

## Current Research Studies

April 2020

### **ACTION: Anti-Cytokine Therapy for Hemodialysis Inflammation Trial**

The purpose of this study is to evaluate the safety and tolerability of the administration of the drug Anakinra in the suppression of inflammation in hemodialysis patients.

### **ASPIRED: Assessing Patient-Reported Experience of Care for Home Dialysis**

This study aims to develop and validate one instrument to measure patient-care experience satisfaction for peritoneal dialysis (PD) and home hemodialysis (HD) with input from patients, caregivers, and kidney care professionals. The ultimate goal of development and validation of these instruments is for dissemination and use in clinical practice for quality improvement initiatives, tailoring aspects of care to patients' values and preferences, and to provide an enhanced voice for home dialysis patients in their ongoing care.

### **APOL-1**

This study evaluates views concerning providing genetic testing information about the Apolipoprotein (APOL1) gene mutation to patients and family members who may be at risk for kidney disease. The goal of the study is to address a bioethics concern, specifically to gain community input on the question of genetic testing for kidney disease risk in African American communities.

### **ATRIA-CKD**

This study uses "real world" data to study the efficacy and safety of atrial fibrillation therapies in patients with chronic kidney disease.

### **BEST CASE/WORST CASE: A Multisite Randomized Clinical Trial of Scenario Planning for Patients with Kidney Disease**

This study aims to assess a scenario-planning communication tool designed to help physicians and patients with advanced kidney disease arrive at treatment decisions aligned with patient goals, values, and preferences.

### **Bio-PD: Biological Determinants of Peritoneal Dialysis**

This study focuses on the peritoneal dialysis population, and creates a repository of plasma, DNA and spent dialysate samples from pre-existing biorepositories as well as prospectively enrolled subjects. The repository will be used to explore common genetic variants that determine the baseline peritoneal membrane function in patients starting treatment with PD and change in function upon treatment.

### **CASIS: Chips in Space**

This project will send a kidney model created through our Kidney on a Chip study to the International Space Station in order to understand how microgravity and other factors affect kidney function, and

to use these discoveries to design better treatments for proteinuria, osteoporosis, and kidney stones on earth.

#### **Cellular Models of Human Kidney Disease and Regeneration**

This is a registry for patients with kidney disease or a disease syndrome with a kidney component. Participants send in urine or hair samples which are used to generate stem cells. The stem cells are used to generate new kidney cells for the study of kidney disease and regeneration in the laboratory.

#### **CoNR: Cross-over Randomized Controlled Trial of Coenzyme Q10 or Nicotinamide Riboside in Chronic Kidney Disease**

This is a randomized clinical trial testing coenzyme Q10 and nicotinamide riboside treatments for improving physical function and exercise efficiency in people with chronic kidney disease.

#### **Conservative care for advanced kidney disease**

The goal of this work is to develop and pilot test a dedicated decision aid for conservative care to improve informed and shared decision-making for the treatment of advanced chronic kidney disease

#### **CureGN: Cure Glomerulonephropathy Network**

This is a multi-center consortium sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) that aims to work collaboratively to address major challenges to understanding the underlying biology of Minimal Change Disease, FSGS, MN and IgAN. The goal is to recruit and maintain a large cohort of patients (2,400) with glomerular disease and follow them prospectively with standardized clinical data and biospecimen collection.

#### **Dialysis Decision-Making among Adults with Advanced Kidney Disease**

This is a longitudinal study that uses qualitative and quantitative research techniques to investigate the process of decision-making for treatment of advanced kidney disease from the patients perspective. The overarching goal of this study is to develop more patient-centric models of care for kidney disease that better support patients in clinical decision-making regarding these treatments.

#### **Emergency Department Management Patterns and Renal Outcomes in Patients with Sepsis**

This study looks at patients presenting to the Emergency Department with sepsis or septic shock. It examines associations between fluid management and time to antimicrobial administration with renal outcomes.

#### **Heart Failure and Atrial Arrhythmias**

This study looks at patients with chronic kidney disease. The goal of this study is to examine the use of biomarkers measured in the blood of patients with kidney disease at the highest risk for heart failure and worsening kidney disease.

### **ICICLE: Impact of Cirrhosis on Kidney Secretory Clearance**

The goal of this study is to evaluate new markers of kidney function that focus on the kidney tubules in people with cirrhosis of the liver.

### **Identification of AKI sub-phenotypes based on trajectory of serum creatinine**

ICU patients included in the ASSESS-AKI study will be evaluated and identified for AKI sub-phenotypes based on the trajectory of serum creatinine. In addition, the association of AKI sub-phenotypes with long-term outcomes such as incidence and progression of chronic kidney disease and need for renal replacement therapy will be identified. The goal is to develop a more accurate and real-time risk stratifying tool to identify patients at increased risk for poor long-term outcomes after development of AKI in the ICU.

### **Kidney on a Chip**

The goal of this research is to develop a model system that predicts drug handling (especially drug excretion and kidney toxicity) in the human kidney. Using this model, researchers will emulate healthy and disease related conditions.

### **KPMP: Kidney Precision Medicine Project**

The KPMP consortia is focused on finding new ways to treat AKI and CKD. Renal tissue will be obtained from participating volunteers, and will be analyzed in an effort to redefine kidney disease in molecular terms and identify novel targeted therapies. The consortia will develop state-of-the-art methods to obtain and analyze these biopsies, linking information on cellular programs with kidney structure. The Kidney Research Institute will serve as the central hub for this project.

### **KRI Registry**

Patients interested in taking part in ongoing and future research studies are invited to join the KRI registry, a database that allows investigators to identify potential subjects for research. The registry increases patient participation in research at the KRI.

### **KRI Repository**

The purpose of the repository is to use banked data and specimens for the study of kidney disease in the future. Samples may come from hemodialysis, peritoneal dialysis and chronic kidney disease patients, as well as people with normal kidney function. Some banked samples from PD patients will be added to the International Bio-PD study, a study that looks at genetic markers that impact how well peritoneal dialysis works at baseline. A second aim is to look at pathways that contribute to the decline of the PD membrane over time. More than 4,800 patients from the U.S., Europe and Australia will participate.

### **NEPTUNE: Nephrotic Syndrome Study Network**

This study is sponsored by the Office of Rare Diseases, NIH, NIDDK, DHHS, NephCure Kidney International, and University of Michigan. It is a longitudinal observational study that, among others, aims to establish a collaborative, integrated and cost-effective investigational infrastructure to conduct clinical and translational research in FSGS, MCD, MN and childhood onset NS.

**PDOPPS: Peritoneal Dialysis Outcomes and Practice Patterns Study**

This observational study is assessing the optimal way to care for peritoneal dialysis patients. The goal is to increase the appropriate use of PD, extend technique survival and improve quality of life for PD patients.

**PERLage: Preventing Early Renal Loss in Diabetes**

This is a multicenter follow-up study for PERL participants. PERL tested medication therapy for people with type 1 diabetes and early stage kidney disease. The PERL study aimed to see if taking allopurinol to decrease uric acid levels may prevent kidney disease in people with type 1 diabetes.

**RBK: Rebuilding the Glomerular Filtration Barrier by Regenerating Adult Podocytes**

This project aims to rebuild kidney glomeruli by regenerating podocytes, terminally differentiated cells in the kidney glomerular filtering units that limit the passage of proteins from the blood into the urine, from two candidate resident stem/progenitor cells, cells of renin lineage (CoRL) and parietal epithelial cells (PECs).

**ROBIN: Review of Biopsies in Diabetic Nephropathy**

This is a retrospective and prospective medical records review to study diabetes in kidney disease in the US. The study will address the following questions: What clinical findings are associated with traditional diabetic kidney disease versus other types of kidney disease co-occurring with diabetes? What clinical and pathology findings are associated with progression to end-stage renal disease and death?

**SKS: Seattle Kidney Study**

We launched the Seattle Kidney Study in 2004 to better understand risk factors and the progression of CKD to ESRD. Almost 700 people have enrolled in this study and we are recording their kidney disease symptoms, medications, physical activity and functioning, and collecting biological specimens.

**SLEEP-HD**

This is a parallel group randomized controlled trial looking at insomnia in the dialysis population. 125 hemodialysis patients will be enrolled in community-based dialysis facilities in Seattle and New Mexico and randomized to 6 week treatment to telehealth cognitive based therapy, trazodone, or medication placebo.

## Upcoming Research Studies

### **CONCORD:**

This study is being done to find out whether treatment of major depression with the medication, Bupropion, Behavioral Activation Teletherapy (BAT), both, Clinical Management (CM) and/or placebo will improve depression, quality of life and overall functioning in CKD patients. The secondary purpose is to find out whether CKD patients will be able to tolerate these treatments.

### **HOPE: The Hemodialysis Opioid Prescription Effort Consortium Clinical Center**

Patients undergoing long-term dialysis with chronic pain needing opioids will be enrolled in a clinical trial to test multiple strategies to see if they help patients get off prescription opioids. Some patients will receive cognitive behavioral therapy (CBT) or CBT augmented by safer medical therapy such as buprenorphine patches. CBT is a type of psychotherapy in which negative thought patterns about the self and the world are challenged to alter unwanted behavior patterns and to treat mood disorders such as depression. This study is upcoming.

### **Improving Medical Decision Making for Older Patients with End Stage Renal Disease**

This is a multi-center clinical trial testing the impact of a video-based decision aid for treatment of advanced kidney disease in supporting patients with making treatment decisions that uphold their healthcare goals.

### **ROKT: Role of kidney tubular function in critical illness.**

Acute kidney injury is a common complication of critical illness that primarily affects the tubules of the kidneys. We developed a new test to measure kidney tubular functions. We will perform this test in patients who are in the intensive care unit and will determine whether this important function is related to kidney recovery.

**OK-D: Association between retinal angiography findings and kidney histopathology in participants with diabetes:** Diabetes affects the small blood vessels of the eye and kidney. This is a cross-sectional, observational study exploring associations between kidney biopsy findings and eye imaging findings in adults with diabetes. We will be using optical coherence tomography, a high-resolution imaging technique, to obtain detailed mapping of retinal blood vessels.

### **For study related questions, please contact:**

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