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	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
1	NCT04847531	REVEAL-CKD: Prevalence and Consequences of Undiagnosed Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: D169AR00003	Recruiting	Chronic Kidney Disease	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Retrospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 1000000 Original Estimated Enrollment: 99999 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: December 15, 2020 Primary Completion: October 31, 2022 (Final data collection date for primary outcome measure) Study Completion: October 31, 2022 First Posted: April 19, 2021 Results First Posted: Last Update Posted: September 10, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
2	NCT04099992	Mindfulness in Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: IRB00110956 5R61AT010457 (U.S. NIH Grant/Contract)	Recruiting	Chronic Kidney Diseases	• Behavioral: Mindfulness-based stress reduction (MBSR) Mindfulness-based stress reduction (MBSR) is delivered in 8 weekly 2.5-hour group sessions and one day-long retreat that occurs after the 6th session. MBSR teaches to become more aware of thoughts, feelings, and sensations, and to skillfully respond to stressors. Each of the sessions includes education about mindfulness and stress; experiential mindfulness practice, and discussion of participants' experiences with mindfulness practice. Participants learn formal mindfulness practices (e.g., meditation, yoga, body scan, body scan) as well as informal such as awareness of breath, thoughts, or emotions, and mindfulness of daily activities. Participants will receive digital audio (MP3) downloads with guided MM practices, a home practice manual, and handouts with each week's assignments. Daily home practice will consist of 40-45 minutes of recorded practice. Participants will log their daily practice. If a participant misses a class, it is possible to make up the class on a different day. • Behavioral: Health enhancement program (HEP) 8-week health enhancement program (HEP) is designed to provide a structurally parallel, active control intervention to MBSR with health benefits in their own right, while omitting any components of mindfulness. HEP matches MBSR in structure and content, and in parallel to MBSR, consists of music therapy, nutritional education, posture and balance movements, walking and stretching. Work with all practices with group discussion and exercises during an all-day "spa day" will match the all-day retreat in MBSR. HEP participants will meet with a health educator in a group setting for 8 weekly 2.5-hour sessions. Participants will receive MP3 downloads on an MP3 player with recordings of health education topics, a home listening manual, and weekly handouts with each week's listening assignments. Participants will listen to these MP3 recordings daily for 40-45 minutes and log their daily adherence. • Device: Transcutaneous Vagus Nerve Stimulation (tVNS) Transcutaneous Vagus Nerve Stimulation (tVNS) is delivered using gammaCore (Electrocore), a multi-use, hand-held, rechargeable portable device consisting of a rechargeable battery, signal generating and amplifying electronics, and a button for operator control of the stimulation intensity. Conductive gel is applied to the stainless steel round discs on the device and placed vertically on the skin overlying the vagus nerve under the angle of the mandible, between the trachea and sternocleidomastoid muscle. A low-voltage electrical signal is delivered consisting of 5-kilohertz (kHz) sine wave series for 1 ms and repeated every 40 ms, with a maximum delivery of 24 V and 60 milliampere (mA) output. Stimulation amplitude is adjusted by the user and is increased until there is a vibration and slight muscle contraction in the lower face or neck. Stimulation is delivered for 2 minutes on the left side of the neck, and 2 minutes on the right side of the neck, for a total 4 minutes per one dose. • Device: Sham-transcutaneous Vagus Nerve Stimulation (tVNS) Sham stimulation will be delivered using a sham device that is identical in appearance and function, but programmed to produce a lower frequency biphasic signal that can be felt by the participant without actually stimulating the vagus nerve.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Protocol 1 (R61): 50 CKD participants will be randomized to MBSR (N=25) versus an active control intervention (health enhancement program, HEP; N=25). Protocol 2 (R33): 75 CKD participants will be randomized to MBSR+tVNS (n=25), MBSR+sham-tVNS (n=25), HEP+tVNS (n=25), and HEP+sham-tVNS (n=25). Masking: Triple (Participant, Investigator, Outcomes Assessor) Masking Description: A third-party investigator outside of the research team will label both real and sham devices with a coded number so that both participants and investigators can remain double-masked during the clinical trial. Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 150 Original Estimated Enrollment: 125 Age: 40 Years to 80 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: National Center for Complementary and Integrative Health (NCCIH)	Study Start: September 20, 2019 Primary Completion: August 2025 (Final data collection date for primary outcome measure) Study Completion: August 2025 First Posted: September 23, 2019 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
3	NCT05504850	Multicultural Healthy Diet in Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: 2021-12753	Recruiting	Chronic Kidney Disease	Other: Multicultural Health Diet The food-based components will be similar to the anti-inflammatory diet of the ongoing MHD study (NCT03240406), which emphasizes limiting animal and high saturated fat foods with focus on anti-inflammatory foods/food components specific to the cultural context of the participant. The diet will also be tailored to needs of the CKD population including a focus on lowering sodium intake. The intervention (dietary counseling) will be delivered by experienced kidney disease nutritionist.	Study Type: Interventional Phase: Not Applicable 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: Not Provided	Actual Enrollment: Estimated Enrollment: 20 Original Estimated Enrollment: *Same as current* Age: 18 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 30, 2022 Primary Completion: November 2023 (Final data collection date for primary outcome measure) Study Completion: February 2024 First Posted: August 17, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
4	NCT02411773	Sympatholysis in Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: IRB00078214 2R01HL135183 (U.S. NIH Grant/Contract)	Recruiting	Chronic Kidney Disease	• Drug: Sodium Bicarbonate Sodium bicarbonate tablet is 650 mg for one tablet. Oral sodium bicarbonate will be given out as 1300mg-2600mg (2-4 pills) prior to each exercise or stretching session. Serum bicarbonate measurements will be monitored throughout the study (at 2 weeks, then every 2-4 weeks thereafter), and bicarbonate dosages will be adjusted to avoid metabolic alkalosis (serum HCO3 > 30). • Drug: Placebo 2-4 placebo pills will be given out prior to each exercise or stretching session • Other: Exercise Training Exercise training consists of riding a stationary bicycle for 20-45 minutes, 3 times per week, supervised by trained exercise specialists, for 6-12 weeks. The exercise program will follow the guidelines provided by the American College of Sports Medicine (ACSM) for optimizing cardiovascular fitness. Exercise intensity will begin at low levels (50 percent of resting heart rate) and increase to no greater than 80 percent of resting heart rate. Exercise time will progress, depending on subject's progress, from 20 minutes per session at first, to a maximum of 45 minutes. Trained staff members will give instructions throughout each exercise session. Before beginning each exercise session, subjects will be instructed on a warm-up focusing on preparing the legs for activity. • Other: Stretching Stretching exercise will consist of muscle stretching and toning for 20-45 minutes, 3 times per week, supervised by trained exercise specialists, for 6-12 weeks. Trained staff members will guide subjects with the stretching exercises, and activities are designed to increase flexibility and range of motion. Before beginning each stretching exercise session, subjects will be instructed to warm-up.	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Factorial Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 110 Original Estimated Enrollment: *Same as current* Age: 18 Years to 75 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: National Heart, Lung, and Blood Institute (NHLBI)	Study Start: May 2015 Primary Completion: November 2023 (Final data collection date for primary outcome measure) Study Completion: November 2023 First Posted: April 8, 2015 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
5	NCT05526157	An Observational Study, Called FINEGUST, to Learn More About How People With Chronic Kidney Disease and Type 2 Diabetes Are Treated and How the Introduction of New Treatment Options, Like Finerenone, Impacts Clinical Practice Study Documents:	Title Acronym: Other Ids: 21956	Not yet recruiting	• Chronic Kidney Disease • Type 2 Diabetes Mellitus	• Drug: Finerenone (Kerendia, BAY 948862) Retrospective analysis using secondary data collection from various sources • Drug: Sodium-glucose cotransporter 2 inhibitors (SGLT2i) Retrospective analysis using secondary data collection from various sources • Drug: Glucagon-like peptide-1 receptor agonists (GLP 1 RA) Retrospective analysis using secondary data collection from various sources • Drug: Steroidal mineral corticoid receptor antagonists (sMRA) Retrospective analysis using secondary data collection from various sources • Drug: Non-steroidal mineral corticoid receptor antagonists (nsMRA) Retrospective analysis using secondary data collection from various sources	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Retrospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 50000 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: October 1, 2022 Primary Completion: September 30, 2024 (Final data collection date for primary outcome measure) Study Completion: September 30, 2024 First Posted: September 2, 2022 Results First Posted: Last Update Posted: September 14, 2022
6	NCT01806610	Study of Safety and Tolerability of BPS804 in Patients With Late-stage Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: CBPS804A2204 2012-003348-63 (EudraCT Number)	Withdrawn	Chronic-kidney Disease Stage 5D on Stable Hemodialysis	• Drug: BPS804 Single dose BPS804 administration. Other Name: Active BPS804. • Drug: Placebo Single dose placebo administration. Other Name: BPS804 placebo.	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: 0 Estimated Enrollment: Original Estimated Enrollment: 10 Age: 18 Years to 80 Years (Adult, Older Adult) Sex: All	Study Sponsors: Novartis Pharmaceuticals Collaborators: • Mereo BioPharma • Novartis	Study Start: August 2013 Primary Completion: April 2014 (Final data collection date for primary outcome measure) Study Completion: April 2014 First Posted: March 7, 2013 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
7	NCT04413266	Effects of Curcumin Supplementation in Patients With Chronic Kidney Disease on Peritoneal Dialysis Study Documents:	Title Acronym: Other Ids: Denise Mafra7	Recruiting	• Chronic Kidney Diseases • Peritoneal Dialysis • Hemodialysis	Dietary Supplement: Curcumin supplementation The patients will receive 3 capsules per day containing 500mg of curcumin for 4 weeks Other Names: • Dietary Supplement • Placebo	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: Triple (Participant, Investigator, Outcomes Assessor) Primary Purpose: Health Services Research Primary Outcome Measures: • Antioxidants and anti-inflammatory biomarkers [Time Frame: 4 weeks] Get blood samples to evaluate the supplementation effects in antioxidants biomarkers- nuclear receptor factor 2 (Nrf2), glutathioneperoxidase (GPx), heme oxygenase-1 (HO-1), NQO1 • Inflammatory biomarkers [Time Frame: 4 weeks] Get blood samples to evaluate the supplementation effects in inflammatory biomarkers- factor nuclear kappa B (NFkB), interleukin 6 (IL-6), tumor necrosis factor alpha (TNF-alpha), PCR, IL-1B, IL-18, TBARS, Inflammassome Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 30 Original Estimated Enrollment: *Same as current* Age: 18 Years to 60 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: October 10, 2020 Primary Completion: June 2023 (Final data collection date for primary outcome measure) Study Completion: June 2023 First Posted: June 2, 2020 Results First Posted: Last Update Posted: September 16, 2022
8	NCT04115345	A Study of a Renal Autologous Cell Therapy (REACT®) in Patients With Chronic Kidney Disease (CKD) From Congenital Anomalies of the Kidney and Urinary Tract (CAKUT). Study Documents:	Title Acronym: Other Ids: REGEN-004	Recruiting	• Chronic Kidney Disease • Congenital Anomalies of Kidney and Urinary Tract	Biological: Renal Autologous Cell Therapy (REACT®) Autologous selected renal cells (SRC)	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Intervention Model Description: Open-label Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: Assess change in eGFR and observe incidence of renal-specific procedure and/or product related adverse events (AEs) through 24 months following two Renal Autologous Cell Therapy (REACT) injections [Safety]. [Time Frame: 12 months following last REACT injection] The primary objective is to assess the safety and optimal delivery of Renal Autologous Cell Therapy (REACT) injected at one site in a recipient kidney as measured by procedure- and/or product related adverse events (AEs) through 12 months post-treatment. Secondary Outcome Measures: Number of subjects with renal-specific adverse events over a 24-month period following injection of Renal Autologous Cell Therapy (REACT). [Time Frame: 24 months following last REACT injection] The number of subjects with renal-specific adverse events over a 24-month period following injection of Renal Autologous Cell Therapy (REACT) will be observed utilizing renal-specific laboratory assessments.The secondary objective will compare the results of laboratory tests from baseline through 12 months following REACT injection, followed by an additional observational period of 18 months for a total of 24 months of observation. Each subject's baseline rate of CKD disease progression serves as his/her own "control" to monitor for changes in renal insufficiency over time.	Actual Enrollment: Estimated Enrollment: 15 Original Estimated Enrollment: *Same as current* Age: 18 Years to 65 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: CTI Clinical Trial and Consulting Services	Study Start: August 13, 2019 Primary Completion: March 31, 2023 (Final data collection date for primary outcome measure) Study Completion: May 30, 2023 First Posted: October 4, 2019 Results First Posted: Last Update Posted: September 16, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
9	NCT04538157	Comprehensive Geriatric Assessment for Frail Older People With Chronic Kidney Disease - The GOAL Trial Study Documents:	Title Acronym: Other Ids: AKTN 20.01	Recruiting	• Frailty • Chronic Kidney Diseases	Other: Comprehensive Geriatric Assessment A CGA is a diagnostic and therapeutic intervention which initially identifies an older person's medical, functional, psychosocial problems and then tailors coordinated management plans to address them. Other Name: CGA	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Single (Outcomes Assessor) Primary Purpose: Supportive Care Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 500 Original Estimated Enrollment: *Same as current* Age: 55 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: National Health and Medical Research Council, Australia	Study Start: March 15, 2021 Primary Completion: March 30, 2023 (Final data collection date for primary outcome measure) Study Completion: December 31, 2023 First Posted: September 3, 2020 Results First Posted: Last Update Posted: September 14, 2022
10	NCT05540431	Evaluation of Protective Effect of Activated Charcoal and Probiotic Against Progression of Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: Uremic toxin in CKD	Not yet recruiting	Uremic Toxin	• Drug: Activated Charcoal RCT • Dietary Supplement: Probiotic RCT • Other: No intervention RCT	Study Type: Interventional Phase: Phase 2 Phase 3 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Interventional (clinical trial) Masking: None (Open Label) Masking Description: None (Open Label) Primary Purpose: Prevention Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 60 Original Estimated Enrollment: *Same as current* Age: 18 Years to 90 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 25, 2022 Primary Completion: September 20, 2023 (Final data collection date for primary outcome measure) Study Completion: December 20, 2023 First Posted: September 14, 2022 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
11	NCT03299816	Five, Plus Nuts and Beans for Kidneys Study Documents:	Title Acronym: Other Ids: IRB00122943 1U01MD010550-01 (U.S. NIH Grant/Contract)	Completed	• Chronic Kidney Disease • Hypertension	• Behavioral: Coaching DASH group (C-DASH) Participants assigned to the C-DASH diet advice group will be provided $30/week worth of fruits, vegetables, nuts and beans ordered through the study coach and delivered to a community location to reach a certain goal of potassium intake (months 0-4). During phase 2 of the study (months 5-12), a study coach will continue telephonic contact with the participants to set goals for following a DASH-like diet without the weekly food allowance. Other Name: Coaching DASH diet advice group (C-DASH) • Behavioral: Self-Shopping DASH group (S-DASH) Participants will be given a brochure containing information about the DASH diet which will be reviewed with a study team member. In months 1-4, participants will receive a gift card equivalent to a weekly allowance of $30 to Klein's ShopRite stores of Maryland for purchases of food and beverages of their choice. During phase two (months 5-12), they will be asked to continue following a DASH-like diet but will not receive a gift card for purchases. Other Name: Self-Shopping DASH diet advice Group (S-DASH)	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Single center, randomized controlled trial with two parallel arms. Masking: Single (Outcomes Assessor) Primary Purpose: Treatment Primary Outcome Measures: • Change in Albuminuria from Baseline to 1 month [Time Frame: Baseline, 1 month] Urine samples will be collected for ACR (albumin-to-creatinine ratio). Albuminuria is defined as an ACR 30 mg/g. • Change in Albuminuria from Baseline to 4 months [Time Frame: Baseline, 4 months] Urine samples will be collected for ACR (albumin-to-creatinine ratio). Albuminuria is defined as an ACR 30 mg/g. • Change in Albuminuria from Baseline to end of study [Time Frame: Baseline, end of study (approximately 12 months)] Urine samples will be collected for ACR (albumin-to-creatinine ratio). Albuminuria is defined as an ACR 30 mg/g. Secondary Outcome Measures: • Change in Systolic Blood Pressure [Time Frame: Baseline, 1 month] Daytime systolic blood pressure monitoring will be determined using OMRON 907-xl • Change in Systolic Blood Pressure [Time Frame: Baseline,4 months] Daytime systolic blood pressure monitoring will be determined using OMRON 907-xl • Change in Systolic Blood Pressure [Time Frame: Baseline, end of study (approximately 12 months)] Daytime systolic blood pressure monitoring will be determined using OMRON 907-xl	Actual Enrollment: 142 Estimated Enrollment: Original Estimated Enrollment: 150 Age: 21 Years to 100 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: National Institute on Minority Health and Health Disparities (NIMHD)	Study Start: February 22, 2018 Primary Completion: November 22, 2021 (Final data collection date for primary outcome measure) Study Completion: December 8, 2021 First Posted: October 3, 2017 Results First Posted: Last Update Posted: September 15, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
12	NCT05457283	A Study to Learn More About How Safe the Study Treatment Finerenone is in Long-term Use When Taken With an ACE Inhibitor or Angiotensin Receptor Blocker Over 18 Months of Use in Children and Young Adults From 1 to 18 Years of Age With Chronic Kidney Disease and Proteinuria Study Documents:	Title Acronym: Other Ids: 20186 2021-002905-89 (EudraCT Number)	Not yet recruiting	• Chronic Kidney Disease • Proteinuria • Children	Drug: Finerenone (Kerendia, BAY94-8862) Finerenone in different doses, treatment duration will be 540 ±7 days.	Study Type: Interventional Phase: Phase 3 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: 100 Original Estimated Enrollment: *Same as current* Age: 1 Year to 18 Years (Child, Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: November 2, 2022 Primary Completion: February 11, 2028 (Final data collection date for primary outcome measure) Study Completion: March 12, 2028 First Posted: July 13, 2022 Results First Posted: Last Update Posted: September 13, 2022
13	NCT05536804	A Study of Tirzepatide (LY3298176) in Participants With Overweight or Obesity and Chronic Kidney Disease With or Without Type 2 Diabetes Study Documents:	Title Acronym: Other Ids: 17217 I8F-MC-GPIG (Other Identifier: Eli Lilly and Company) 2021-005273-47 (EudraCT Number)	Not yet recruiting	• Overweight • Obesity • Chronic Kidney Disease • Type 2 Diabetes • T2D	• Drug: Tirzepatide Administered SC • Drug: Placebo Administered SC	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: 140 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: October 14, 2022 Primary Completion: October 10, 2025 (Final data collection date for primary outcome measure) Study Completion: November 7, 2025 First Posted: September 13, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
14	NCT05543291	Multi-omics Analysis of Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: SHYS-IEC-5.0/22K162/P01	Recruiting	Potential Mechanisms Underlying the Microbiota-Gut-Kidney Axis in CKD	Behavioral: renal function levels of eGFR	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: 150 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: January 1, 2022 Primary Completion: December 31, 2024 (Final data collection date for primary outcome measure) Study Completion: December 31, 2024 First Posted: September 16, 2022 Results First Posted: Last Update Posted: September 16, 2022
15	NCT05254002	A Study to Learn How Well the Treatment Combination of Finerenone and Empagliflozin Works and How Safe it is Compared to Each Treatment Alone in Adult Participants With Long-term Kidney Disease (Chronic Kidney Disease) and Type 2 Diabetes Study Documents:	Title Acronym: Other Ids: 21839 2021-003037-11 (EudraCT Number)	Recruiting	• Type 2 Diabetes Mellitus • Chronic Kidney Disease	• Drug: Finerenone (Kerendia, BAY94-8862) oral administration, once daily • Drug: Empagliflozin oral administration, once daily • Drug: Placebo oral administration, once daily Other Name: Placebo to finerenone, and placebo to empagliflozin	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment 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: Estimated Enrollment: 807 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 23, 2022 Primary Completion: December 15, 2023 (Final data collection date for primary outcome measure) Study Completion: January 12, 2024 First Posted: February 24, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
16	NCT05531214	Creating A Cardiorenal Multidisciplinary Team for Management HF and CKD Patients Study Documents:	Title Acronym: Other Ids: NCR224155	Recruiting	• Heart Failure • Chronic Kidney Diseases	Behavioral: Multidisciplinary Care Coordination Team The intervention group will be patients whose primary care clinicians will be receiving guidance and recommendations from the multidisciplinary team consisting of cardiologists, nephrologists, and specialty pharmacists.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Our pragmatic randomized controlled trial will firstly identify primary care clinicians (PCCs) currently working at the George Washington University Medical Faculty Associates (GW-MFA) who care for adult patients diagnosed with both heart failure with a reduced ejection fraction (HFrEF) and chronic kidney disease (CKD). 164 patients who meet our inclusion criteria will be first identified via their respective PCCs at the GW-MFA. These PCCs will be randomized to the control and intervention arms, and the intervention arm will be receiving recommendations from a multidisciplinary team of cardiologists and nephrologists. Masking: Single (Participant) Masking Description: These primary care clinicians will then be block randomized using a 1:1 ratio to either arm of treatment utilizing random number generation. Primary care clinicians will be stratified by the size of their individual practices, and patients will be stratified by EF prior to their enrollment to balance the representation of patients with HFrEF (EF < 50%) and heart failure with mildly reduced ejection fraction (HFmrEF) (EF 41-49%), respectively. Primary Purpose: Other Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 160 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 1, 2022 Primary Completion: January 1, 2023 (Final data collection date for primary outcome measure) Study Completion: June 1, 2023 First Posted: September 7, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
17	NCT04724837	Zibotentan and Dapagliflozin for the Treatment of CKD (ZENITH-CKD Trial) Study Documents:	Title Acronym: Other Ids: D4325C00001 2020-004101-32 (EudraCT Number)	Recruiting	Chronic Kidney Disease	• Drug: Zibotentan Participants will receive zibotentan as per the arms they are randomized. • Drug: Dapagliflozin Participants will receive dapagliflozin as per the arms they are randomized. • Drug: Placebo Participants will receive placebo as per the arms they are randomized to.	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Triple (Participant, Care Provider, Investigator) Primary Purpose: Treatment Primary Outcome Measures: Change in Log-transformed Urinary Albumin to Creatinine Ratio (UACR) from baseline to Week 12 [Time Frame: From baseline (Week 0 [Day 1]) until Week 12 (Day 84)] Integrated data from Part A and B will be used for assessment of effect of zibotentan and dapagliflozin in combination and alone versus placebo on UACR. Secondary Outcome Measures: • Change in Log-transformed UACR from baseline to Week 12 [Time Frame: From baseline (Week 0 [Day 1]) until Week 12 (Day 84)] Integrated data from Part A and B will be used for assessment of the change in UACR for doses of zibotentan combined with 10 mg dapagliflozin versus 10 mg dapagliflozin alone. • Change in Blood Pressure from baseline to Week 12 [Time Frame: From baseline (Week 0 [Day 1]) until Week 12 (Day 84)] Integrated data from Part A and B will be used for assessment of the change in office systolic and diastolic blood pressure (BP) for doses of zibotentan combined with 10 mg dapagliflozin and for zibotentan and 10 mg dapagliflozin alone versus placebo. Integrated data from Part A and B • Least Squares Mean Change of UACR at Week 12 for Zibotentan and Dapagliflozin in Combination and Dapagliflozin alone [Time Frame: At Week 12 (Day 84)] Integrated data from Part A and B will be used for assessment of dose-response significance and relationship across different dose of zibotentan/dapagliflozin and dapagliflozin alone on UACR reduction. Integrated data from Part A and B. • Change in eGFR from Baseline to Week 1, Week 12 and Week 14 [Time Frame: From baseline (Week 0 [Day 1]) until Week 1, Week 12, and Week 14] Integrated data from Part A and B will be used for assessment of the effect of ranging doses of zibotentan and dapagliflozin in combination and alone on eGFR. • Change in eGFR from Week 1 to Week 12 [Time Frame: From Week 1 (Day 8) until Week 12 (Day 84)] Integrated data from Part A and B will be used for assessment of the effect of ranging doses of zibotentan and dapagliflozin in combination and alone on eGFR. • Number of Participants Experiencing Adverse events [Time Frame: From Week 0 (Day 1) until Follow-up visit (Week 14 [Day 98])] Integrated data from Part A and B will be used for assessment of the safety and tolerability of ranging doses of zibotentan and dapagliflozin in combination and alone versus placebo.	Actual Enrollment: Estimated Enrollment: 495 Original Estimated Enrollment: 660 Age: 18 Years to 130 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: April 28, 2021 Primary Completion: March 10, 2023 (Final data collection date for primary outcome measure) Study Completion: March 10, 2023 First Posted: January 26, 2021 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
18	NCT05544513	Oral Iron Supplementation for Patients With Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: DeniseMafra14	Active, not recruiting	• Chronic Renal Disease • Iron-Deficiency Anemia • Anemia of Chronic Kidney Disease • Dysbiosis	Drug: Ferrous sulfate Ferrous sulfate supplementation	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Single (Participant) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: *Same as current* Estimated Enrollment: Original Estimated Enrollment: Age: 18 Years to 75 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: August 1, 2022 Primary Completion: December 29, 2023 (Final data collection date for primary outcome measure) Study Completion: December 30, 2026 First Posted: September 16, 2022 Results First Posted: Last Update Posted: September 16, 2022
19	NCT05543928	Phase 3 Safety and Efficacy Study of CTAP101 Extended-release Capsules in Children With Secondary Hyperparathyroidism Study Documents:	Title Acronym: Other Ids: CTAP101-CL-3007	Not yet recruiting	• Chronic Kidney Disease stage3 • Chronic Kidney Disease stage4 • Vitamin d Deficiency • Secondary Hyperparathyroidism	• Drug: CTAP101 CTAP101 Capsules is an extended-release (ER) oral formulation of calcifediol which was approved as Rayaldee® ER Capsules in June 2016 by the United States (US) Food and Drug Administration (FDA) for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency (VDI), defined as serum total 25-hydroxyvitamin D levels less than 30 ng/mL. • Drug: Placebo Placebo	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Randomized Intervention Model: Sequential Assignment 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: Estimated Enrollment: 108 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: October 2022 Primary Completion: July 2025 (Final data collection date for primary outcome measure) Study Completion: July 2025 First Posted: September 16, 2022 Results First Posted: Last Update Posted: September 16, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
20	NCT03832595	Kidney Coordinated Health Management Partnership Study Documents:	Title Acronym: Other Ids: PRO18070620 R18DK118460 (U.S. NIH Grant/Contract) 1R01DK116957-01A1 (U.S. NIH Grant/Contract)	Enrolling by invitation	Chronic Kidney Diseases	• Other: Intervention Arm An EHR in-basket message will be sent to the patient's PCP which identifies the patient's high-risk CKD status and indicates that the patient will receive: 1. Nephrologist led electronic consultation: review of the patient's EHR with recommendations sent to the PCP every ~6 months, 2. Medication therapy management: PharmD led telephonic medication therapy management with the patient every ~6 months, 3. and Nurse led CKD patient education, every ~6-12 months unless the PCP opts the patient out of the interventions (by responding to the EHR in-basket message and providing an opt-out reason or requesting an office consultation with nephrology). • Other: Usual Care Patients in the usual care arm will continue to receive CKD care guided by their PCPs as per usual care practices (i.e., specialty consultation, pharmacotherapy, nurse education, etc. may be ordered by the PCP according to their usual practice).	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Cluster randomized controlled trial with randomization occurring at the Primary Care Physician practice level Masking: Single (Outcomes Assessor) Masking Description: outcomes are ascertained by data programmers who are blinded to study arm assignment Primary Purpose: Treatment Primary Outcome Measures: Decline in estimated Glomerular Filtration Rate (eGFR) or End Stage Renal Disease (ESRD) [Time Frame: Through study completion, an average of 24 months] A less than or equal to 40% decline in eGFR or ESRD. eGFR decline will be adjudicated based on the baseline creatinine and eGFR determined from the CKD-epidemiology (CKD-EPI) equation and measured routinely in clinical practice. ESRD will be defined as an eGFR less than or equal to 10ml/min to account for patients with markedly reduced baseline eGFR values (i.e., 16-20ml/min). Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 1650 Original Estimated Enrollment: *Same as current* Age: 18 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • Vanderbilt University Medical Center • National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	Study Start: May 1, 2019 Primary Completion: July 31, 2022 (Final data collection date for primary outcome measure) Study Completion: August 2024 First Posted: February 6, 2019 Results First Posted: Last Update Posted: September 13, 2022
21	NCT05348733	A Study Called FINE-REAL to Learn More About the Use of the Drug Finerenone in a Routine Medical Care Setting Study Documents:	Title Acronym: Other Ids: 21785	Recruiting	• Chronic Kidney Disease • Type 2 Diabetes Mellitus	Drug: Kerendia (Finerenone, BAY94-8862) Decision will taken by the treating physician to initiate treatment with finerenone.	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: • Descriptive analysis of clinical characteristics of patients with chronic kidney disease (CKD) and with type 2 diabetes(T2D). [Time Frame: Approximately 42 months] • Descriptive summary of reasons for introducing finerenone. [Time Frame: Approximately 42 months] • Descriptive summary of reasons for discontinuation of finerenone. [Time Frame: Approximately 42 months] • Planned and actual duration of treatment with finerenone [Time Frame: Approximately 42 months] • Descriptive summary of dose of finerenone treatment [Time Frame: Approximately 42 months] • Descriptive summary of frequency of finerenone treatment [Time Frame: Approximately 42 months] • Descriptive summary of concomitant medication used in patients with CKD and T2D. [Time Frame: Approximately 42 months] Secondary Outcome Measures: • Occurrence of adverse events (AEs) and serious adverse events (SAEs) [Time Frame: Approximately 42 months] • Occurrence of hyperkalemia [Time Frame: Approximately 42 months] leading to study drug discontinuation, dialysis or hospitalization	Actual Enrollment: Estimated Enrollment: 4000 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 13, 2022 Primary Completion: November 15, 2025 (Final data collection date for primary outcome measure) Study Completion: March 15, 2026 First Posted: April 27, 2022 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
22	NCT00345839	E.V.O.L.V.E. Trial™: EValuation Of Cinacalcet Hydrochloride (HCl) Therapy to Lower CardioVascular Events Study Documents:	Title Acronym: Other Ids: 20050182	Completed	• Secondary Hyperparathyroidism • Chronic Kidney Disease	• Drug: Cinacalcet Possible doses: 30, 60, 90, 120, and 180 mg using tablet strengths of 30, 60, or 90 mg. Sequential titration starting at 30 mg daily (QD), once every 4 weeks for the first 20 weeks and once every 8 weeks after Week 20. Titration increases or decreases based on PTH values, serum calcium, and safety. Daily dosing unless temporary hold criteria or withdrawal criteria is met, or until study completion; estimated 2.5 to 4 years of intervention. • Drug: Placebo Possible doses: 30, 60, 90, 120, and 180 mg using tablet strengths of 30, 60, or 90 mg. Sequential titration starting at 30 mg QD, once every 4 weeks for the first 20 weeks and once every 8 weeks after Week 20. Titration increases or decreases based on PTH values, serum calcium, and safety. Daily dosing unless temporary hold criteria or withdrawal criteria is met, or until study completion; estimated 2.5 to 4 years of intervention.	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Investigator) Primary Purpose: Treatment Primary Outcome Measures: Time to the composite event comprising all-cause mortality or non-fatal cardiovascular events (MI, hospitalization for unstable angina, HF, or peripheral vascular event) Secondary Outcome Measures: • Time to all-cause mortality • Time to cardiovascular mortality • Time to fatal and non-fatal MI • Time to fatal and non-fatal hospitalization for unstable angina • Time to fatal and non-fatal HF event • Time to fatal and non-fatal peripheral vascular event • Time to fatal and non-fatal stroke • Time to bone fracture • Time to parathyroidectomy	Actual Enrollment: 3883 Estimated Enrollment: Original Estimated Enrollment: Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: August 22, 2006 Primary Completion: April 10, 2012 (Final data collection date for primary outcome measure) Study Completion: April 10, 2012 First Posted: January 22, 2014 Results First Posted: January 22, 2014 Last Update Posted: September 10, 2022
23	NCT05142501	Observation of the Immune Response After COVID-19 Additional Vaccine Doses in Chronic Patients in Hemodialysis Therapy Study Documents:	Title Acronym: Other Ids: HD-COVID-IR-EU	Terminated	• Chronic Kidney Diseases • COVID-19 • Hemodialysis	Other: Blood samples Four consecutive blood sampling throughout the overall follow-up period of 12 months.	Study Type: Observational Phase: Study Design: Observational Model: Other Time Perspective: Prospective Primary Outcome Measures: Humoral immune response [Time Frame: 12 months after start of study] The humoral immune response will be assessed at four different timepoints (Sample 1: prior to the third vaccine dose; sample 2: 1 months after the third vaccine dose; sample 3: 6 months after the third vaccine dose; sample 4: 12 months after the third vaccine dose or max. 4 weeks prior to the fourth vaccine dose, whichever comes first) through the measurement of the titers of Bioplex IgG antibody panel in study participant's blood samples. Secondary Outcome Measures: Not Provided	Actual Enrollment: 23 Estimated Enrollment: Original Estimated Enrollment: 340 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: April 25, 2022 Primary Completion: September 2, 2022 (Final data collection date for primary outcome measure) Study Completion: September 2, 2022 First Posted: December 2, 2021 Results First Posted: Last Update Posted: September 15, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
24	NCT05524467	Cross-sectional Study to Assess Prevalence and Burden of CKD-associated Pruritus in Haemodialysis Patients Study Documents:	Title Acronym: Other Ids: CS-DFK-2021-0712	Not yet recruiting	Chronic Kidney Disease-associated Pruritus	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Cross-Sectional Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 4810 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: November 2022 Primary Completion: September 2023 (Final data collection date for primary outcome measure) Study Completion: December 2023 First Posted: September 1, 2022 Results First Posted: Last Update Posted: September 13, 2022
25	NCT05497700	Comparative Efficacity of Ephedrine Versus Norepinephrine to Correct Anesthesia Induction Related Hypotension Study Documents:	Title Acronym: Other Ids: VASO_IRC	Recruiting	Hypotension on Induction	• Drug: Ephedrine Bolus injection of 6 mg ephedrine to keep mean arterial blood pressure above 65 mm Hg • Drug: Norepinephrine Bolus injection of either 6 mcg norepinephrine to keep mean arterial blood pressure above 65 mm Hg	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) Masking Description: Drug will be prepared by an anesthesia nurse not involved in the care of the patient and labeled as "VASO-IRC-inclusion number". Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 60 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: September 15, 2022 Primary Completion: September 30, 2023 (Final data collection date for primary outcome measure) Study Completion: October 30, 2023 First Posted: August 11, 2022 Results First Posted: Last Update Posted: September 16, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
26	NCT02683889	Use of Acthar in Patients With FSGS That Will be Undergoing Renal Transplantation Study Documents:	Title Acronym: Other Ids: 17-2336	Recruiting	FSGS	Drug: Acthar patients will receive acthar 80 units twice a week for 6 months and will measure recurrence of FSGS	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Prevention 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 to 80 Years (Adult, Older Adult) Sex: All	Study Sponsors: Georgetown University Collaborators: Not Provided	Study Start: February 1, 2019 Primary Completion: December 2023 (Final data collection date for primary outcome measure) Study Completion: December 2023 First Posted: February 17, 2016 Results First Posted: Last Update Posted: September 16, 2022
27	NCT05288452	Food Delivery, Remote Monitoring, and Coaching-Enhanced Education for Optimized Diabetes Management (FREEDOM) Study Documents:	Title Acronym: Other Ids: IRB-300008387	Not yet recruiting	Diabetes Mellitus, Type 2	• Behavioral: Digital Health Coaching The digital health coaching intervention program involves an evidence-based curriculum and one-on-one support to promote positive health behaviors and patient self-management of diabetes. • Dietary Supplement: Food Box Delivery The food box intervention component will consist of biweekly food boxes delivered directly to participants over the course of 6 months. The food boxes will contain shelf-stable groceries that adhere to ADA nutritional guidelines for individuals with T2DM. • Behavioral: Remote Patient Monitoring (RPM) The RPM team will instruct the participants to monitor blood glucose levels 4 times daily. Glucose levels will be monitored 8 a.m. to 5 p.m.Monday to Friday. Data summaries will be reviewed bi-monthly with RNs and pharmacists. Participants will be provided with a glucometer, test strips, and mobile divide to record their blood glucose levels. • Behavioral: Core Intervention: Diabetes Self-Management Education and Support (DSMES) Program DSMES program is certified by the American Diabetes Association (ADA) and provided by an ADA-certified diabetes educator. DSMES includes 4-6 hours of interactive group classes covering topics related to diabetes management.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Factorial Assignment Intervention Model Description: We used the multiphase optimization strategy (MOST) as the ideal approach for the proposed study as, with the three proposed intervention components, identifying an optimal intervention through a single randomized controlled trial (RCT) with multiple arms or through multiple RCTs would be methodologically inefficient and resource-intensive. Given this, we rely on the eloquent and rigorous MOST-based optimization design, which leverages factorial experimentation to identify an optimal set of intervention component(s). In a factorial experiment, the goal is not to compare individual experimental conditions (in this case, eight conditions), but to use combinations of conditions to estimate the main and interaction effects of the intervention components. Thus, numerous intervention components can be evaluated simultaneously while utilizing the entire randomized sample. Masking: Single (Investigator) Primary Purpose: Supportive Care Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 304 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • University of Mississippi Medical Center • Cooper Green Mercy Health Systems • Pack Health	Study Start: November 15, 2022 Primary Completion: December 1, 2024 (Final data collection date for primary outcome measure) Study Completion: December 1, 2026 First Posted: March 21, 2022 Results First Posted: Last Update Posted: September 10, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
28	NCT03736005	Skeletal Muscle Wasting and Renal Dysfunction After Critical Illness Trauma - Outcomes Study Study Documents:	Title Acronym: Other Ids: KRATOSProtocolv1.2	Completed	• Critical Illness • Acute Kidney Injury • Muscle Loss • Major Trauma • Quality of Life • Chronic Kidney Diseases	Other: Exposure of significant critical illness Exposure. Observational study with all patients invited to follow-up clinic for kidney, muscle and functional assessments.	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: 40 Estimated Enrollment: Original Estimated Enrollment: 62 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: December 19, 2018 Primary Completion: December 1, 2021 (Final data collection date for primary outcome measure) Study Completion: January 1, 2022 First Posted: November 8, 2018 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
29	NCT03534141	Mild Hypothermia and Acute Kidney Injury in Liver Transplantation Study Documents:	Title Acronym: Other Ids: 17-22384	Recruiting	• Cirrhosis • End Stage Liver Disease • Acute Kidney Injury • Liver Transplant; Complications • Chronic Kidney Diseases • Hepatitis c • Hepatitis B • NASH - Nonalcoholic Steatohepatitis • Alcoholic Cirrhosis • Hepatocellular Carcinoma	• Device: Esophageal cooling/warming device The EnsoETM (formerly known as Esophageal Cooling Device) is a non-sterile multilumen silicone tube placed in the esophagus for the purpose of cooling or warming a patient while allowing gastric decompression and drainage. It is placed in a manner identical to a standard orogastric tube, which is standard equipment for liver transplant surgery. It is removed at the end of surgery. Control of the patient's temperature is achieved by connecting the EnsoETM to an external heat exchanger (Gaymar Medi-Therm III or similar system). The Medi-Therm III is a standard device used in operating rooms for warming patients with a conductive table warming pad. The Medi-Therm III circulates temperature-controlled water through a closed-loop system via the two outer lumens of the EnsoETM. Water temperature ranges from 4°C - 42°C. Other Names: ○ EnsoETM ○ ECD - Esophageal Cooling Device • Other: Mild hypothermia Cooling will be initiated after induction of anesthesia and maintained throughout the anhepatic phase of liver transplantation. In all feasible cases the surgeon will cover the peritoneal surface over the right kidney , which is exposed during the operation, with ice-cold sponges to enhance cooling of the renal parenchyma. After blood flow is completely restored to the liver, the esophageal cooling device and other standard measures (forced-air, fluid, and table warmers, plus a heated anesthesia circuit) will be used to actively re-warm the patient (expected warming rate 1 deg C/hour). The goal is to achieve normothermia by case end. • Other: Normothermia After induction of anesthesia, the esophageal cooling/warming device and standard warming measures will be used to maintain normothermia throughout the operation.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Outcomes Assessor) Primary Purpose: Prevention Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 230 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • University of Colorado, Denver • The Methodist Hospital Research Institute	Study Start: July 7, 2018 Primary Completion: June 30, 2023 (Final data collection date for primary outcome measure) Study Completion: December 31, 2023 First Posted: May 23, 2018 Results First Posted: Last Update Posted: September 14, 2022