# ClinicalTrials.gov: chronic kidney diseases | Last update posted in the last 7 days

| | NCT Number | Title | Other Names | Status | Conditions | Interventions | Characteristics | Population | Sponsor/Collaborators | Dates |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | NCT04411758 | Propolis for Patients With Chronic Kidney Disease.<br>Study Documents: | Title Acronym:<br>Other Ids: Denise Mafra8 | Recruiting | • Chronic Kidney Diseases<br>• Inflammation | Dietary Supplement: Propolis<br>4 capsules of 500mg/day containing concentrated and standardized dry EPP-AF® green propolis extract for 2 months and after washout, more two months crossover | Study Type: Interventional<br>Phase: Not Applicable<br>Study Design: Allocation: Randomized<br>Intervention Model: Crossover Assignment<br>Intervention Model Description: In this clinical trial, participants with CKD undergoing hemodialysis or peritoneal dialysis will be instructed to use 4 capsules of 500mg/day containing concentrated and standardized dry EPP-AF® green propolis extract for 2 months or placebo (4 capsules of 500mg/day of magnesium stearate, silicon dioxide and microcrystalline cellulose) for two months, and then the groups will be crossed and will receive the same amount of propolis as the first group.<br>Masking: Triple (Participant, Investigator, Outcomes Assessor)<br>Primary Purpose: Health Services Research<br>Primary Outcome Measures:<br>• Change in cytokines plasma levels measured by ELISA after supplementation with propolis. [ Time Frame: 4 months ]<br>• Change the expression of transcription factors (Nrf2 and NF-kB), antioxidant enzymes (NQO1, HO-1), NLRP3 receptor, PPAR- [ Time Frame: 4 months ]<br>• Change the profile of the intestinal microbiota of stool samples [ Time Frame: 4 months ]<br>Secondary Outcome Measures: Not Provided | Actual Enrollment:<br>Estimated Enrollment: 60<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years to 65 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: January 12, 2021<br>Primary Completion: May 29, 2023 (Final data collection date for primary outcome measure)<br>Study Completion: June 20, 2023<br>First Posted: June 2, 2020<br>Results First Posted:<br>Last Update Posted: September 19, 2022 |
| 2 | NCT05550467 | 24-hour Urinary Electrolyte Excretion in Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: 2015BAI12B06-03 | Completed | • Chronic Kidney Diseases<br>• Electrolyte Imbalance | Not Provided | Study Type: Observational<br>Phase:<br>Study Design: Observational Model: Cohort<br>Time Perspective: Retrospective<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment: *Same as current*<br>Estimated Enrollment:<br>Original Estimated Enrollment:<br>Age: 18 Years to 100 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: January 1, 2014<br>Primary Completion: July 30, 2022 (Final data collection date for primary outcome measure)<br>Study Completion: July 31, 2022<br>First Posted: September 22, 2022<br>Results First Posted:<br>Last Update Posted: September 22, 2022 |

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| 3 | NCT01652872 | Strategies Using Darbepoetin Alfa to Avoid Transfusions in Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: 20110226 | Completed | Anemia in Chronic Kidney Disease Patients Not on Dialysis | • Biological: Darbepoetin alfa<br>Darbepoetin alfa was presented as single use prefilled syringes (PFS). Investigational product was administered SC Q4W for the duration of the treatment period.<br>Other Name: Aranesp<br>• Other: Placebo<br>Placebo was presented as single use PFS. Participants received a SC placebo injection in place of darbepoetin alfa therapy when the dose of study drug was withheld per the dosing algorithm for the duration of the treatment period. | Study Type: Interventional<br>Phase: Phase 3<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Triple (Participant, Care Provider, Investigator)<br>Primary Purpose: Treatment<br>Primary Outcome Measures: Receipt of 1 or more RBC transfusion [ Time Frame: Approximately 2 years ]<br>Secondary Outcome Measures:<br>• Total number of units of red blood cells (RBC) transfused. Time to first red blood cell transfusion. [ Time Frame: Approximately 2 years ]<br>• Average achieved hemoglobin (Hb) concentration while receiving investigational product. [ Time Frame: Up to 2 years ]<br>• Cumulative dose of darbepoetin alfa [ Time Frame: Up to 2 years ]<br>• Time to first RBC transfusion [ Time Frame: From randomization to the first RBC transfusion ] | Actual Enrollment: 756<br>Estimated Enrollment:<br>Original Estimated Enrollment: 750<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: July 30, 2012<br>Primary Completion: October 19, 2017 (Final data collection date for primary outcome measure)<br>Study Completion: October 19, 2017<br>First Posted: November 8, 2018<br>Results First Posted: November 8, 2018<br>Last Update Posted: September 21, 2022 |
| 4 | NCT04413266 | Effects of Curcumin Supplementation in Patients With Chronic Kidney Disease on Peritoneal Dialysis<br>Study Documents: | Title Acronym:<br>Other Ids: Denise Mafra7 | Recruiting | • Chronic Kidney Diseases<br>• Peritoneal Dialysis<br>• Hemodialysis | Dietary Supplement: Curcumin supplementation<br>The patients will receive 3 capsules per day containing 500mg of curcumin for 4 weeks<br>Other Names:<br>• Dietary Supplement<br>• Placebo | Study Type: Interventional<br>Phase: Not Applicable<br>Study Design: Allocation: Randomized<br>Intervention Model: Crossover Assignment<br>Masking: Triple (Participant, Investigator, Outcomes Assessor)<br>Primary Purpose: Health Services Research<br>Primary Outcome Measures:<br>• Antioxidants and anti-inflammatory biomarkers [ Time Frame: 4 weeks ]<br>Get blood samples to evaluate the supplementation effects in antioxidants biomarkers- nuclear receptor factor 2 (Nrf2), glutathioneperoxidase (GPx), heme oxygenase-1 (HO-1), NQO1<br>• Inflammatory biomarkers [ Time Frame: 4 weeks ]<br>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<br>Secondary Outcome Measures: Not Provided | Actual Enrollment:<br>Estimated Enrollment: 30<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years to 60 Years (Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: October 10, 2020<br>Primary Completion: June 2023 (Final data collection date for primary outcome measure)<br>Study Completion: June 2023<br>First Posted: June 2, 2020<br>Results First Posted:<br>Last Update Posted: September 16, 2022 |

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| 5 | NCT05342623 | A Study to Evaluate the Safety and Efficacy of Difelikefalin in Advanced Chronic Kidney Disease Patients With Moderate-to-Severe Pruritus and Not on Dialysis<br>Study Documents: | Title Acronym:<br>Other Ids: CR845-310301 | Recruiting | • Chronic Kidney Diseases<br>• Pruritus | • Drug: Difelikefalin 1 mg Oral Tablet<br>Difelikefalin 1 mg medication taken orally 1 time/day<br>Other Name: CR845<br>• Drug: Placebo Oral Tablet<br>Placebo tablet taken orally 1 time/day | Study Type: Interventional<br>Phase: Phase 3<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Intervention Model Description:<br>Randomized, double-blind, placebo controlled study<br>Masking: Double (Participant, Investigator)<br>Masking Description:<br>Difelikefalin and placebo will be provided as enteric-coated tablets. All tablets are white in color with no markings and are identical in appearance. Difelikefalin tablets will be provided at doses of 1 mg.<br>Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 400<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years to 85 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: May 17, 2022<br>Primary Completion: July 2024 (Final data collection date for primary outcome measure)<br>Study Completion: October 2024<br>First Posted: April 22, 2022<br>Results First Posted:<br>Last Update Posted: September 19, 2022 |
| 6 | 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).<br>Study Documents: | Title Acronym:<br>Other Ids: REGEN-004 | Recruiting | • Chronic Kidney Disease<br>• Congenital Anomalies of Kidney and Urinary Tract | Biological: Renal Autologous Cell Therapy (REACT®)<br>Autologous selected renal cells (SRC) | Study Type: Interventional<br>Phase: Phase 1<br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Intervention Model Description:<br>Open-label<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br>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 ]<br>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.<br>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 ]<br>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:<br>Estimated Enrollment: 15<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years to 65 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: CTI Clinical Trial and Consulting Services | Study Start: August 13, 2019<br>Primary Completion: March 31, 2023 (Final data collection date for primary outcome measure)<br>Study Completion: May 30, 2023<br>First Posted: October 4, 2019<br>Results First Posted:<br>Last Update Posted: September 16, 2022 |

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| 7 | NCT05196035 | A Study to Learn More About How Well the Study Treatment Finerenone Works, How Safe it is, How it Moves Into, Through, and Out of the Body, and the Effects it Has on the Body When Taken With an ACE Inhibitor or Angiotensin Receptor Blocker in Children With Chronic Kidney Disease and Proteinuria<br><br>Study Documents: | Title Acronym:<br><br>Other Ids: 19920 2021-002071-19 ( EudraCT Number ) | Recruiting | • Chronic Kidney Disease<br>• Proteinuria | • Drug: Finerenone (Kerendia, BAY94-8862)<br>Finerenone in different doses, treatment duration will be 180±7 days<br>• Drug: Placebo<br>Placebo to finerenone, treatment duration will be 180±7 days | Study Type: Interventional<br><br>Phase: Phase 3<br><br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: *Same as current*<br><br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br><br>Estimated Enrollment: 219<br><br>Original Estimated Enrollment: *Same as current*<br><br>Age: 6 Months to 17 Years (Child)<br><br>Sex: All | Study Sponsors: *Same as current*<br><br>Collaborators: Not Provided | Study Start: March 28, 2022<br><br>Primary Completion: August 12, 2026 (Final data collection date for primary outcome measure)<br><br>Study Completion: September 11, 2026<br><br>First Posted: January 19, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 22, 2022 |

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| 8 | NCT03325322 | Inflammation and Stem Cells in Diabetic and Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: 16-010521 | Recruiting | • Chronic Kidney Diseases<br>• Diabetes Mellitus<br>• Diabetic Nephropathies | • Dietary Supplement: Fisetin Flavonoid family<br>• Drug: Placebo oral capsule Placebo<br>Other Name: Placebo | Study Type: Interventional<br>Phase: Phase 2<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Triple (Participant, Care Provider, Investigator)<br>Primary Purpose: Treatment<br>Primary Outcome Measures:<br>• Effect on markers of inflammation including C-reactive protein [ Time Frame: 14 days ]<br>To examine the effect of study drug (compared to placebo) on markers of inflammation in skin, fat, plasma, and urine measured at baseline and day 14<br>• Effect on Mesenchymal stem cell function including cell migration [ Time Frame: 14 days ]<br>To examine the effect of study drug (compared to placebo) on mesenchymal stem cell function and vitality measured at baseline and day 14<br>Secondary Outcome Measures:<br>• Effect on measures of Frailty including Fried Criteria [ Time Frame: 4 months ]<br>To examine the effect of study drug (compared to placebo) on markers of physical frailty (frailty phenotype).<br>• Kidney function including estimated glomerular filtration rate [ Time Frame: 4 months ]<br>To examine the effect of study drug (compared to placebo) on kidney function.<br>• Kidney function including urine protein excretion rate [ Time Frame: 4 months ]<br>To examine the effect of study drug (compared to placebo) on kidney function protein excretion<br>• Number of participants with treatment-related adverse events including hospitalization [ Time Frame: 12 months ]<br>To assess the safety and tolerability of study drug taken over two days (compared to placebo)<br>• Mesenchymal stem cells in vitro including cell migration [ Time Frame: 14 days ]<br>To determine the reversibility of mesenchymal stem/stromal cell dysfunction utilizing incubation with study drug in vitro.<br>• Mesenchymal stem cells -molecular characteristics examined by second generation sequencing [ Time Frame: 14 days ]<br>To examine the molecular characteristics of MSC before and after study drug by using high throughput RNA sequencing | Actual Enrollment:<br>Estimated Enrollment: 30<br>Original Estimated Enrollment: *Same as current*<br>Age: 40 Years to 80 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: January 2, 2018<br>Primary Completion: January 2023 (Final data collection date for primary outcome measure)<br>Study Completion: April 2025<br>First Posted: October 30, 2017<br>Results First Posted:<br>Last Update Posted: September 22, 2022 |

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| 9 | NCT04911491 | Inspiratory Muscle Strength Training in Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: 21-3000<br>R01DK130255 ( U.S. NIH Grant/Contract ) | Recruiting | • Chronic Kidney Diseases<br>• Hypertension<br>• Aging<br>• Blood Pressure | • Device: IMST<br>Inspiratory muscle strength training (IMST) is a form of physical training that utilizes the diaphragm and accessory respiratory muscles to repeatedly inhale against resistance using a handheld device.<br>• Device: Sham Training<br>Repeated inhalations against a low resistance will be performed using a handheld device. | Study Type: Interventional<br>Phase: Not Applicable<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)<br>Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 108<br>Original Estimated Enrollment: *Same as current*<br>Age: 50 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators:<br>• University of Colorado, Boulder<br>• National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) | Study Start: March 1, 2022<br>Primary Completion: July 1, 2026 (Final data collection date for primary outcome measure)<br>Study Completion: July 1, 2026<br>First Posted: June 3, 2021<br>Results First Posted:<br>Last Update Posted: September 21, 2022 |
| 10 | NCT05012020 | Feasibility Study of a mHealth Platform for Remote Patient Monitoring of CKD and Peritoneal Dialysis Patients<br>Study Documents: | Title Acronym:<br>Other Ids: SG-CLI-DOC-328 | Active, not recruiting | Chronic Kidney Diseases | Device: mHealth Remote Monitoring platform<br>Clinic Portal and Mobile Application for remote monitoring of Chronic Kidney Disease patients and patients on Peritoneal Dialysis | Study Type: Interventional<br>Phase: Not Applicable<br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Supportive Care<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment: 35<br>Estimated Enrollment:<br>Original Estimated Enrollment: 30<br>Age: 21 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Singapore General Hospital | Study Start: December 1, 2021<br>Primary Completion: January 2023 (Final data collection date for primary outcome measure)<br>Study Completion: January 2023<br>First Posted: August 19, 2021<br>Results First Posted:<br>Last Update Posted: September 22, 2022 |

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| 11 | NCT05536804 | A Study of Tirzepatide (LY3298176) in Participants With Overweight or Obesity and Chronic Kidney Disease With or Without Type 2 Diabetes<br>Study Documents: | Title Acronym:<br>Other Ids: 17217 I8F-MC-GPIG ( Other Identifier: Eli Lilly and Company ) 2021-005273-47 ( EudraCT Number ) | Not yet recruiting | • Overweight<br>• Obesity<br>• Chronic Kidney Disease<br>• Type 2 Diabetes<br>• T2D | • Drug: Tirzepatide Administered SC<br>• Drug: Placebo Administered SC | Study Type: Interventional<br>Phase: Phase 2<br>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Investigator) Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 140<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: October 14, 2022<br>Primary Completion: October 10, 2025 (Final data collection date for primary outcome measure)<br>Study Completion: November 7, 2025<br>First Posted: September 13, 2022<br>Results First Posted:<br>Last Update Posted: September 21, 2022 |
| 12 | NCT05543291 | Multi-omics Analysis of Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>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<br>Phase:<br>Study Design: Observational Model: Cohort Time Perspective: Cross-Sectional<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: Not Provided | Actual Enrollment:<br>Estimated Enrollment: 150<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: January 1, 2022<br>Primary Completion: December 31, 2024 (Final data collection date for primary outcome measure)<br>Study Completion: December 31, 2024<br>First Posted: September 16, 2022<br>Results First Posted:<br>Last Update Posted: September 16, 2022 |

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| 13 | NCT05182840 | A Study to Test Whether Different Doses of BI 690517 Alone or in Combination With Empagliflozin Improve Kidney Function in People With Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: 1378.5 2021-001434-19 ( EudraCT Number ) 1378-0005 ( Other Identifier: Boehringer Ingelheim ) | Recruiting | Kidney Disease, Chronic | • Drug: BI 690517<br>BI 690517<br>• Drug: Placebo to BI 690517<br>Placebo to BI 690517<br>• Drug: Empagliflozin<br>Empagliflozin<br>• Drug: Placebo to empagliflozin<br>Placebo to empagliflozin | Study Type: Interventional<br>Phase: Phase 2<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)<br>Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 552<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: January 11, 2022<br>Primary Completion: June 6, 2023 (Final data collection date for primary outcome measure)<br>Study Completion: July 4, 2023<br>First Posted: January 10, 2022<br>Results First Posted:<br>Last Update Posted: September 21, 2022 |
| 14 | NCT05183737 | Effects of Microencapsulated Propolis and Turmeric in Patients With Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: DeniseMafra13 | Active, not recruiting | • Chronic Kidney Diseases<br>• Inflammation | Dietary Supplement: Microcapsules with turmeric and propolis<br>Participants will receive microcapsules containing 0.250 milligrams of turmeric 95% curcumin and 0.250 milligrams of green propolis, twice a day for 12 weeks | Study Type: Interventional<br>Phase: Not Applicable<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Intervention Model Description: The study is a longitudinal randomized, double-blind, placebo-controlled clinical trial with patients with CKD undergoing hemodialysis. Patients will be randomized and divided into two groups: intervention group, which will receive microcapsules containing 250mg of propolis and 250mg of turmeric, twice a day, for 12 weeks, and placebo group, which will receive for the same amount of capsules containing arabic gum and cornstarch.<br>Masking: Triple (Participant, Investigator, Outcomes Assessor)<br>Primary Purpose: Health Services Research<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 34<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years to 60 Years (Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: March 7, 2022<br>Primary Completion: December 2022 (Final data collection date for primary outcome measure)<br>Study Completion: December 2022<br>First Posted: January 11, 2022<br>Results First Posted:<br>Last Update Posted: September 19, 2022 |

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| 15 | NCT05544513 | Oral Iron Supplementation for Patients With Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: DeniseMafra14 | Active, not recruiting | • Chronic Renal Disease<br>• Iron-Deficiency Anemia<br>• Anemia of Chronic Kidney Disease<br>• Dysbiosis | Drug: Ferrous sulfate<br>Ferrous sulfate supplementation | Study Type: Interventional<br>Phase: Phase 2<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Single (Participant)<br>Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment: *Same as current*<br>Estimated Enrollment:<br>Original Estimated Enrollment:<br>Age: 18 Years to 75 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: August 1, 2022<br>Primary Completion: December 29, 2023 (Final data collection date for primary outcome measure)<br>Study Completion: December 30, 2026<br>First Posted: September 16, 2022<br>Results First Posted:<br>Last Update Posted: September 16, 2022 |
| 16 | NCT05378750 | Fluid Overload Management and Vascular Stiffness in Chronic Kidney Disease Patients With Hypertension<br>Study Documents: | Title Acronym:<br>Other Ids: Pro00108113 | Not yet recruiting | Hypertension | Other: Diuretic algorithm<br>Implementing diuretic algorithm | Study Type: Interventional<br>Phase: Not Applicable<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br>Primary Outcome Measures:<br>• Fluid status [ Time Frame: 12 months ]<br>Decrease in fluid status<br>• Blood pressure [ Time Frame: 12 months ]<br>Decrease in blood pressure<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 172<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: October 1, 2022<br>Primary Completion: January 7, 2023 (Final data collection date for primary outcome measure)<br>Study Completion: January 7, 2023<br>First Posted: May 18, 2022<br>Results First Posted:<br>Last Update Posted: September 22, 2022 |

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| 17 | NCT05283512 | Intravenous vs. Oral Hydration to Reduce the Risk of Intravenous Contrast-induced Acute Kidney Injury After Cardiac Computed Tomography in Patients With Severe Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: S-20210126 Danish Data Protection Act ( Registry Identifier: 21/66779 ) | Recruiting | • Contrast-induced Nephropathy<br>• Kidney Injury<br>• Kidney Failure, Chronic<br>• Risk Reduction | • Other: Kidney prophylaxis with IV-hydration IV-hydration with isotonic NaCl<br>• Other: Kidney prophylaxis with oral hydration Oral hydration with regular bottled water | Study Type: Interventional<br>Phase: Not Applicable<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Intervention Model Description:<br>Patients are allocated to either oral- or IV-hydration<br>Masking: None (Open Label)<br>Primary Purpose: Prevention<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 258<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators:<br>• Department of Nephrology, Odense University Hospital<br>• Department of Clinical Immunology, Odense University Hospital<br>• The A.P. Moller Foundation<br>• The Research Counsil of Odense University Hospital<br>• Copenhagen University's Research Foundation for Medical Students | Study Start: April 20, 2022<br>Primary Completion: March 16, 2025 (Final data collection date for primary outcome measure)<br>Study Completion: March 16, 2026<br>First Posted: March 17, 2022<br>Results First Posted:<br>Last Update Posted: September 22, 2022 |
| 18 | NCT05543928 | Phase 3 Safety and Efficacy Study of CTAP101 Extended-release Capsules in Children With Secondary Hyperparathyroidism<br>Study Documents: | Title Acronym:<br>Other Ids: CTAP101-CL-3007 | Not yet recruiting | • Chronic Kidney Disease stage3<br>• Chronic Kidney Disease stage4<br>• Vitamin d Deficiency<br>• Secondary Hyperparathyroidism | • Drug: CTAP101<br>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.<br>• Drug: Placebo<br>Placebo | Study Type: Interventional<br>Phase: Phase 3<br>Study Design: Allocation: Randomized<br>Intervention Model: Sequential Assignment<br>Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)<br>Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 108<br>Original Estimated Enrollment: *Same as current*<br>Age: 8 Years to 17 Years (Child)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: October 2022<br>Primary Completion: July 2025 (Final data collection date for primary outcome measure)<br>Study Completion: July 2025<br>First Posted: September 16, 2022<br>Results First Posted:<br>Last Update Posted: September 16, 2022 |

| | NCT Number | Title | Other Names | Status | Conditions | Interventions | Characteristics | Population | Sponsor/Collaborators | Dates |
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| 19 | NCT05546099 | Patient-driven Management of BP in CKD<br>Study Documents: | Title Acronym:<br>Other Ids: IIR 21-255 | Not yet recruiting | Chronic Kidney Disease | • Behavioral: Self-management of BP medications<br>Patients will be educated on how to manage their home BP based on a pre-determined protocol. They will then monitor home BP and adjust meds accordingly and under the guidance of the clinical pharmacist.<br>• Behavioral: Self-monitoring of home BP<br>Patients will be educated on how to monitor home BP and will be educated to contact their primary care provider/CKD provider if the BP is above the goal. | Study Type: Interventional<br>Phase: Phase 3<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Intervention Model Description:<br>Patients will monitor home BP and adjust meds based on a protocol and under the guidance of a clinical pharmacist.<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 160<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: November 1, 2022<br>Primary Completion: September 30, 2026 (Final data collection date for primary outcome measure)<br>Study Completion: November 20, 2026<br>First Posted: September 19, 2022<br>Results First Posted:<br>Last Update Posted: September 19, 2022 |
| 20 | NCT01156428 | Inflammatory and Immune Profiling of Kidney Tissue Obtained From Patients With Newly Diagnosed Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: 0908010598 | Completed | • Proteinuria<br>• Kidney Injury<br>• Chronic Kidney Disease | Not Provided | Study Type: Observational<br>Phase:<br>Study Design: Observational Model: Case-Control<br>Time Perspective: Prospective<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment: 119<br>Estimated Enrollment:<br>Original Estimated Enrollment: 80<br>Age: 18 Years to 90 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Janssen Research & Development, LLC | Study Start: July 2010<br>Primary Completion: November 2016 (Final data collection date for primary outcome measure)<br>Study Completion: November 2016<br>First Posted: July 2, 2010<br>Results First Posted:<br>Last Update Posted: September 19, 2022 |

| | NCT Number | Title | Other Names | Status | Conditions | Interventions | Characteristics | Population | Sponsor/Collaborators | Dates |
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| 21 | NCT05094934 | A Research Study Looking Into Levels of the Medicine NNC0385-0434 in the Body and How Well it is Tolerated in Participants With Impaired Kidney Function Compared to Participants With Normal Kidney Function<br><br>Study Documents: | Title Acronym:<br><br>Other Ids: NN6435-4749 U1111-1264-2693 ( Other Identifier: World Health Organization (WHO) ) 2021-000462-16 ( EudraCT Number ) | Terminated | Chronic Kidney Disease | Drug: NNC0385-0434 A 100 mg<br>All participants will receive the same dose (100 mg) of the study medicine NNC0385-0434, which will be given for 10 days in a row. Participants will get the study medicine in a tablet taken orally once-daily. The study medicine needs to be taken in the morning after overnight fasting and 30 minutes before the first meal of the day. | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: Non-Randomized<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: *Same as current*<br><br>Secondary Outcome Measures:<br>• Cmax,0434,Day10: the maximum plasma concentration of NNC0385-0434 after last dose of oral NNC0385-0434 [ Time Frame: From last dose (Day 10) to post treatment follow-up (Day 65) ]<br>nmol/L<br>• tmax,0434,Day10: time from last dose administration to maximum plasma concentration of oral NNC0385-0434 [ Time Frame: From last dose (Day 10) to post treatment follow-up (Day 65) ]<br>h<br>• t½,0434,Day10; the terminal half-life of NNC0385-0434 after last dose of oral NNC0385-0434 [ Time Frame: From last dose (Day 10) to post treatment follow-up (Day 65) ]<br>h<br>• CLR,0434,Day10; the renal clearance of NNC0385-0434 after last dose of oral NNC0385-0434 [ Time Frame: From last dose (Day 10) to 48 hours post treatment (Day 12) ]<br>mL/h<br>• CL/F0434,Day10; the apparent clearance of NNC0385-0434 after last dose of oral NNC0385-0434 [ Time Frame: From last dose (day 10) to post treatment follow-up (day 65) ]<br>mL/h<br>• Vz/F0434,Day10; the apparent volume of distribution of NNC0385-0434 in the terminal phase [ Time Frame: From last dose (Day 10) to post treatment follow-up (Day 65) ]<br>L<br>• AUC0-24h,SNAC,Day10: the area under the SNAC plasma concentration-time curve from time 0 to 24 hours after last dose of oral NNC0385-0434 [ Time Frame: From last dose (Day 10) to 24 hours post treatment (Day 11) ]<br>h*nmol/L<br>• Cmax,SNAC,Day10; the maximum plasma concentration of SNAC after last dose of oral NNC0385-0434 [ Time Frame: From last dose (Day 10) to 24 hours post treatment (Day 11) ]<br>nmol/L<br>• Cmin,SNAC,Day10; the minimum plasma concentration of SNAC before last dose of oral NNC0385-0434 [ Time Frame: Pre-dose (Day 10) ]<br>nmol/L<br>• tmax,SNAC,Day10; the time to maximum observed plasma concentration of SNAC after last dose of oral NNC0385-0434 [ Time Frame: From last dose (Day 10) to 24 hours post treatment (Day 11) ]<br>hours<br>• t½,SNAC,Day10; the terminal half-life of SNAC after last dose of oral NNC0385-0434 [ Time Frame: From last dose (Day 10) to 24 hours post treatment (Day 11) ] | Actual Enrollment: 60<br><br>Estimated Enrollment:<br><br>Original Estimated Enrollment: *Same as current*<br><br>Age: 18 Years to 75 Years (Adult, Older Adult)<br><br>Sex: All | Study Sponsors: *Same as current*<br><br>Collaborators: Not Provided | Study Start: November 8, 2021<br><br>Primary Completion: August 29, 2022 (Final data collection date for primary outcome measure)<br><br>Study Completion: August 29, 2022<br><br>First Posted: October 26, 2021<br><br>Results First Posted:<br><br>Last Update Posted: September 21, 2022 |

| | NCT Number | Title | Other Names | Status | Conditions | Interventions | Characteristics | Population | Sponsor/Collaborators | Dates |
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| 22 | NCT05465317 | Evaluating Comparative Effectiveness of Empagliflozin in Type 2 Diabetes Population With and Without Chronic Kidney Disease<br>Study Documents: | Title Acronym:<br>Other Ids: 1245-0228 | Active, not recruiting | Diabetes Mellitus, Type 2 | • Drug: Empagliflozin<br>Empagliflozin<br>• Drug: Dipeptidyl Peptidate-4 inhibitors<br>Dipeptidyl Peptidate-4 inhibitors<br>• Drug: Sodium glucose co-transporter-2 inhibitors<br>Sodium glucose co-transporter-2 inhibitors<br>• Drug: Glucagon-like Peptide-1 Receptor Agonists<br>Glucagon-like Peptide-1 Receptor Agonists | Study Type: Observational<br>Phase:<br>Study Design: Observational Model: Cohort<br>Time Perspective: Retrospective<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment: 30400<br>Estimated Enrollment:<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: August 8, 2022<br>Primary Completion: September 30, 2022 (Final data collection date for primary outcome measure)<br>Study Completion: September 30, 2022<br>First Posted: July 19, 2022<br>Results First Posted:<br>Last Update Posted: September 21, 2022 |
| 23 | NCT05407662 | A Study Using Surveys to Learn More About Treatment With Steroidal Mineralocorticoid Receptor Antagonists, How They Are Used, What Side Effects They Have, and How Satisfied People Who Receive Them Are in the US<br>Study Documents: | Title Acronym:<br>Other Ids: 22114 | Not yet recruiting | • Chronic Kidney Disease<br>• Type 2 Diabetes Mellitus<br>• Heart Failure | Other: sMRA therapies<br>No drug will be provided to participants. Patients follow routine clinical practice/administration.<br>Other Name: Steroidal mineralocorticoid receptor antagonist therapies | Study Type: Observational<br>Phase:<br>Study Design: Observational Model: Cohort<br>Time Perspective: Cross-Sectional<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 600<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: September 30, 2022<br>Primary Completion: November 1, 2022 (Final data collection date for primary outcome measure)<br>Study Completion: November 1, 2022<br>First Posted: June 7, 2022<br>Results First Posted:<br>Last Update Posted: September 22, 2022 |

| | NCT Number | Title | Other Names | Status | Conditions | Interventions | Characteristics | Population | Sponsor/Collaborators | Dates |
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| 24 | NCT05497700 | Comparative Efficacy of Ephedrine Versus Norepinephrine to Correct Anesthesia Induction Related Hypotension<br>Study Documents: | Title Acronym:<br>Other Ids: VASO_IRC | Recruiting | Hypotension on Induction | • Drug: Ephedrine<br>Bolus injection of 6 mg ephedrine to keep mean arterial blood pressure above 65 mm Hg<br>• Drug: Norepinephrine<br>Bolus injection of either 6 mcg norepinephrine to keep mean arterial blood pressure above 65 mm Hg | Study Type: Interventional<br>Phase: Phase 3<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)<br>Masking Description:<br>Drug will be prepared by an anesthesia nurse not involved in the care of the patient and labeled as "VASO-IRC-inclusion number".<br>Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: Not Provided | Actual Enrollment:<br>Estimated Enrollment: 60<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years to 70 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: September 15, 2022<br>Primary Completion: September 30, 2023 (Final data collection date for primary outcome measure)<br>Study Completion: October 30, 2023<br>First Posted: August 11, 2022<br>Results First Posted:<br>Last Update Posted: September 16, 2022 |
| 25 | NCT02683889 | Use of Acthar in Patients With FSGS That Will be Undergoing Renal Transplantation<br>Study Documents: | Title Acronym:<br>Other Ids: 17-2336 | Recruiting | FSGS | Drug: Acthar<br>patients will receive acthar 80 units twice a week for 6 months and will measure recurrence of FSGS | Study Type: Interventional<br>Phase: Phase 3<br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Prevention<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 20<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years to 80 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: Georgetown University<br>Collaborators: Not Provided | Study Start: February 1, 2019<br>Primary Completion: December 2023 (Final data collection date for primary outcome measure)<br>Study Completion: December 2023<br>First Posted: February 17, 2016<br>Results First Posted:<br>Last Update Posted: September 16, 2022 |

| | NCT Number | Title | Other Names | Status | Conditions | Interventions | Characteristics | Population | Sponsor/Collaborators | Dates |
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| 26 | NCT05022758 | A Study to Learn Whether There Are Differences in the Kidney's Ability to Work Properly in Korean Patients With Non-valvular Atrial Fibrillation (Irregular and Often Rapid Heartbeat Not Caused by a Heart Valve Problem) Treated With Rivaroxaban as Compared to Those Treated With Warfarin<br>Study Documents: | Title Acronym:<br>Other Ids: 21615 | Active, not recruiting | Non-valvular Atrial Fibrillation (NVAF) | • Drug: Rivaroxaban (Xarelto, BAY59-7939)<br>One of NOAC (Non-vitamin K antagonist oral anticoagulants)<br>• Drug: Warfarin<br>One of OAC (Oral anticoagulation therapy) | Study Type: Observational<br>Phase:<br>Study Design: Observational Model: Cohort<br>Time Perspective: Retrospective<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment: 45000<br>Estimated Enrollment:<br>Original Estimated Enrollment: *Same as current*<br>Age: 20 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: October 6, 2021<br>Primary Completion: November 15, 2022 (Final data collection date for primary outcome measure)<br>Study Completion: November 15, 2022<br>First Posted: August 26, 2021<br>Results First Posted:<br>Last Update Posted: September 22, 2022 |
| 27 | NCT02579096 | CSP594 Comparative Effectiveness in Gout: Allopurinol vs. Febuxostat<br>Study Documents: | Title Acronym:<br>Other Ids: 594 | Completed | • Gout<br>• Chronic Kidney Diseases | • Drug: allopurinol capsule, 100-800 mg by mouth once daily<br>Patients will be up-titrated up to the dose required to reach target uric acid levels.<br>Other Name: Zyloprim; CAS: 315-30-0<br>• Drug: febuxostat tablet 40-120 mg by mouth once daily<br>Patients will be up-titrated to the dose required to reach target uric acid levels.<br>Other Name: Uloric; CAS: 144060-53-7; NDCs: 64764-677-11, 64764-677-13, 64764-677-19, 64764-677-30, 64764-918-11, 64764-918-18, 64764-918-30, 64764-918-90<br>• Drug: Placebo, vehicle control (febuxostat-shaped)<br>Placebo tablets resembling febuxostat will be given with allopurinol.<br>• Drug: Placebo, vehicle control (allopurinol-shaped)<br>Placebo capsules resembling allopurinol will be given with febuxostat. | Study Type: Interventional<br>Phase: Phase 4<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)<br>Primary Purpose: Treatment<br>Primary Outcome Measures: Proportion of participants who have at least one gout flare in the allopurinol group compared to the febuxostat group [ Time Frame: Phase III of the study (months 12-18 of study duration) ]<br>Proportion of participants who have at least one gout flare in the allopurinol group compared to the febuxostat group<br>Secondary Outcome Measures: Not Provided | Actual Enrollment: 950<br>Estimated Enrollment:<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: March 6, 2017<br>Primary Completion: February 1, 2021 (Final data collection date for primary outcome measure)<br>Study Completion: April 15, 2021<br>First Posted: January 11, 2022<br>Results First Posted: January 11, 2022<br>Last Update Posted: September 19, 2022 |

| | NCT Number | Title | Other Names | Status | Conditions | Interventions | Characteristics | Population | Sponsor/Collaborators | Dates |
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| 28 | NCT05136664 | Trial Evaluating the Efficacy and Safety of Patiromer in Chinese Subjects<br>Study Documents: | Title Acronym:<br>Other Ids: PAT-CHINA-303 CTR20212173 ( Registry Identifier: Center for Drug Evaluation (CDE), NMPA ) | Recruiting | • Hyperkalemia<br>• Renal Insufficiency, Chronic | • Drug: Patiromer Powder for Oral Suspension (Part A)<br>Participants initiate patiromer at an oral dose of 1 packet/day (8.4g/day as powder for suspension). The dose is adjusted ate the following visit based on local serum potassium (sK+) levels.<br>The content of each packet should be mixed with water, apple or cranberry juice before administration.<br>• Drug: Placebo (Part B)<br>Placebo is provided in packets, each containing 6 g of placebo as powder for suspension. Participants will take 1 packet per day, by mixing its content with water, apple or cranberry juice.<br>• Drug: Patiromer Powder for Orals Suspension (Part B)<br>Participants will continue to receive the same number of packets established during Part A, but dose may be up- or down titrated depending on sK+ levels.<br>The content of each packet should be mixed with water, apple or cranberry juice before administration. | Study Type: Interventional<br>Phase: Phase 3<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Intervention Model Description:<br>2-part, single-blind, randomised withdrawal, placebo-controlled (Part B), parallel group study that includes a 4-week patiromer treatment phase (Part A) followed by an 8-week randomised placebo-controlled withdrawal phase (Part B).<br>Masking: Single (Participant)<br>Primary Purpose: Treatment<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 200<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years and older (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Tigermed Consulting Co., Ltd | Study Start: February 10, 2022<br>Primary Completion: March 2024 (Final data collection date for primary outcome measure)<br>Study Completion: March 2024<br>First Posted: November 29, 2021<br>Results First Posted:<br>Last Update Posted: September 16, 2022 |
| 29 | NCT05549154 | A Study on Prevention Strategies for CKD-SHPT and Related Complications Based on General Vitamin D Supplementation<br>Study Documents: | Title Acronym:<br>Other Ids: XJTU1AF2022LSK-320 | Not yet recruiting | • Chronic Kidney Disease 5D<br>• Secondary Hyperparathyroidism Due to Renal Causes<br>• Vitamin D Deficiency | • Drug: High-dose vitamin D2 softgels<br>5000U/capsule of vitamin D2 soft capsule; High-dose VD group 50,000 U/week, 5 vitamin D2 softgels given twice a week each time; 25(OH)D > 80ng/ml after 3 months of intervention or within 3 months in both groups, changed to 5,000 U/ weekly maintenance until the full 6 months of intervention. To prevent unmasking, the maintenance dose was still given twice weekly (the first time 1 vitamin D2 capsule + 4 placebo capsules were given and the second time 5 placebo capsules were given)<br>• Drug: low-dose vitamin D2 softgels<br>5000U/capsule of vitamin D2 soft capsule; low-dose VD group 25,000 U/week, 3 vitamin D2 softgels + 2 placebo in the first dose, 2 vitamin D2 softgels + 3 placebo in the second dose, 25(OH)D > 80ng/ml after 3 months of intervention or within 3 months in both groups, changed to 5,000 U/ weekly maintenance until the full 6 months of intervention. To prevent unmasking, the maintenance dose was still given twice weekly (the first time 1 vitamin D2 capsule + 4 placebo capsules were given and the second time 5 placebo capsules were given);<br>• Drug: placebo<br>placebo was filled with excipients (aniseed ether, refined vegetable oil), and the shape and size were the same as vitamin D2 soft capsule.the control group was given placebo, 5 placebo capsules twice weekly for 6 months of the intervention. The medication was dispensed by a designated person (not the investigator) in advance and independently according to the patient's medication number (only the drug number was provided on the outer packaging). | Study Type: Interventional<br>Phase: Not Applicable<br>Study Design: Allocation: Randomized<br>Intervention Model: Parallel Assignment<br>Masking: Triple (Participant, Care Provider, Investigator)<br>Primary Purpose: Prevention<br>Primary Outcome Measures: *Same as current*<br>Secondary Outcome Measures: *Same as current* | Actual Enrollment:<br>Estimated Enrollment: 372<br>Original Estimated Enrollment: *Same as current*<br>Age: 18 Years to 90 Years (Adult, Older Adult)<br>Sex: All | Study Sponsors: *Same as current*<br>Collaborators: Not Provided | Study Start: October 1, 2022<br>Primary Completion: August 1, 2023 (Final data collection date for primary outcome measure)<br>Study Completion: October 30, 2023<br>First Posted: September 22, 2022<br>Results First Posted:<br>Last Update Posted: September 22, 2022 |