ClinicalTrials.gov: metabolite | Last update posted in the last 7 days

	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
2	NCT03573349	Ketamine Associated ACC GABA and Glutamate Change and Depression Remission: Study Documents:	Title Acronym: Other Ids: 17-011373	Enrolling by invitation	• Major Depressive Disorder • Treatment Resistant Depression • Bipolar Depression	Drug: Ketamine We will enroll 20 adults (aged 18-65 years) with treatment-resistant depression and will provide two i.v. ketamine infusions (0.5 mg/kg, infused over 40 minutes) and measure their depressive symptom responses. Biomarkers will be developed using blood samples from study subjects, taken prior to (predictive biomarkers), and following ketamine treatment (change biomarkers). This will be an open-label feasibility trial.	Study Type: Interventional Phase: Early Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: Glutamate [Time Frame: 1 day] Evaluate change in central glutamate and peripheral glutamate with MRS after a single 40-minute infusion of i.v. racemic ketamine Secondary Outcome Measures: Mood [Time Frame: 1 day] Measure the change in depression symptoms using MADRS scale in participants with treatment-resistant major depression before receiving and 24 hours after the Ketamine infusion	Actual Enrollment: Estimated Enrollment: 20 Original Estimated Enrollment: 10 Age: 18 Years to 65 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: January 3, 2019 Primary Completion: December 2023 (Final data collection date for primary outcome measure) Study Completion: December 2023 First Posted: June 29, 2018 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
3	NCT03492177	A Clinical Study of to Confirm the Doses of Selexipag in Children With Pulmonary Arterial Hypertension Study Documents:	Title Acronym: Other Ids: AC-065A203 2018-000145-39 (EudraCT Number) AC-065A203 (Other Identifier: Actelion)	Active, not recruiting	Pulmonary Arterial Hypertension	Drug: selexipag (Uptravi) Film-coated tablets for oral administration Other Names: • ACT-293987 • JNJ-67896049	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: Area under the plasma concentration-time curve over a dose interval at steady state of selexipag and ACT-333679 combined (AUC,ss, combined) [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] The AUC,ss,combined is the sum of the selexipag and ACT-333679 exposures weighted by their potency ratio, and determined during the 12 weeks up-titration period. The model will describe the body weight dependence of dose-exposure relationship for pediatric PAH patients. Blood samples for pharmacokinetic analyses will be collected in the 3 age cohorts. Secondary Outcome Measures: • Area under the plasma concentration-time curve over a dose interval at steady state (AUC,ss) of selexipag [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] The AUC,ss for selexipag is calculated by non compartmental analysis to determine the total exposure to selexipag over a dosing interval • Area under the plasma concentration-time curve over a dose interval at steady state (AUC,ss) of ACT-333679 [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] The AUC,ss for ACT-333679 is calculated by non compartmental analysis to determine the total exposure to ACT-333679 over a dosing interval • Maximum observed plasma concentration (Cmax,ss) of selexipag at steady state [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] Cmax,ss of selexipag is directly obtained from the selexipag concentrations measured in the blood samples collected after at least 3 days on the same dose in order to reach steady state • Maximum observed plasma concentration (Cmax,ss) of ACT-333679 at steady state [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] Cmax,ss of ACT-333679 is directly obtained from the ACT-333679 concentrations measured in the blood samples collected after at least 3 days on the same dose in order to reach steady state • Time to the maximum observed plasma concentration (tmax,ss) of selexipag at steady state [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] tmax,ss of selexipag is directly obtained from the selexipag concentrations measured in the blood samples collected after at least 3 days on the same dose in order to reach steady state • Time to the maximum observed plasma concentration (tmax,ss) of ACT-333679 at steady state [Time Frame:	Actual Enrollment: 63 Estimated Enrollment: Original Estimated Enrollment: 55 Age: 2 Years to 17 Years (Child) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: July 23, 2018 Primary Completion: April 18, 2022 (Final data collection date for primary outcome measure) Study Completion: December 9, 2026 First Posted: April 10, 2018 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
4	NCT05480488	A Study to Examine the Effect of Daridorexant on the Way the Body Absorbs, Distributes, and Gets Rid of Midazolam and Warfarin in Healthy Male Subjects Study Documents:	Title Acronym: Other Ids: ID-078-126	Recruiting	Healthy	• Drug: Midazolam Subjects will receive a single oral dose of 2 mg midazolam (Treatment A, B, and C). • Drug: Warfarin Subjects will receive a single oral dose of 25 mg warfarin (Treatment A and B). • Drug: Daridorexant Subjects will receive an o.d. oral dose of 50 mg daridorexant from Day 1 to Day 7 of Treatment B and a single oral dose of 50 mg daridorexant on Day 1 of Treatment C.	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Sequential Assignment Intervention Model Description: This is a prospective, open-label, fixed-sequence Phase 1 study. Masking: None (Open Label) Primary Purpose: Other 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 45 Years (Adult) Sex: Male	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: August 23, 2022 Primary Completion: September 15, 2022 (Final data collection date for primary outcome measure) Study Completion: September 15, 2022 First Posted: July 29, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
5	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
6	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
7	NCT05489744	Human Mass Balance and Biotransformation Study of [14C]Afuresertib Study Documents:	Title Acronym: Other Ids: LAE002CN1001	Recruiting	Healthy Volunteer	Drug: [14C]Afuresertib Suspension containing approximately 125 mg of Afuresertib (containing 150 µCi of [14C]Afuresertib) is administered orally on an empty stomach, with approximately 240 mL of water for suspending and drug taking. Other Name: [14C]LAE002	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 10 Original Estimated Enrollment: *Same as current* Age: 18 Years to 45 Years (Adult) Sex: Male	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: July 28, 2022 Primary Completion: March 2023 (Final data collection date for primary outcome measure) Study Completion: May 2023 First Posted: August 5, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
8	NCT02932410	A Study to Assess Whether Macitentan Delays Disease Progression in Children With Pulmonary Arterial Hypertension (PAH) Study Documents:	Title Acronym: Other Ids: AC-055-312	Recruiting	Pulmonary Arterial Hypertension	• Drug: Macitentan Dispersible tablet; Oral use Other Name: ACT-064992 • Other: Standard-of-care Standard-of-care as per site's clinical practice which may comprise treatment with PAH non-specific treatment and/or up to two PAH-specific medications excluding macitentan and IV/SC prostanoids.	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: Time to the first CEC-confirmed disease progression event [Time Frame: Between randomization and EOS/study closure; up to 6 years] Time to the first of the following CEC-confirmed disease progression events: • Death (all causes) • Atrial septostomy or Potts' anastomosis, or registration on lung transplant list • Hospitalization due to worsening PAH • Clinical worsening of PAH Secondary Outcome Measures: • Time to first CEC-confirmed hospitalization for PAH occurring between randomization and EOS [Time Frame: Between randomization and EOS/study closure; up to 6 years] • Time to CEC-confirmed death due to PAH occurring between randomization and EOS [Time Frame: Between randomization and EOS/study closure; up to 6 years] • Time to death (all causes) occurring between randomization and Study Closure [Time Frame: Between randomization and EOS/study closure; up to 6 years]	Actual Enrollment: Estimated Enrollment: 300 Original Estimated Enrollment: *Same as current* Age: 1 Month to 17 Years (Child) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: October 24, 2017 Primary Completion: February 29, 2024 (Final data collection date for primary outcome measure) Study Completion: February 29, 2024 First Posted: October 13, 2016 Results First Posted: Last Update Posted: September 14, 2022
9	NCT03218761	POTS NET mRNA Functional Correlation With NET Activity Study Documents:	Title Acronym: Other Ids: IRB#170714	Enrolling by invitation	Postural Tachycardia Syndrome	• Diagnostic Test: NET mRNA level quantification of mRNA to the Norepinephrine Transporter (NET) • Diagnostic Test: Plasma catechols plasma for assay of norepinephrine (NE), DHPG (intraneuronal metabolite of NE), and other catechols • Diagnostic Test: Urine Catechols urine for assay of norepinephrine (NE), DHPG (intraneuronal metabolite of NE), and other catechols	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: 200 Original Estimated Enrollment: *Same as current* Age: 13 Years to 80 Years (Child, Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • National Institute of Neurological Disorders and Stroke (NINDS) • University of Calgary • Dysautonomia International	Study Start: July 14, 2017 Primary Completion: December 31, 2025 (Final data collection date for primary outcome measure) Study Completion: December 31, 2025 First Posted: July 17, 2017 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
10	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
11	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
12	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
13	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
14	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
15	NCT04448392	Valacyclovir in Neonatal Herpes Simplex Virus Disease Study Documents:	Title Acronym: Other Ids: 300005567	Recruiting	Neonatal Herpes Simplex Infection	Drug: Valacyclovir Upon completion of standard of care acyclovir for treatment of neonatal HSV disease, valacyclovir oral suspension (per ASHP recipe), 20 mg/kg every 8 hours, to be given for 2 (up to 7) days	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 10 Original Estimated Enrollment: *Same as current* Age: 2 Weeks to 12 Weeks (Child) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: July 1, 2021 Primary Completion: October 2025 (Final data collection date for primary outcome measure) Study Completion: November 2025 First Posted: June 25, 2020 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
16	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

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
17	NCT03370991	Blueberries for Improving Vascular Endothelial Function in Postmenopausal Women With Elevated Blood Pressure Study Documents:	Title Acronym: Other Ids: 1255927	Completed	• Menopause • Elevated Blood Pressure • Hypertension • Endothelial Dysfunction	• Dietary Supplement: Blueberry Powder 22 g/day freeze-dried blueberry powder for 12 weeks • Dietary Supplement: Placebo Powder 22 g/day placebo powder for 12 weeks	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Triple (Participant, Investigator, Outcomes Assessor) Primary Purpose: Treatment Primary Outcome Measures: • Endothelium-dependent dilation [Time Frame: Baseline] Assessed as brachial artery flow-mediated dilation • Endothelium-dependent dilation [Time Frame: 12 weeks] Assessed as brachial artery flow-mediated dilation • Endothelium-independent dilation [Time Frame: Baseline] Assessed as brachial artery diameter responses to sublingual nitroglycerin • Endothelium-independent dilation [Time Frame: 12 weeks] Assessed as brachial artery diameter responses to sublingual nitroglycerin Secondary Outcome Measures: • Vascular oxidative stress [Time Frame: Baseline and 12 weeks] Change in brachial artery flow-mediated dilation following acute infusion of ascorbic acid (a dose known to scavenge superoxide) as an index of vascular oxidative stress • Endothelial cell nitric oxide production, oxidative stress, and inflammation [Time Frame: Baseline and 12 weeks] Protein expression markers will be measured by quantitative immunofluorescence in biopsied venous endothelial cells • Systemic markers of cardiometabolic health [Time Frame: Baseline and 12 weeks] Circulating markers of lipid and glucose metabolism, nitric oxide, and inflammation • Plasma blueberry polyphenol metabolites [Time Frame: Baseline and 12 weeks] Targeted analysis of plasma metabolites by GC-MS and LC-MS • Peripheral blood mononuclear cell inflammation and oxidative stress [Time Frame: Baseline and 12 weeks] Exploratory measures analyzed by flow cytometry • Episodic memory [Time Frame: Baseline and 12 weeks] Exploratory measures assessed using the NIH Cognitive Toolbox iPad app • Executive function and attention [Time Frame: Baseline and 12 weeks] Exploratory measures assessed using the NIH Cognitive Toolbox iPad app • Working memory [Time Frame: Baseline and 12 weeks] Exploratory measures assessed using the NIH Cognitive Toolbox iPad app • Language [Time Frame: Baseline and 12 weeks] Exploratory measures assessed using the NIH Cognitive Toolbox iPad app • Processing speed [Time Frame: Baseline and 12 weeks]	Actual Enrollment: 43 Estimated Enrollment: Original Estimated Enrollment: 58 Age: 45 Years to 65 Years (Adult, Older Adult) Sex: Female	Study Sponsors: *Same as current* Collaborators: U.S. Highbush Blueberry Council	Study Start: December 2, 2017 Primary Completion: September 30, 2021 (Final data collection date for primary outcome measure) Study Completion: September 30, 2021 First Posted: December 13, 2017 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
18	NCT05365451	Pharmacokinetic Drug-Drug Interaction Study to Identify Biomarkers of Kidney Transporters Study Documents:	Title Acronym: Other Ids: 19163 R01HD081299 (U.S. NIH Grant/Contract)	Recruiting	• Interaction • Endogenous Biomarkers	• Drug: MetFORMIN Oral Solution liquid Other Name: Riomet • Drug: Cimetidine 400 MG tablet Other Name: Tagamet • Drug: Furosemide Oral Liquid Product oral solution Other Name: Lasix • Drug: Probenecid 500 MG tablet Other Name: Probalan	Study Type: Interventional Phase: Early Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Crossover Assignment Masking: None (Open Label) Primary Purpose: Basic Science Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 32 Original Estimated Enrollment: *Same as current* Age: 18 Years to 65 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) • National Institutes of Health (NIH)	Study Start: April 11, 2022 Primary Completion: June 30, 2023 (Final data collection date for primary outcome measure) Study Completion: June 30, 2024 First Posted: May 9, 2022 Results First Posted: Last Update Posted: September 14, 2022
19	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
20	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 19, 2022
21	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
22	NCT04540744	A Study of Macitentan/Tadalafil Combination Administered a Fixed-dose Combination Formulation Compared to the Reference Free Combination of Macitentan and Tadalafil Study Documents:	Title Acronym: Other Ids: CR108794 2020-000566-42 (EudraCT Number) 67896062PAH1001 (Other Identifier: Janssen Research & Development, LLC)	Completed	Healthy	• Drug: FDC of macitentan/tadalafil (10 mg/20 mg) FDC of macitentan/tadalafil (10 mg/20 mg) tablet will be administered orally as per assigned treatment sequence. Other Names: ○ Opsumit ○ Adcirca • Drug: Macitentan 10 mg Macitentan 10 mg tablet will be administered orally as a free combination as per assigned treatment sequence. Other Name: Opsumit • Drug: Tadalafil 20 mg Tadalafil 20 mg tablet will be administered orally as a free combination as per assigned treatment sequence. Other Name: Adcirca	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: 18 Estimated Enrollment: 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: April 30, 2021 Primary Completion: August 8, 2021 (Final data collection date for primary outcome measure) Study Completion: August 30, 2021 First Posted: September 7, 2020 Results First Posted: Last Update Posted: September 14, 2022
23	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

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
24	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
25	NCT05490888	Single Dose Escalation of PHIN-214 in Child-Pugh A and B Liver Cirrhotics Study Documents:	Title Acronym: Other Ids: PHIN-001	Recruiting	• Cirrhosis, Liver • Liver Fibrosis • Ascites Hepatic	Drug: PHIN-214 Subcutaneous injection Single subcutaneous injection with PHIN-214 terlipressin derivative, single ascending dose Other Name: Terlipressin derivative	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Sequential Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 13 Original Estimated Enrollment: *Same as current* Age: 18 Years to 70 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: January 3, 2022 Primary Completion: December 31, 2022 (Final data collection date for primary outcome measure) Study Completion: February 28, 2023 First Posted: August 8, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
26	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
27	NCT00687765	Study of the Poly (ADP-ribose) Polymerase-1 (PARP-1) Inhibitor BSI-201 in Patients With Newly Diagnosed Malignant Glioma Study Documents:	Title Acronym: Other Ids: TCD11616 20070104 (Other Identifier: BiPar)	Completed	Glioblastoma	Drug: bsi-201 plus temozolomide BSI-201 given iv. 2x weekly, temozolomide given orally	Study Type: Interventional Phase: Phase 1 Phase 2 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: Not Provided	Actual Enrollment: 126 Estimated Enrollment: Original Estimated Enrollment: 100 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: BiPar Sciences Collaborators: Not Provided	Study Start: July 2008 Primary Completion: June 2015 (Final data collection date for primary outcome measure) Study Completion: June 2015 First Posted: June 2, 2008 Results First Posted: Last Update Posted: September 14, 2022