Completion: December 2022 (Final data collection date for primary outcome measure) Study Completion: December 2022 First Posted: January 20, 2022 Results First Posted: Last Update Posted: September 19, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
10	NCT05042414	Acute Effects of Endurance Exercise on Breastmilk Composition Study Documents:	Title Acronym: Other Ids: 263493	Recruiting	Breastmilk	• Behavioral: High intensity interval training Four times four minutes treadmill interval training • Behavioral: Moderate intensity training Moderate intensity treadmill training • Behavioral: Resting No training	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Sequential Assignment Masking: None (Open Label) Primary Purpose: Basic Science Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 20 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: Female	Study Sponsors: *Same as current* Collaborators: St. Olavs Hospital	Study Start: August 24, 2021 Primary Completion: June 1, 2025 (Final data collection date for primary outcome measure) Study Completion: June 1, 2025 First Posted: September 13, 2021 Results First Posted: Last Update Posted: September 19, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
11	NCT05115513	Standardized Field Test for Marijuana Impairment II Study Documents:	Title Acronym: Other Ids: HHC-2021-0333 DTNH2216C00022 (Other Identifier: Department of Transportation)	Recruiting	Marijuana Impairment	• Drug: Medium THC Marijuana flower with medium THC • Drug: Placebo THC Marijuana flower with no THC	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Crossover Assignment Masking: Single (Participant) Primary Purpose: Other Primary Outcome Measures: • Marijuana induced performance changes on Cogstate Groton Maze Learning task. [Time Frame: Post placebo at 30 min and post active dose administration at: 30, 60, 90, 120, 150, 180 min.] The Cogstate Groton Maze Learning task assesses spatial learning and memory, it will be administered prior to dosing and at various time points after dosing. • Marijuana induced performance changes on Inquisit Maze Learning task. [Time Frame: Post placebo at 30 min and post active dose administration at: 30, 60, 90, 120, 150, 180 min.] The Inquisit Maze Learning task assesses spatial learning and memory, it will be administered prior to dosing and at various time points after dosing. • Marijuana induced performance changes on the Time Reproduction Task. [Time Frame: Post placebo at 30 min and post active dose administration at: 30, 60, 90, 120, 150, 180 min.] The Time Reproduction Task assesses general motor coordination plus timing, it will be administered prior to dosing and at various time points after dosing. Secondary Outcome Measures: • Change in concentration of THC/metabolites in blood samples. [Time Frame: Post placebo at 5 min and post active dose administration at: 5, 30, 90, 150 min.] Blood samples with be collected at 5 times throughout each day to assess for changes of THC and its metabolite levels. • Change in performance on simulated driving Road Tracking Task. [Time Frame: Post placebo at 10 min and post active dose administration at 210 min.] The Road Tracking Task measures operational control of the vehicle. Operational control is measured by standard deviation of lane position from the center point of the lane.	Actual Enrollment: Estimated Enrollment: 32 Original Estimated Enrollment: *Same as current* Age: 18 Years to 55 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • National Highway Traffic Safety Administration (NHTSA) • Hartford Hospital • National Institute on Drug Abuse (NIDA)	Study Start: August 25, 2022 Primary Completion: February 2024 (Final data collection date for primary outcome measure) Study Completion: February 2025 First Posted: November 10, 2021 Results First Posted: Last Update Posted: September 21, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
12	NCT05545501	Ketone Ester and Acute Salt (KEAS) in Young Adults Study Documents:	Title Acronym: Other Ids: AU IRB #22-025	Not yet recruiting	• Salt; Excess • Hypertension	• Dietary Supplement: No Salt, No -OHB Participants will consume the following for ten days. Enteric capsules will be filled with a dextrose placebo. The placebo supplement will be a -OHB-free, taste and viscosity-matched, beverage produced by KetoneAid. • Dietary Supplement: High Salt, No -OHB Participants will consume the following for ten days. Enteric capsules will be filled with Morton's table salt. Sodium consumption will be normalized to caloric intake (2 mg Sodium/Calorie). The placebo supplement will be a -OHB-free, taste and viscosity-matched, beverage produced by KetoneAid. • Dietary Supplement: High Salt, High -OHB Participants will consume the following for ten days. Enteric capsules will be filled with Morton's table salt. Sodium consumption will be normalized to caloric intake (2 mg Sodium/Calorie). Ketone beverage will be the -OHB supplement produced by KetoneAid. Participants will consume 24 mL (12 grams -OHB) of the ketone beverage three times a day (total 36 grams -OHB).	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Intervention Model Description: Placebo-controlled, double-blinded, randomized Masking: Double (Participant, Investigator) Masking Description: Participants will be randomized to a condition order. A single lab member, not involved in data collection or analysis, will know condition order and contents and distribute them to participants. Primary Purpose: Basic Science Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 35 Original Estimated Enrollment: *Same as current* Age: 18 Years to 39 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • University of Utah • University of Missouri-Columbia	Study Start: October 1, 2022 Primary Completion: September 30, 2025 (Final data collection date for primary outcome measure) Study Completion: September 30, 2026 First Posted: September 19, 2022 Results First Posted: Last Update Posted: September 19, 2022
13	NCT05515588	A Study in Healthy Men to Test How BI 690517 is Taken up and Handled by the Body Study Documents:	Title Acronym: Other Ids: 1378-0013 2022-001818-18 (EudraCT Number)	Recruiting	Healthy	• Drug: BI 690517 (C-14) BI 690517 (C-14) • Drug: BI 690517 BI 690517	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 14 Original Estimated Enrollment: *Same as current* Age: 18 Years to 55 Years (Adult) Sex: Male	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 19, 2022 Primary Completion: November 11, 2022 (Final data collection date for primary outcome measure) Study Completion: November 11, 2022 First Posted: August 25, 2022 Results First Posted: Last Update Posted: September 21, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
14	NCT05547204	Impact of Coffeeberry Extract on Skill Performance During Simulated Match Play in Academy Football Players Study Documents:	Title Acronym: Other Ids: PEP-2114	Recruiting	• Skill Performance • Soccer Performance • Coffeeberry Effects	Other: Beverage Free from added carbohydrates (contain 1g CHO only) and electrolytes are absent.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) Primary Purpose: Basic Science Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 15 Original Estimated Enrollment: *Same as current* Age: 16 Years to 28 Years (Child, Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 30, 2022 Primary Completion: January 31, 2023 (Final data collection date for primary outcome measure) Study Completion: January 31, 2023 First Posted: September 21, 2022 Results First Posted: Last Update Posted: September 21, 2022
15	NCT05329142	ASSIST: A Surveillance Study of Illicit Substance Toxicity Study Documents:	Title Acronym: Other Ids: GN21AE239	Recruiting	• Overdose, Drug • Drug Use • Drug Abuse • Drug Toxicity • Drug Effect • Illicit Drug Use • Illicit Drug Overdose • Illicit Drug Intoxication	Diagnostic Test: Surplus sample toxicology analysis Anonymised surplus blood sample will be analysed for drugs and their metabolites by way of Mass Spectrometry and LGC Group, Cambridge.	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 1000 Original Estimated Enrollment: *Same as current* Age: 16 Years and older (Child, Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Public Health Scotland	Study Start: August 19, 2022 Primary Completion: August 19, 2023 (Final data collection date for primary outcome measure) Study Completion: August 19, 2023 First Posted: April 14, 2022 Results First Posted: Last Update Posted: September 19, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
16	NCT00078078	Clinical and Laboratory Study of Methylmalonic Acidemia Study Documents:	Title Acronym: Other Ids: 040127 04-HG-0127	Recruiting	• Organic Acidemia • Methylmalonic Acidemia • Inborn Errors of Metabolism	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: Not Provided Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 2275 Original Estimated Enrollment: Age: 1 Month and older (Child, Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 7, 2004 Primary Completion: Not Provided Study Completion: Not Provided First Posted: February 19, 2004 Results First Posted: Last Update Posted: September 21, 2022
17	NCT05386758	A Study to Evaluate Molnupiravir (MK-4482; MOV) in Participants With Severe Renal Impairment (MK-4482-003) Study Documents:	Title Acronym: Other Ids: 4482-003 MK-4482-003 (Other Identifier: Merck)	Recruiting	Renal Impairment	Drug: Molnupiravir Four 200 mg capsules administered orally as a single dose Other Name: MK-4482; MOV; EIDD-2801	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: Estimated Enrollment: 18 Original Estimated Enrollment: *Same as current* Age: 18 Years to 75 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 29, 2022 Primary Completion: November 7, 2022 (Final data collection date for primary outcome measure) Study Completion: November 18, 2022 First Posted: May 23, 2022 Results First Posted: Last Update Posted: September 16, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
18	NCT03244722	Maternal Metabolic and Molecular Changes Induced by Preconception Weight Loss and Their Effects on Birth Outcomes Study Documents:	Title Acronym: Other Ids: HUM00124673 1R01DK124862 (U.S. NIH Grant/Contract)	Recruiting	• Obesity; Familial • Pregnancy Related	• Dietary Supplement: Very-low energy Diet (VLED) Structured, intensive dietary intervention using liquid meal replacements aimed at providing 800 kcal/day with a weight loss goal of 15% from baseline • Other: Standard of care (SOC) Standard consultation with registered dietitian to determine appropriate caloric deficit for a low calorie diet, education and advice to achieve weight loss in obese women. Standard of care for normal weight women	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Basic Science Primary Outcome Measures: Rate of development of gestational diabetes [Time Frame: 40 weeks after conception or 24-28 weeks of gestation or 0 to 40 weeks after conception] The number of patients who develop gestational diabetes will be tracked throughout pregnancy. Diagnosis will be made based on one abnormal value per participant. Gestational diabetes will be measured using an oral glucose tolerance test. Secondary Outcome Measures: Birthweight [Time Frame: within 12 hours of birth] Newborn birthweight will be measured within 12 hours of birth.	Actual Enrollment: Estimated Enrollment: 352 Original Estimated Enrollment: 540 Age: 18 Years to 40 Years (Adult) Sex: Female	Study Sponsors: *Same as current* Collaborators: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	Study Start: April 10, 2018 Primary Completion: August 31, 2025 (Final data collection date for primary outcome measure) Study Completion: August 31, 2025 First Posted: August 9, 2017 Results First Posted: Last Update Posted: September 21, 2022
19	NCT04990869	Inflammation in COPD and the Effect of Nicotinamide Riboside Study Documents:	Title Acronym: Other Ids: NR-COPD	Completed	COPD	• Dietary Supplement: Nicotinamide Riboside The patients will receive 1 g of Nicotinamide Riboside or placebo orally every morning and evening for 6 weeks. • Dietary Supplement: Placebo Placebo	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Randomized, double-blind, placebo-controlled Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: 60 Estimated Enrollment: *Same as current* Age: 60 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • Bispebjerg Hospital • Elysium Health	Study Start: July 1, 2021 Primary Completion: August 18, 2022 (Final data collection date for primary outcome measure) Study Completion: August 18, 2022 First Posted: August 5, 2021 Results First Posted: Last Update Posted: September 21, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
20	NCT02795442	Daily Protein Intake Patterns on Energy Metabolism and the Motivation to Snack Study Documents:	Title Acronym: Other Ids: GFHNRC500	Recruiting	Obesity	• Other: Even protein 5 day intake of even protein 3 day rotating menu. • Other: Skewed protein 5 day intake of skewed protein 3 day rotating menu.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: Postprandial lipid oxidation rate [Time Frame: 4 hours after meal consumption] Secondary Outcome Measures: Relative reinforcing value (RRV) of energy-dense snack foods as assessed by indicator [Time Frame: Day 6] RRV of energy-dense snack foods will be assessed by evaluating the number of responses (mouse button presses) a participant is willing to complete to gain access to an energy-dense snack food or an alternative vegetable item.	Actual Enrollment: Estimated Enrollment: 40 Original Estimated Enrollment: *Same as current* Age: 20 Years to 60 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 2016 Primary Completion: September 2023 (Final data collection date for primary outcome measure) Study Completion: December 2023 First Posted: June 10, 2016 Results First Posted: Last Update Posted: September 19, 2022
21	NCT05545865	Chardonnay Marc and Vascular Response Study Documents:	Title Acronym: Other Ids: 1810396	Recruiting	• Cardiovascular Diseases • Vascular Dilation • Oxidative Stress	• Other: Low Flavanol Cocoa Powder Cocoa Powder providing 30 mg of cocoa flavanols • Other: High Flavanol Cocoa Powder Cocoa Powder providing 435 mg of cocoa flavanols • Other: Vine to Bar Chocolate - 2 servings Chocolate providing both cocoa flavanols and Chardonnay marc • Other: Vine to Bar Chocolate - 1 serving Chocolate providing both cocoa flavanols and Chardonnay marc • Other: Vine to Bar Chocolate covered almonds Almonds covered with Vine to Bar Chocolate that provides both cocoa flavanols and Chardonnay marc	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Intervention Model Description: Acute crossover design Masking: Double (Participant, Investigator) Masking Description: Low and High flavanol cocoa will be provided in coded packaging. Primary Purpose: Other Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 5 Original Estimated Enrollment: *Same as current* Age: 30 Years to 50 Years (Adult) Sex: Male	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 1, 2022 Primary Completion: June 30, 2023 (Final data collection date for primary outcome measure) Study Completion: June 30, 2023 First Posted: September 19, 2022 Results First Posted: Last Update Posted: September 19, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
22	NCT04939883	Effects of Carvedilol on Cardiotoxicity in Cancer Patients Submitted to Anthracycline Therapy Study Documents:	Title Acronym: Other Ids: AVAP-NG 989	Recruiting	Cancer	• Drug: Carvedilol Carvedilol will be dispensed in a staggered and progressive manner, initially from 6.25 mg twice daily, then increased to 12.5 mg twice daily, until maximum dose of 25 mg twice daily or development of contraindications • Drug: Placebo Patients will receive placebo in a presumed staggered and progressive manner similar to the intervention group. The placebo will ideally be maintained for up to 30 days after the end of chemotherapy.	Study Type: Interventional Phase: Phase 4 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Investigator) Masking Description: Randomization will be in the proportion of 1: 1 (carvedilol x placebo). Both randomization and allocation of patients will be chosen in a veiled manner to patients and to assess. Data on randomization and allocation will be under custody of the Data analysis and safety committee. Primary Purpose: Prevention Primary Outcome Measures: *Same as current* Secondary Outcome Measures: • Drop in ejection fraction within 24 months. [Time Frame: 24 months] Drop in ejection fraction greater than 10% and values less than 55% • Reduction in myocardial strain in 24 months from the start of treatment. [Time Frame: 24 months] Relative reduction of more than 15% in myocardial strain • Diastolic dysfunction within 24 months [Time Frame: 24 months] Development of diastolic dysfunction within 24 months • Elevation of biomarkers during chemotherapy and up to 24 months of follow-up [Time Frame: 24 months] Elevation of biomarkers (NT-pro BNP and troponin) during chemotherapy and up to 24 months of follow-up • Quality of life in up to 24 months. [Time Frame: 24 months] Quality of life measured by questionnaire in up to 24 months. • Cardiovascular complications in 24 months. [Time Frame: 24 months] Cardiovascular complications (death, resuscitated cardiac arrest, myocardial infarction, heart failure and cardiac arrhythmias) in 24 months.	Actual Enrollment: Estimated Enrollment: 1018 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Ministério da Saúde	Study Start: August 1, 2021 Primary Completion: December 30, 2023 (Final data collection date for primary outcome measure) Study Completion: December 30, 2024 First Posted: June 25, 2021 Results First Posted: Last Update Posted: September 21, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
23	NCT05000996	Gut Microbiota in Metabolic Surgery Study Documents:	Title Acronym: Other Ids: VUMC_IRB#201652 R01DK126721 (U.S. NIH Grant/Contract)	Recruiting	• Bariatric Surgery Candidate • Cardiovascular Diseases • Type 2 Diabetes • Dyslipidemias • Hypertension • Morbid Obesity	Procedure: Bariatric Surgery Roux-en-Y gastric bypass (RYGB) and vertical sleeve gastrectomy (VSG)	Study Type: Observational [Patient Registry] Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 300 Original Estimated Enrollment: *Same as current* Age: 21 Years to 65 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	Study Start: August 19, 2021 Primary Completion: June 1, 2026 (Final data collection date for primary outcome measure) Study Completion: June 1, 2031 First Posted: August 11, 2021 Results First Posted: Last Update Posted: September 19, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
24	NCT02818283	Soy Modulation of Immune Activation, LDL- Levels, and Lowering Inflammation by Pretzel Isoflavone Dietary Intervention Study Documents:	Title Acronym: Other Ids: 2015H0375	Recruiting	• Human Immunodeficiency Virus (HIV) Infection • Hypercholesterolemia	• Other: Soy Pretzel Each packet (5oz.) of soy pretzel contains high gluten wheat flour, soy flour, soymilk, vegetable shortening, sugar, yeast, salt, and ascorbic acid. Each packet provides ~280 calories (16% fat, 54% total carbohydrates, and 30% protein). • Other: Wheat Pretzel Each packet (5oz.) of wheat pretzel contains high gluten wheat flour, vital wheat gluten, shortening, sugar, yeast, salt, and ascorbic acid. Each packet provides ~290 calories (16% fat, 54% total carbohydrates, and 30% protein).	Study Type: Interventional Phase: Phase 1 Phase 2 Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: Triple (Participant, Care Provider, Outcomes Assessor) Primary Purpose: Prevention Primary Outcome Measures: • Serious and Non-Serious Adverse Events with Pretzel Intervention (Division of AIDS Adverse Event version 2.0) [Time Frame: 10 weeks or 28 weeks] Number of participants having adverse events with daily consumption of pretzels. • Self-Reported Daily Diary to Assess Adherence of Dietary Intervention [Time Frame: 10 weeks or 28 weeks] Number of participants reporting 80% adherence to pretzels will have quantifiable levels of isoflavone (naturally occurring compounds in soy) metabolites in urine during soy pretzel intervention. Secondary Outcome Measures: • Evidence of Improved lipid parameters in Antiretroviral Therapy Treated HIV+ patients with soy pretzel intervention [Time Frame: baseline to 10 weeks or baseline to 28 weeks] Number of participants with changes in lipid parameters before (baseline) and after (10 or 28 weeks) after soy pretzel intervention • Evidence of Improved Arterial Function in Antiretroviral Therapy-Treated HIV+ Patients after Soy Pretzel Intervention [Time Frame: baseline to 10 weeks or baseline to 28 weeks] Number of participants with changes in arterial function before (baseline) and after (10 or 28 weeks) after soy pretzel intervention • Evidence of Improved Immunologic Function of Soy Pretzels in Antiretroviral Therapy-Treated HIV+ patients [Time Frame: 28 weeks] Ex vivo measurement of plasma markers of immune activation, inflammation and phenotypic analyses of monocyte and lymphocyte subpopulations during the dietary intervention will be coupled with in vitro assays aimed at assessing the mechanism(s) related to the modulation of inflammation and immune activation by soy metabolites.	Actual Enrollment: Estimated Enrollment: 100 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 2016 Primary Completion: June 2023 (Final data collection date for primary outcome measure) Study Completion: December 2023 First Posted: June 29, 2016 Results First Posted: Last Update Posted: September 21, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
25	NCT05307692	A Study of Seltorexant in Participants With Probable Alzheimer's Disease Study Documents:	Title Acronym: Other Ids: CR109177 42847922ALZ2001 (Other Identifier: Janssen Research and Development, LLC)	Recruiting	Alzheimer Disease	• Drug: Seltorexant Seltorexant 20 mg will be administered orally as a tablet. Other Name: JNJ-42847922 • Drug: Placebo Matching placebo will be administered orally as a tablet.	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Investigator) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 86 Original Estimated Enrollment: *Same as current* Age: 55 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: May 19, 2022 Primary Completion: April 19, 2023 (Final data collection date for primary outcome measure) Study Completion: April 19, 2023 First Posted: April 1, 2022 Results First Posted: Last Update Posted: September 15, 2022