

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	<a href="#">REVEAL-CKD: Prevalence and Consequences of Undiagnosed Chronic Kidney Disease</a>  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 12, 2022
2	NCT04741646	<a href="#">Ferric Citrate and Chronic Kidney Disease in Children</a>  Study Documents:	Title Acronym:  Other Ids: <a href="#">1U01DK122013-01</a> ( <a href="#">U.S. NIH Grant/Contract</a> ) <a href="#">1U01DK122013</a> ( <a href="#">U.S. NIH Grant/Contract</a> )	Recruiting	Chronic Kidney Diseases	<ul style="list-style-type: none"><li>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: Auryxia</li><li>Drug: Placebo Placebo to match Ferric Citrate tablets</li></ul>	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: <i>Same as current</i>  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

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3	NCT04523727	<a href="#">Study to Evaluate the Safety and Tolerability of Ferric Citrate in Children With Hyperphosphate mia Related to Chronic Kidney Disease</a>  Study Documents:	Title Acronym:  Other Ids: KRX-0502-308	Not yet recruiting	Hyperphosphate mia Related to Chronic Kidney Disease	Drug: ferric citrate oral tablets  Other Name: KRX-0502	Study Type: Interventional  Phase: Phase 3  Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment  Primary Outcome Measures: <ul style="list-style-type: none"><li>Number of participants with serious and non-serious treatment-emergent adverse events [ Time Frame: up to Week 40 ]</li><li>Number of participants with clinically significant laboratory abnormalities [ Time Frame: up to Week 40 ]</li><li>Number of participants with treatment-emergent adverse events leading to the discontinuation of ferric citrate [ Time Frame: up to Week 40 ]</li></ul> Secondary Outcome Measures: Change from baseline in serum phosphorus to Week 36/early termination (ET) [ Time Frame: Baseline; up to Week 36 ]	Actual Enrollment:  Estimated Enrollment: 45  Original Estimated Enrollment: 40  Age: 12 Years to 17 Years (Child)  Sex: All	Study Sponsors: <a href="#">Same as current</a>  Collaborators: Not Provided	Study Start: September 2022  Primary Completion: April 2024 (Final data collection date for primary outcome measure)  Study Completion: June 2024  First Posted: August 24, 2020  Results First Posted:  Last Update Posted: September 6, 2022
4	NCT05047263	<a href="#">A Trial to Learn How Well Finerenone Works and How Safe it is in Adult Participants With Non-diabetic Chronic Kidney Disease</a>  Study Documents:	Title Acronym:  Other Ids: 21177 2021-000421-27 ( EudraCT Number )	Recruiting	Non-diabetic Chronic Kidney Disease	<ul style="list-style-type: none"><li>Drug: Finerenone (BAY94-8862) Tablet, 10 mg or 20 mg, once daily (OD), oral</li><li>Drug: Placebo Tablet, once daily, oral</li></ul>	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: <a href="#">Same as current</a>  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

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5	NCT05432167	<a href="#">A Study to Evaluate CIN-107 for the Treatment of Patients With Uncontrolled Hypertension and Chronic Kidney Disease</a>  Study Documents:	Title Acronym:  Other Ids: CIN-107-123	Recruiting	<ul style="list-style-type: none"><li>Uncontrolled Hypertension</li><li>Chronic Kidney Diseases</li></ul>	<ul style="list-style-type: none"><li>Drug: CIN-107 Patients will take CIN-107 tablets by mouth once daily.</li><li>Drug: Placebo Patients will take placebo tablets by mouth once daily.</li></ul>	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: 300  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: Parexel	Study Start: May 27, 2022  Primary Completion: October 2023 (Final data collection date for primary outcome measure)  Study Completion: October 2023  First Posted: June 27, 2022  Results First Posted:  Last Update Posted: September 6, 2022
6	NCT04115345	<a href="#">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).</a>  Study Documents:	Title Acronym:  Other Ids: REGEN-004	Recruiting	<ul style="list-style-type: none"><li>Chronic Kidney Disease</li><li>Congenital Anomalies of Kidney and Urinary Tract</li></ul>	Biological: Renal Autologous Cell Therapy (REACT®) Autologous selected renal cells (SRC)	Study Type: Interventional  Phase: Phase 1  Study Design: Allocation: N/A Intervention Model: Single Group Assignment Intervention Model Description: Open-label Masking: None (Open Label) Primary Purpose: Treatment  Primary Outcome Measures: Assess change in eGFR and observe incidence of renal-specific procedure and/or product related adverse events (AEs) through 24 months following two Renal Autologous Cell Therapy (REACT) injections [Safety]. [ Time Frame: 12 months following last REACT injection ] The primary objective is to assess the safety and optimal delivery of Renal Autologous Cell Therapy (REACT) injected at one site in a recipient kidney as measured by procedure-and/or product related adverse events (AEs) through 12 months post-treatment.  Secondary Outcome Measures: Number of subjects with renal-specific adverse events over a 24-month period following injection of Renal Autologous Cell Therapy (REACT). [ Time Frame: 24 months following last REACT injection ] The number of subjects with renal-specific adverse events over a 24-month period following injection of Renal Autologous Cell Therapy (REACT) will be observed utilizing renal-specific laboratory assessments.The secondary objective will compare the results of laboratory tests from baseline through 12 months following REACT injection, followed by an additional observational period of 18 months for a total of 24 months of observation. Each subject's baseline rate of CKD disease progression serves as his/her own "control" to monitor for changes in renal insufficiency over time.	Actual Enrollment:  Estimated Enrollment: 15  Original Estimated Enrollment: <i>Same as current</i>  Age: 18 Years to 65 Years (Adult, Older Adult)  Sex: All	Study Sponsors: <i>Same as current</i>  Collaborators: CTI Clinical Trial and Consulting Services	Study Start: August 13, 2019  Primary Completion: March 31, 2023 (Final data collection date for primary outcome measure)  Study Completion: May 30, 2023  First Posted: October 4, 2019  Results First Posted:  Last Update Posted: September 12, 2022

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7	NCT02542319	<a href="#">Effect of Oral Magnesium on Vascular Calcification in Chronic Kidney Disease</a>  Study Documents:	Title Acronym:  Other Ids: MagiCal-CKD	Completed	<ul style="list-style-type: none"><li>Chronic Kidney Disease</li><li>Vascular Calcification</li><li>Uremic Osteodystrophy</li></ul>	<ul style="list-style-type: none"><li>Dietary Supplement: Mablet 360 mg</li><li>Dietary Supplement: Placebo</li></ul>	Study Type: Interventional  Phase: Phase 2  Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Randomized, double-blind, placebo-controlled, parallel-group Masking: Triple (Participant, Investigator, Outcomes Assessor) Primary Purpose: Treatment  Primary Outcome Measures: <i>Same as current</i>  Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: 148  Estimated Enrollment:  Original Estimated Enrollment: 250  Age: 18 Years and older (Adult, Older Adult)  Sex: All	Study Sponsors: <a href="#">Same as current</a>  Collaborators: Herlev Hospital	Study Start: November 2015  Primary Completion: November 2020 (Final data collection date for primary outcome measure)  Study Completion: July 2021  First Posted: September 7, 2015  Results First Posted:  Last Update Posted: September 6, 2022
8	NCT05531214	<a href="#">Creating A Cardiorenal Multidisciplinary Team for Management HF and CKD Patients</a>  Study Documents:	Title Acronym:  Other Ids: NCR224155	Recruiting	<ul style="list-style-type: none"><li>Heart Failure</li><li>Chronic Kidney Diseases</li></ul>	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: <a href="#">Same as current</a>  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 7, 2022

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9	NCT03594110	<a href="#">EMPA-KIDNEY (The Study of Heart and Kidney Protection With Empagliflozin)</a>  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"><li>• Drug: Empagliflozin Taken daily with or without food</li><li>• Drug: Matching placebo Taken daily with or without food</li></ul>	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"><li>• Time to first hospitalization for heart failure or cardiovascular death [ Time Frame: Median follow-up approx. 3.1 years ]</li><li>• Occurrences of all-cause hospitalization (first and recurrent) [ Time Frame: Median follow-up approx. 3.1 years ]</li><li>• Time to death from any cause [ Time Frame: Median follow-up approx. 3.1 years ]</li><li>• Time to first occurrence of kidney disease progression [ Time Frame: Median follow-up approx. 3.1 years ]</li><li>• Time to cardiovascular death [ Time Frame: Median follow-up approx. 3.1 years ]</li><li>• Time to cardiovascular death or ESKD [ Time Frame: Median follow-up approx. 3.1 years ]</li></ul>	Actual Enrollment: 6609  Estimated Enrollment:  Original Estimated Enrollment: 5000  Age: 18 Years and older (Adult, Older Adult)  Sex: All	Study Sponsors: <a href="#">Same as current</a>  Collaborators: <ul style="list-style-type: none"><li>• Medical Research Council Population Health Research Unit, CTSU, University of Oxford (academic lead)</li><li>• Eli Lilly and Company</li></ul>	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
10	NCT05182840	<a href="#">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</a>  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"><li>• Drug: BI 690517 BI 690517</li><li>• Drug: Placebo to BI 690517 Placebo to BI 690517</li><li>• Drug: Empagliflozin Empagliflozin</li><li>• Drug: Placebo to empagliflozin Placebo to empagliflozin</li></ul>	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: <a href="#">Same as current</a>  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

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11	NCT05527574	<a href="#">Home-based Interventions for FrAilty preveNTion in AdultS With DiabeTes and Chronic Kidney Disease</a>  Study Documents:	Title Acronym:  Other Ids: Pro00089513	Recruiting	<ul style="list-style-type: none"><li>Diabetes Type 2</li><li>Frailty</li><li>Kidney Diseases</li></ul>	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: <a href="#">Same as current</a>  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
12	NCT05305495	<a href="#">Empagliflozin in Acute Heart Failure</a>  Study Documents:	Title Acronym:  Other Ids: 2022-8411	Not yet recruiting	<ul style="list-style-type: none"><li>Acute Heart Failure</li><li>Chronic Kidney Diseases</li></ul>	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: <a href="#">Same as current</a>  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
13	NCT05138419	<a href="#">A Pragmatic Approach to CKD Patient Education</a>  Study Documents:	Title Acronym:  Other Ids: 262853	Recruiting	<ul style="list-style-type: none"><li>Chronic Kidney Disease stage3</li><li>Chronic Kidney Disease stage4</li><li>Chronic Kidney Disease Stage 5</li><li>Patient Engagement</li></ul>	<ul style="list-style-type: none"><li>Other: CKD "What You Need To Know" Workbook System 139 page Workbook including CKD Action Plan, Web-Based Resources, Interactive CKD Patient education material</li><li>Other: 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.</li><li>Other: CKD Web-based Resource List CKD Patient education material used separately for control arm</li><li>Other: Food Label reading exercise CKD Patient education material used separately in all arms.</li></ul>	<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"><li>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.</li><li>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.</li><li>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 occurred</li><li>Patient 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</li></ul>	<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>

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14	NCT04102527	<a href="#">Evaluation of the Impact of Transit Troubles in Patients Undergoing Peritoneal Dialysis</a>  Study Documents:	Title Acronym:  Other Ids: CHV 2018-1	Recruiting	<ul style="list-style-type: none"><li>Peritoneal Dialysis Complication</li><li>Constipation</li></ul>	Other: Questionnaires Patients have to complete the study questionnaires every 2 months : <ul style="list-style-type: none"><li>Digestive Functional Score of Neurological Patients</li><li>Bowel Function Index</li><li>Severity score for constipation</li><li>Bristol Scale</li><li>Constipation assessment scale</li><li>Estimate scale of risk of constipation</li></ul>	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: <a href="#">Same as current</a>  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
15	NCT05530291	<a href="#">Incidence and Burden of Erythropoietin Hyporesponsiveness - a Retrospective Database Analysis</a>  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: <a href="#">Same as current</a>  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



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16	NCT05306210	<a href="#">Forxiga CKD Japan Post-Marketing Surveillance (PMS)</a>  Study Documents:	Title Acronym:  Other Ids: D169AC00007	Recruiting	Chronic Kidney Disease	Not Provided	Study Type: Observational  Phase:  Study Design: Observational Model: Cohort Time Perspective: Prospective  Primary Outcome Measures: <i>Same as current</i>  Secondary Outcome Measures: Not Provided	Actual Enrollment:  Estimated Enrollment: 960  Original Estimated Enrollment: <i>Same as current</i>  Age: Child, Adult, Older Adult  Sex: All	Study Sponsors: <i>Same as current</i>  Collaborators: Not Provided	Study Start: April 12, 2022  Primary Completion: April 16, 2025 (Final data collection date for primary outcome measure)  Study Completion: April 16, 2025  First Posted: April 1, 2022  Results First Posted:  Last Update Posted: September 6, 2022
17	NCT03749447	<a href="#">An Extended Access Program for Bardoxolone Methyl in Patients With CKD (EAGLE)</a>  Study Documents:	Title Acronym:  Other Ids: 402-C-1803	Recruiting	<ul style="list-style-type: none"><li>Chronic Kidney Diseases</li><li>Alport Syndrome</li><li>Autosomal Dominant Polycystic Kidney</li></ul>	Drug: Bardoxolone methyl Bardoxolone methyl capsules Other Name: RTA 402	Study Type: Interventional  Phase: Phase 3  Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment  Primary Outcome Measures: <i>Same as current</i>  Secondary Outcome Measures: Not Provided	Actual Enrollment:  Estimated Enrollment: 480  Original Estimated Enrollment: 180  Age: 12 Years and older (Child, Adult, Older Adult)  Sex: All	Study Sponsors: <i>Same as current</i>  Collaborators: Not Provided	Study Start: March 8, 2019  Primary Completion: December 2025 (Final data collection date for primary outcome measure)  Study Completion: December 2025  First Posted: November 21, 2018  Results First Posted:  Last Update Posted: September 6, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
18	NCT05134701	<a href="#">Dapagliflozin Post Marketing Surveillance in HF and CKD</a>  Study Documents:	Title Acronym:  Other Ids: D1699R00007	Recruiting	<ul style="list-style-type: none"><li>Heart Failure With Reduced Ejection Fraction</li><li>Chronic Kidney Disease</li></ul>	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	NCT05171686	<a href="#">Diuretics and Volume Overload in Early CKD</a>  Study Documents:	Title Acronym:  Other Ids: NEPH-001-21S <a href="#">1IK2CX002368-01A1 ( U.S. NIH Grant/Contract )</a>	Not yet recruiting	<ul style="list-style-type: none"><li>Chronic Kidney Disease</li><li>Hypertension</li></ul>	Drug: Diuretic augmentation (hydrochlorothiazide, chlorthalidone, furosemide, torsemide, or bumetanide) The participant's blood pressure medication regimen will then be altered to initiate a thiazide-type (hydrochlorothiazide or chlorthalidone) or loop diuretic (furosemide, bumetanide, or torsemide) in those not already prescribed a diuretic, or to increase the dose if one is already prescribed	Study Type: Interventional  Phase: Phase 4  Study Design: Allocation: N/A Intervention Model: Single Group Assignment Intervention Model Description: Open label single arm clinical trial 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: 46  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: Not Provided	Study Start: November 1, 2022  Primary Completion: December 31, 2024 (Final data collection date for primary outcome measure)  Study Completion: December 31, 2024  First Posted: December 29, 2021  Results First Posted:  Last Update Posted: September 6, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
20	NCT00345839	<a href="#">E.V.O.L.V.E. Trial™: Evaluation Of Cinacalcet Hydrochloride (HCl) Therapy to Lower CardioVascular Events</a>  Study Documents:	Title Acronym:  Other Ids: 20050182	Completed	<ul style="list-style-type: none"><li>Secondary Hyperpara thyroidism</li><li>Chronic Kidney Disease</li></ul>	<ul style="list-style-type: none"><li>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.</li><li>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.</li></ul>	<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"><li>Time to all-cause mortality</li><li>Time to cardiovascular mortality</li><li>Time to fatal and non-fatal MI</li><li>Time to fatal and non-fatal hospitalization for unstable angina</li><li>Time to fatal and non-fatal HF event</li><li>Time to fatal and non-fatal peripheral vascular event</li><li>Time to fatal and non-fatal stroke</li><li>Time to bone fracture</li><li>Time to parathyroidectomy</li></ul>	<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: <a href="#">Same as current</a></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 12, 2022</p>
21	NCT05491642	<a href="#">A Study in Male and Female Participants (After Menopause) With Mild to Moderate High Blood Pressure to Learn How Safe the Study Treatment BAY3283142 is, How it Affects the Body and How it Moves Into, Through and Out of the Body After Taking Single and Multiple Doses</a>  Study Documents:	Title Acronym:  Other Ids: 21592 2022-001268-84 ( EudraCT Number )	Not yet recruiting	<ul style="list-style-type: none"><li>Chronic Kidney Disease</li><li>Hypertensi on</li></ul>	<ul style="list-style-type: none"><li>Drug: BAY3283142 Oral administration</li><li>Drug: Placebo to BAY3283142 Oral administration</li></ul>	<p>Study Type: Interventional</p> <hr/> <p>Phase: Phase 1</p> <hr/> <p>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Single (Participant) 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:</p> <hr/> <p>Estimated Enrollment: 54</p> <hr/> <p>Original Estimated Enrollment: <i>Same as current</i></p> <hr/> <p>Age: 30 Years to 78 Years (Adult, Older Adult)</p> <hr/> <p>Sex: All</p>	<p>Study Sponsors: <a href="#">Same as current</a></p> <hr/> <p>Collaborators: Not Provided</p>	<p>Study Start: September 8, 2022</p> <hr/> <p>Primary Completion: May 15, 2023 (Final data collection date for primary outcome measure)</p> <hr/> <p>Study Completion: June 26, 2023</p> <hr/> <p>First Posted: August 8, 2022</p> <hr/> <p>Results First Posted:</p> <hr/> <p>Last Update Posted: September 6, 2022</p>

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
22	NCT03386539	<a href="#">Tacrolimus/Everolimus vs. Tacrolimus/MMF in Pediatric Heart Transplant Recipients Using the MATE Score</a>  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"><li>• Pediatric Heart Transplantation</li><li>• Immunosuppression</li><li>• Chronic Kidney Diseases</li><li>• Cardiac Allograft Vasculopathy</li><li>• Heart Transplant Failure and Rejection</li><li>• Post-transplant Lymphoproliferative Disorder</li><li>• Heart Transplant Infection</li></ul>	<ul style="list-style-type: none"><li>• Drug: Everolimus Everolimus tablet Other Name: Zortress</li><li>• Drug: Tacrolimus Tacrolimus capsule or liquid suspension Other Name: Prograf</li><li>• Drug: Mycophenolate Mofetil Mycophenolate Mofetil capsule or liquid suspension Other Name: Cellcept</li></ul>	Study Type: Interventional  Phase: Phase 3  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  Primary Outcome Measures: <i>Same as current</i>  Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: 211  Estimated Enrollment:  Original Estimated Enrollment: 210  Age: up to 21 Years (Child, Adult)  Sex: All	Study Sponsors: <a href="#">Same as current</a>  Collaborators: <ul style="list-style-type: none"><li>• Stanford University</li><li>• United States Department of Defense</li></ul>	Study Start: January 29, 2018  Primary Completion: February 2023 (Final data collection date for primary outcome measure)  Study Completion: February 2023  First Posted: December 29, 2017  Results First Posted:  Last Update Posted: September 9, 2022
23	NCT05465317	<a href="#">Evaluating Comparative Effectiveness of Empagliflozin in Type 2 Diabetes Population With and Without Chronic Kidney Disease</a>  Study Documents:	Title Acronym:  Other Ids: 1245-0228	Active, not recruiting	Diabetes Mellitus, Type 2	<ul style="list-style-type: none"><li>• Drug: Empagliflozin Empagliflozin</li><li>• Drug: Dipeptidyl Peptidate-4 inhibitors Dipeptidyl Peptidate-4 inhibitors</li><li>• Drug: Sodium glucose co-transporter-2 inhibitors Sodium glucose co-transporter-2 inhibitors</li><li>• Drug: Glucagon-like Peptide-1 Receptor Agonists Glucagon-like Peptide-1 Receptor Agonists</li></ul>	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: <a href="#">Same as current</a>  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

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
24	NCT05321368	<a href="#">A Cardiometabolic Health Program Linked With Clinical-Community Support and Mobile Health Telemonitoring to Reduce Health Disparities</a>  Study Documents:	Title Acronym:  Other Ids: IRB00311760	Not yet recruiting	<ul style="list-style-type: none"><li>Hypertension</li><li>High Blood Pressure</li><li>Diabetes</li><li>Chronic Kidney Diseases</li></ul>	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	<a href="#">Food Delivery, Remote Monitoring, and Coaching-Enhanced Education for Optimized Diabetes Management (FREEDOM)</a>  Study Documents:	Title Acronym:  Other Ids: IRB-300008387	Not yet recruiting	Diabetes Mellitus, Type 2	<ul style="list-style-type: none"><li>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.</li><li>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.</li><li>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.</li><li>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.</li></ul>	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"><li>University of Mississippi Medical Center</li><li>Cooper Green Mercy Health Systems</li><li>Pack Health</li></ul>	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 12, 2022



	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
26	NCT03871894	<a href="#">Indirect Calorimeter Based Study in Patients With Liver Cirrhosis</a>  Study Documents:	Title Acronym:  Other Ids: ILBS-METALIC01	Completed	Liver Cirrhoses	<ul style="list-style-type: none"><li>Other: Indirect calorimetry based nutritional intervention till patient in ICU(Intensive care unit) Nutrition therapy based on indirect calorimetry (IC) measurements(measured resting energy expenditure and/or substrate utilization) and to be adjusted according to the variations shown by IC. and protein intake 1.5g/kg IBW/day</li><li>Other: Standard and fixed nutritional intervention till patient in ICU Fixed standard nutritional therapy 35-40 Kcal/Kg IBW/day and 1.5 g protein /Kg IBW/Day throughout the period of ICU stay</li></ul>	<p>Study Type: Interventional</p> <hr/> <p>Phase: Not Applicable</p> <hr/> <p>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Single (Participant) Primary Purpose: Treatment</p> <hr/> <p>Primary Outcome Measures:</p> <ul style="list-style-type: none"><li>To study and compare the resting energy expenditure(REE) measured by Indirect Calorimetry between all the groups [ Time Frame: 1 day ]</li><li>To study and compare the substrate utilization(Respiratory quotient- RQ) at fasting state measured by Indirect Calorimetry between all the groups. [ Time Frame: 1 day ]</li><li>The effect of nutritional therapy as per standard versus measured protocol during ICU stay on duration of mechanical ventilation in critically ill ventilated patients with cirrhosis [ Time Frame: 28 days ]</li><li>The effect of nutritional therapy as per standard versus measured protocol during ICU (Intensive Care Unit) stay on mortality in critically ill ventilated patients with cirrhosis [ Time Frame: 28 days ]</li></ul> <hr/> <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none"><li>The effect of nutritional therapy as per standard versus measured protocol during ICU stay on the changes non esterified fatty acid levels (NEFA) in critically ill ventilated patients with cirrhosis [ Time Frame: 28 days ]</li><li>The effect of nutritional therapy as per standard versus measured protocol during ICU stay on the levels of interleukin 6 (IL6) in critically ill ventilated patients with cirrhosis [ Time Frame: 28 days ]</li><li>The effect of nutritional therapy as per standard versus measured protocol during ICU stay on the Fraction of Inspired oxygen (FiO2) in critically ill ventilated patients with cirrhosis [ Time Frame: 28 days ]</li><li>The effect of nutritional therapy as per standard versus measured protocol during ICU stay on the incidence of new onset infection in critically ill ventilated patients with cirrhosis [ Time Frame: 28 days ]</li><li>The effect of nutritional therapy as per standard versus measured protocol during ICU stay on NUTRIC (The Nutrition Risk in Critically ill score) score range (0-9 ) in critically ill ventilated patients with cirrhosis. [ Time Frame: 28 days ]</li></ul> <hr/>	<p>Actual Enrollment: 83</p> <hr/> <p>Estimated Enrollment:</p> <hr/> <p>Original Estimated Enrollment: 50</p> <hr/> <p>Age: 18 Years to 70 Years (Adult, Older Adult)</p> <hr/> <p>Sex: All</p>	<p>Study Sponsors: <a href="#">Same as current</a></p> <hr/> <p>Collaborators: Not Provided</p>	<p>Study Start: March 12, 2019</p> <hr/> <p>Primary Completion: August 31, 2022 (Final data collection date for primary outcome measure)</p> <hr/> <p>Study Completion: August 31, 2022</p> <hr/> <p>First Posted: March 12, 2019</p> <hr/> <p>Results First Posted:</p> <hr/> <p>Last Update Posted: September 6, 2022</p>

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
27	NCT03487913	<a href="#">The ELISA Study - Evaluation of Lixivaptan in Subjects With Autosomal Dominant Polycystic Kidney Disease</a>  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"><li>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 drug</li><li>Evaluation 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 dose</li><li>Mean 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.</li><li>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.</li></ul></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: <a href="#">Same as current</a></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>