

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	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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 1000000 Original Estimated Enrollment: 99999 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> 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
2	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: <i>Same as current</i> Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 20 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> 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
3	NCT04741646	Ferric Citrate and Chronic Kidney Disease in Children Study Documents:	Title Acronym: Other Ids: 1U01DK122013-01(U.S. NIH Grant/Contract) 1U01DK122013(U.S. NIH Grant/Contract)	Recruiting	Chronic Kidney Diseases	<ul style="list-style-type: none">Drug: Ferric Citrate Auryxia® 210 mg ferric iron tablets equivalent to 1 g of FC and matching placebo will be supplied as 200 tablets in 400cc high-density polyethylene bottles. Other Name: AuryxiaDrug: Placebo Placebo to match Ferric Citrate tablets	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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 160 Original Estimated Enrollment: <i>Same as current</i> Age: 6 Years to 17 Years (Child) Sex: All	Study Sponsors: Same as current Collaborators: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	Study Start: May 16, 2022 Primary Completion: December 1, 2025 (Final data collection date for primary outcome measure) Study Completion: December 1, 2025 First Posted: February 5, 2021 Results First Posted: Last Update Posted: September 7, 2022
4	NCT05047263	A Trial to Learn How Well Finerenone Works and How Safe it is in Adult Participants With Non-diabetic Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: 21177 2021-000421-27 (EudraCT Number)	Recruiting	Non-diabetic Chronic Kidney Disease	<ul style="list-style-type: none">Drug: Finerenone (BAY94-8862) Tablet, 10 mg or 20 mg, once daily (OD), oralDrug: Placebo Tablet, once daily, oral	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Investigator) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 1580 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: September 21, 2021 Primary Completion: November 4, 2025 (Final data collection date for primary outcome measure) Study Completion: December 8, 2025 First Posted: September 17, 2021 Results First Posted: Last Update Posted: September 7, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
5	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	<ul style="list-style-type: none">Chronic Kidney DiseaseCongenital Anomalies of Kidney and Urinary Tract	Biological: Renal Autologous Cell Therapy (REACT®) Autologous selected renal cells (SRC)	<div>Study Type: Interventional</div> <div>Phase: Phase 1</div> <div>Study Design: Allocation: N/A Intervention Model: Single Group Assignment Intervention Model Description: Open-label Masking: None (Open Label) Primary Purpose: Treatment</div> <div>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.</div> <div>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.</div>	<div>Actual Enrollment:</div> <div>Estimated Enrollment: 15</div> <div>Original Estimated Enrollment: <i>Same as current</i></div> <div>Age: 18 Years to 65 Years (Adult, Older Adult)</div> <div>Sex: All</div>	<div>Study Sponsors: <i>Same as current</i></div> <div>Collaborators: CTI Clinical Trial and Consulting Services</div>	<div>Study Start: August 13, 2019</div> <div>Primary Completion: March 31, 2023 (Final data collection date for primary outcome measure)</div> <div>Study Completion: May 30, 2023</div> <div>First Posted: October 4, 2019</div> <div>Results First Posted:</div> <div>Last Update Posted: September 10, 2022</div>
6	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	<ul style="list-style-type: none">Chronic Kidney DiseaseProteinuriaChildren	Drug: Finerenone (Kerendia, BAY94-8862) Finerenone in different doses, treatment duration will be 540 ±7 days.	<div>Study Type: Interventional</div> <div>Phase: Phase 3</div> <div>Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment</div> <div>Primary Outcome Measures: <i>Same as current</i></div> <div>Secondary Outcome Measures: <i>Same as current</i></div>	<div>Actual Enrollment:</div> <div>Estimated Enrollment: 100</div> <div>Original Estimated Enrollment: <i>Same as current</i></div> <div>Age: 1 Year to 18 Years (Child, Adult)</div> <div>Sex: All</div>	<div>Study Sponsors: <i>Same as current</i></div> <div>Collaborators: Not Provided</div>	<div>Study Start: November 2, 2022</div> <div>Primary Completion: February 11, 2028 (Final data collection date for primary outcome measure)</div> <div>Study Completion: March 12, 2028</div> <div>First Posted: July 13, 2022</div> <div>Results First Posted:</div> <div>Last Update Posted: September 13, 2022</div>

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
7	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	<ul style="list-style-type: none">• Overweight• Obesity• Chronic Kidney Disease• Type 2 Diabetes• T2D	<ul style="list-style-type: none">• 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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 140 Original Estimated Enrollment: <i>Same as current</i> 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
8	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	<ul style="list-style-type: none">• Type 2 Diabetes Mellitus• Chronic Kidney Disease	<ul style="list-style-type: none">• 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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 807 Original Estimated Enrollment: <i>Same as current</i> 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
9	NCT05531214	Creating A Cardiorenal Multidisciplinary Team for Management HF and CKD Patients Study Documents:	Title Acronym: Other Ids: NCR224155	Recruiting	<ul style="list-style-type: none">Heart FailureChronic 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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 160 Original Estimated Enrollment: <i>Same as current</i> 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
10	NCT03594110	EMPA-KIDNEY (The Study of Heart and Kidney Protection With Empagliflozin) Study Documents:	Title Acronym: Other Ids: 1245-0137 2017-002971-24 (EudraCT Number)	Active, not recruiting	Chronic Kidney Disease	<ul style="list-style-type: none">• Drug: Empagliflozin Taken daily with or without food• Drug: Matching placebo Taken daily with or without food	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Investigator) Primary Purpose: Treatment Primary Outcome Measures: Composite primary outcome:Time to first occurrence of (i) kidney disease progression (defined as ESKD, a sustained decline in eGFR to <10 mL/min/1.73m², renal death, or a sustained decline of 40% in eGFR from randomization) or (ii) Cardiovascular death [Time Frame: Median follow-up approx. 3.1 years] End Stage Kidney Disease (ESKD) is defined as the initiation of maintenance dialysis or receipt of a kidney transplant Secondary Outcome Measures: <ul style="list-style-type: none">• Time to first hospitalization for heart failure or cardiovascular death [Time Frame: Median follow-up approx. 3.1 years]• Occurrences of all-cause hospitalization (first and recurrent) [Time Frame: Median follow-up approx. 3.1 years]• Time to death from any cause [Time Frame: Median follow-up approx. 3.1 years]• Time to first occurrence of kidney disease progression [Time Frame: Median follow-up approx. 3.1 years]• Time to cardiovascular death [Time Frame: Median follow-up approx. 3.1 years]• Time to cardiovascular death or ESKD [Time Frame: Median follow-up approx. 3.1 years]	Actual Enrollment: 6609 Estimated Enrollment: Original Estimated Enrollment: 5000 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: <ul style="list-style-type: none">• Medical Research Council Population Health Research Unit, CTSU, University of Oxford (academic lead)• Eli Lilly and Company	Study Start: January 31, 2019 Primary Completion: July 5, 2022 (Final data collection date for primary outcome measure) Study Completion: January 31, 2025 First Posted: July 20, 2018 Results First Posted: Last Update Posted: September 7, 2022
11	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 Study Documents:	Title Acronym: Other Ids: 1378.5 2021-001434-19 (EudraCT Number) 1378-0005 (Other Identifier: Boehringer Ingelheim)	Recruiting	Kidney Disease, Chronic	<ul style="list-style-type: none">• Drug: BI 690517 BI 690517• Drug: Placebo to BI 690517 Placebo to BI 690517• Drug: Empagliflozin Empagliflozin• Drug: Placebo to empagliflozin 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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 552 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: January 11, 2022 Primary Completion: June 6, 2023 (Final data collection date for primary outcome measure) Study Completion: July 4, 2023 First Posted: January 10, 2022 Results First Posted: Last Update Posted: September 7, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
12	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	<ul style="list-style-type: none">• 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.	<div>Study Type: Interventional</div> <div>Phase: Phase 2</div> <div>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Triple (Participant, Care Provider, Investigator) Primary Purpose: Treatment</div> <div>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.</div> <div>Secondary Outcome Measures:<ul style="list-style-type: none">• 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.</div>	<div>Actual Enrollment:</div> <div>Estimated Enrollment: 495</div> <div>Original Estimated Enrollment: 660</div> <div>Age: 18 Years to 130 Years (Adult, Older Adult)</div> <div>Sex: All</div>	<div>Study Sponsors: Same as current</div> <div>Collaborators: Not Provided</div>	<div>Study Start: April 28, 2021</div> <div>Primary Completion: March 10, 2023 (Final data collection date for primary outcome measure)</div> <div>Study Completion: March 10, 2023</div> <div>First Posted: January 26, 2021</div> <div>Results First Posted:</div> <div>Last Update Posted: September 13, 2022</div>

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13	NCT05527574	Home-based Interventions for FrAilty preveNTion in AdultS With DiabeTes and Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: Pro00089513	Recruiting	<ul style="list-style-type: none">Diabetes Type 2FrailtyKidney Diseases	Other: Resistance Exercise Participants are enrolled in 30-40 minutes of resistance exercise training using elastic bands for 30-40 minutes/session three times per week over six months	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 120 Original Estimated Enrollment: <i>Same as current</i> Age: 50 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: November 30, 2019 Primary Completion: December 30, 2023 (Final data collection date for primary outcome measure) Study Completion: August 22, 2025 First Posted: September 2, 2022 Results First Posted: Last Update Posted: September 7, 2022
14	NCT05305495	Empagliflozin in Acute Heart Failure Study Documents:	Title Acronym: Other Ids: 2022-8411	Not yet recruiting	<ul style="list-style-type: none">Acute Heart FailureChronic Kidney Diseases	Drug: Empagliflozin 25 MG Patients who fulfill the inclusion criteria will receive an intravenous dose of 1.0-1.5 mg/kg of furosemide (120 mg) and urine output will be monitored for three hours. Those with a urine output < 300 ml in the first two hours post furosemide administration will receive a single oral dose of 25 mg of empagliflozin. Two hours after taking empagliflozin, patients will receive a second intravenous dose of 1.0-1.5 mg/kg of furosemide with another timed urine collection at three hours. Empagliflozin will then be continued daily for five days or until hospital discharge, unless the treating physician considers this not to be clinically appropriate. Other Name: Jardiance (DIN: 02443945)	Study Type: Interventional Phase: Phase 4 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Intervention Model Description: Prospective, interventional, single arm, cohort study Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 25 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: December 2022 Primary Completion: August 2024 (Final data collection date for primary outcome measure) Study Completion: July 2025 First Posted: March 31, 2022 Results First Posted: Last Update Posted: September 7, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
15	NCT05138419	A Pragmatic Approach to CKD Patient Education Study Documents:	Title Acronym: Other Ids: 262853	Recruiting	<ul style="list-style-type: none">Chronic Kidney Disease stage3Chronic Kidney Disease stage4Chronic Kidney Disease Stage 5Patient Engagement	<ul style="list-style-type: none">Other: CKD "What You Need To Know" Workbook System 139 page Workbook including CKD Action Plan, Web-Based Resources, Interactive CKD Patient education materialOther: CKD Action Plan Goals based on international guidelines that can protect kidney function (1 knowledge and 10 action goals) Patient education material used separately for control arm.Other: CKD Web-based Resource List CKD Patient education material used separately for control armOther: Food Label reading exercise CKD Patient education material used separately in all arms.	<p>Study Type: Interventional</p> <hr/> <p>Phase: Not Applicable</p> <hr/> <p>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: This is a randomized control pilot study using non-nephrology clinicians to educate patients at high risk for CKD how to protect the kidneys and be ready for RRT if needed utilizing nephrology developed educational tools. Pharmacists screen subjects in the MTM program or with the same medical conditions, enroll them in familial or peer clusters of 1 or more subjects and randomized into 1 of the 3 study arms using a site specific randomization schedule. In clusters of more than 1 subject, the group chooses a leader who receives the assigned intervention and shares it other cluster members. All subjects will receive pre and post testing, health literacy evaluation and completes a program evaluation. The 3 arms include 2 education arms and a control arm with various levels of intervention. The two education arms use the CKD: What You Need to Know Workbook including the CKD AP as self-study tools. The control arm receives the CKD AP and a list of CKD Web-based Resources.</p> <p>Masking: None (Open Label) Primary Purpose: Prevention</p> <hr/> <p>Primary Outcome Measures: <i>Same as current</i></p> <hr/> <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none">Intra cluster analysis to evaluate effectiveness of each teaching style used by peer educators [Time Frame: Up to 4 months] Clusters of more than 1 subject will undergo intra cluster analysis per each arm using data from the evaluation form to determine effectiveness of each teaching style used. Examples: Comparisons of self study versus cluster group participation of Workbook content and Handouts materials (Workbook, Chapter Post Tests, Chapter Frequently Asked Questions, Web-sites accessed, Food label exercise outcomes. Number of cluster meetings, Were modality choices discussed, How helpful was their experience (1-5 scale). Open comment section for subjects to expand on their experience, what was especially helpful and what could be improved.Patient Engagement (percent of applicable AP goals selected) [Time Frame: up to 4 months] Patient Engagement will be measured by the percent of applicable AP goals selected The AP has 10 performance goals that are specific, actionable and realistic addressing these areas 1) Diabetes: Goal AIC 2) B/P Goal 3) Exercise Goal 4) Medications to Avoid, ensure taken, system to reorder 5) Stop Smoking 6-7) Kidney Friendly Diet: salt/water/edema, phosphorus/ protein 8) Monitor System for glucose checks, home blood pressure, weight, diet diary 9) Weight Management 10) Anemia: Goal hemoglobin. When AP is initiated goals already met or are don't apply to subject will be identified. Subject can then select goals to start.Patient engagement (percent of visits where a patient-initiated CKD discussion takes place) [Time Frame: up to 4 months] Patient Engagement will be measured by the percent of visits where a patient-initiated CKD discussion occurredPatient engagement (percent of goals met) [Time Frame: up to 4 months] Patient Engagement will be measured by the percent of goals met (self-reported or provider-confirmed). Goal completion will be determined from evaluation form, AP	<p>Actual Enrollment:</p> <hr/> <p>Estimated Enrollment: 125</p> <hr/> <p>Original Estimated Enrollment: <i>Same as current</i></p> <hr/> <p>Age: 18 Years to 105 Years (Adult, Older Adult)</p> <hr/> <p>Sex: All</p>	<p>Study Sponsors: <i>Same as current</i></p> <hr/> <p>Collaborators: Not Provided</p>	<p>Study Start: September 2022</p> <hr/> <p>Primary Completion: November 2022 (Final data collection date for primary outcome measure)</p> <hr/> <p>Study Completion: November 2022</p> <hr/> <p>First Posted: December 1, 2021</p> <hr/> <p>Results First Posted:</p> <hr/> <p>Last Update Posted: September 7, 2022</p>

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
16	NCT04102527	Evaluation of the Impact of Transit Troubles in Patients Undergoing Peritoneal Dialysis Study Documents:	Title Acronym: Other Ids: CHV 2018-1	Recruiting	<ul style="list-style-type: none">Peritoneal Dialysis ComplicationConstipation	Other: Questionnaires Patients have to complete the study questionnaires every 2 months : <ul style="list-style-type: none">Digestive Functional Score of Neurological PatientsBowel Function IndexSeverity score for constipationBristol ScaleConstipation assessment scaleEstimate scale of risk of constipation	Study Type: Observational Phase: Study Design: Observational Model: Other Time Perspective: Prospective Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 180 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: University Hospital, Clermont-Ferrand	Study Start: December 19, 2019 Primary Completion: December 31, 2023 (Final data collection date for primary outcome measure) Study Completion: December 31, 2024 First Posted: September 25, 2019 Results First Posted: Last Update Posted: September 8, 2022
17	NCT05530291	Incidence and Burden of Erythropoietin Hyporesponsiveness - a Retrospective Database Analysis Study Documents:	Title Acronym: Other Ids: 1517-MA-3435	Not yet recruiting	Chronic Kidney Disease	Other: Non-interventional Epidemiology of anemia associated with chronic kidney disease, rather than to evaluate specific drugs	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Retrospective Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 50000 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: September 30, 2022 Primary Completion: September 30, 2022 (Final data collection date for primary outcome measure) Study Completion: September 30, 2022 First Posted: September 7, 2022 Results First Posted: Last Update Posted: September 7, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
18	NCT05134701	Dapagliflozin Post Marketing Surveillance in HF and CKD Study Documents:	Title Acronym: Other Ids: D1699R00007	Recruiting	<ul style="list-style-type: none">Heart Failure With Reduced Ejection FractionChronic Kidney Disease	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Case-Only Time Perspective: Prospective Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 900 Original Estimated Enrollment: <i>Same as current</i> Age: 19 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: Not Provided	Study Start: March 10, 2022 Primary Completion: May 30, 2024 (Final data collection date for primary outcome measure) Study Completion: May 30, 2024 First Posted: November 26, 2021 Results First Posted: Last Update Posted: September 7, 2022
19	NCT03832595	Kidney Coordinated Health Management Partnership Study Documents:	Title Acronym: Other Ids: PRO18070620 R18DK118460 (U.S. NIH Grant/Contract) IR01DK116957-01A1 (U.S. NIH Grant/Contract)	Enrolling by invitation	Chronic Kidney Diseases	<ul style="list-style-type: none">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: <ol style="list-style-type: none">Nephrologist led electronic consultation: review of the patient's EHR with recommendations sent to the PCP every ~6 months,Medication therapy management: PharmD led telephonic medication therapy management with the patient every ~6 months,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: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 1650 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: <ul style="list-style-type: none">Vanderbilt University Medical CenterNational 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

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
20	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	<ul style="list-style-type: none">Secondary Hyperpara thyroidismChronic Kidney Disease	<ul style="list-style-type: none">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.	<p>Study Type: Interventional</p> <hr/> <p>Phase: Phase 3</p> <hr/> <p>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Investigator) Primary Purpose: Treatment</p> <hr/> <p>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)</p> <hr/> <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none">Time to all-cause mortalityTime to cardiovascular mortalityTime to fatal and non-fatal MITime to fatal and non-fatal hospitalization for unstable anginaTime to fatal and non-fatal HF eventTime to fatal and non-fatal peripheral vascular eventTime to fatal and non-fatal strokeTime to bone fractureTime to parathyroidectomy	<p>Actual Enrollment: 3883</p> <hr/> <p>Estimated Enrollment:</p> <hr/> <p>Original Estimated Enrollment:</p> <hr/> <p>Age: 18 Years and older (Adult, Older Adult)</p> <hr/> <p>Sex: All</p>	<p>Study Sponsors: Same as current</p> <hr/> <p>Collaborators: Not Provided</p>	<p>Study Start: August 22, 2006</p> <hr/> <p>Primary Completion: April 10, 2012 (Final data collection date for primary outcome measure)</p> <hr/> <p>Study Completion: April 10, 2012</p> <hr/> <p>First Posted: January 22, 2014</p> <hr/> <p>Results First Posted: January 22, 2014</p> <hr/> <p>Last Update Posted: September 10, 2022</p>
21	NCT03386539	Tacrolimus/Everolimus vs. Tacrolimus/MMF in Pediatric Heart Transplant Recipients Using the MATE Score Study Documents:	Title Acronym: Other Ids: P00025970 PR160574 (Other Grant/Funding Number: U.S. Department of Defense) IND 127980 (Other Identifier: Food and Drug Administration)	Active, not recruiting	<ul style="list-style-type: none">Pediatric Heart Transplant ationImmunosu ppressionChronic Kidney DiseasesCardiac Allograft Vasculopa thyHeart Transplant Failure and RejectionPost-transplant Lymphopr oliferative DisorderHeart Transplant Infection	<ul style="list-style-type: none">Drug: Everolimus Everolimus tablet Other Name: ZortressDrug: Tacrolimus Tacrolimus capsule or liquid suspension Other Name: PrografDrug: Mycophenolate Mofetil Mycophenolate Mofetil capsule or liquid suspension Other Name: Cellcept	<p>Study Type: Interventional</p> <hr/> <p>Phase: Phase 3</p> <hr/> <p>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Multicenter open-label randomized clinical trial with randomization within 4 strata, defined by donor-specific antibody status and center annual transplant volume. There are 2 parallel groups of equal sizes for randomization: everolimus/low-dose tacrolimus and tacrolimus/mycophenolate mofetil. Masking: Single (Outcomes Assessor) Masking Description: The Coronary Angiography Core Laboratory readers will be blinded to treatment assignment and time point (study visit). The Adjudication Committee members will be blinded to treatment assignment. Primary Purpose: Treatment</p> <hr/> <p>Primary Outcome Measures: <i>Same as current</i></p> <hr/> <p>Secondary Outcome Measures: <i>Same as current</i></p>	<p>Actual Enrollment: 211</p> <hr/> <p>Estimated Enrollment:</p> <hr/> <p>Original Estimated Enrollment: 210</p> <hr/> <p>Age: up to 21 Years (Child, Adult)</p> <hr/> <p>Sex: All</p>	<p>Study Sponsors: Same as current</p> <hr/> <p>Collaborators: <ul style="list-style-type: none">Stanford UniversityUnited States Departmen t of Defense</p>	<p>Study Start: January 29, 2018</p> <hr/> <p>Primary Completion: February 2023 (Final data collection date for primary outcome measure)</p> <hr/> <p>Study Completion: February 2023</p> <hr/> <p>First Posted: December 29, 2017</p> <hr/> <p>Results First Posted:</p> <hr/> <p>Last Update Posted: September 9, 2022</p>

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
22	NCT05465317	Evaluating Comparative Effectiveness of Empagliflozin in Type 2 Diabetes Population With and Without Chronic Kidney Disease Study Documents:	Title Acronym: Other Ids: 1245-0228	Active, not recruiting	Diabetes Mellitus, Type 2	<ul style="list-style-type: none">• Drug: Empagliflozin Empagliflozin• Drug: Dipeptidyl Peptidate-4 inhibitors Dipeptidyl Peptidate-4 inhibitors• Drug: Sodium glucose co-transporter-2 inhibitors Sodium glucose co-transporter-2 inhibitors• Drug: Glucagon-like Peptide-1 Receptor Agonists Glucagon-like Peptide-1 Receptor Agonists	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Retrospective Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: 30400 Estimated Enrollment: Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: August 8, 2022 Primary Completion: September 17, 2022 (Final data collection date for primary outcome measure) Study Completion: September 17, 2022 First Posted: July 19, 2022 Results First Posted: Last Update Posted: September 9, 2022
23	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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 4810 Original Estimated Enrollment: <i>Same as current</i> 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

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
24	NCT05321368	A Cardiometabolic Health Program Linked With Clinical-Community Support and Mobile Health Telemonitoring to Reduce Health Disparities Study Documents:	Title Acronym: Other Ids: IRB00311760	Not yet recruiting	<ul style="list-style-type: none">HypertensionHigh Blood PressureDiabetesChronic Kidney Diseases	Behavioral: LINKED-HEARTS Program The intervention arm will include training on home blood pressure monitoring, Sphygmo blood pressure telemonitoring app, Community Health Worker visit for education, counseling on lifestyles modification and Pharmacist to collaborate with other providers to optimize pharmacologic therapy to improve hypertension outcomes and with payors to ensure consistent access to drug therapy.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Prevention Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 600 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: National Institute on Minority Health and Health Disparities (NIMHD)	Study Start: October 31, 2022 Primary Completion: October 1, 2024 (Final data collection date for primary outcome measure) Study Completion: September 1, 2026 First Posted: April 11, 2022 Results First Posted: Last Update Posted: September 9, 2022
25	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	<ul style="list-style-type: none">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: <i>Same as current</i> Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 304 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: <ul style="list-style-type: none">University of Mississippi Medical CenterCooper Green Mercy Health SystemsPack 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
26	NCT03487913	The ELISA Study - Evaluation of Lixivaptan in Subjects With Autosomal Dominant Polycystic Kidney Disease Study Documents:	Title Acronym: Other Ids: PA-102	Completed	Autosomal Dominant Polycystic Kidney Disease	Drug: Lixivaptan Oral vasopressin V2 receptor antagonist Other Name: VPA-985	<div>Study Type: Interventional</div> <div>Phase: Phase 2</div> <div>Study Design: Allocation: Non-Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment</div> <div>Primary Outcome Measures: Number of study participants with treatment-emerging adverse events [Time Frame: 35 days] The number of study participants who experience treatment-emerging adverse events during the study will be measured.</div> <div>Secondary Outcome Measures:<ul style="list-style-type: none">Evaluation of the maximum observed plasma concentration of Lixivaptan in ADPKD patients [Time Frame: 10 days] The pharmacokinetic parameter Cmax will be used to measure the highest concentration of Lixivaptan in plasma after multiple doses of drugEvaluation of the area under the concentration-time curve from time 0 until the last quantifiable concentration of Lixivaptan in ADPKD patients [Time Frame: 10 days] The pharmacokinetic parameter AUC0-last for Lixivaptan, calculated using the linear trapezoidal rule for increasing values and the log trapezoidal rule for decreasing values, will be measured and summarized by doseMean change from baseline in trough urine osmolality after 7 days of treatment with Lixivaptan in ADPKD patients [Time Frame: 7 days] Spot urine osmolality at trough (mOsm/kg) will be determined for urine samples collected immediately prior to morning dosing for Day 1 (Baseline) and Day 7.Mean change from baseline in serum creatinine after 7 days of treatment with Lixivaptan in ADPKD patients [Time Frame: 7 days] Serum creatinine (mg/dL) will be determined from plasma samples collected immediately prior to morning dosing for Day 1 (Baseline) and Day 7.</div>	<div>Actual Enrollment: 31</div> <div>Estimated Enrollment:</div> <div>Original Estimated Enrollment: 32</div> <div>Age: 18 Years to 65 Years (Adult, Older Adult)</div> <div>Sex: All</div>	<div>Study Sponsors: Same as current</div> <div>Collaborators: Not Provided</div>	<div>Study Start: September 14, 2018</div> <div>Primary Completion: December 2, 2019 (Final data collection date for primary outcome measure)</div> <div>Study Completion: February 11, 2020</div> <div>First Posted: April 4, 2018</div> <div>Results First Posted:</div> <div>Last Update Posted: September 9, 2022</div>