STUDY TITLE: A Multi-Center, Pilot Study to Assess the Safety and Efficacy of a Selective Cytopheretic Device (SCD) in Pediatric Patients with Acute Kidney Injury (AKI)

STUDY NUMBER: 2015-3005

FUNDING ORGANIZATION: National Institutes of Health

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ABOUT THIS CONSENT FORM

- If you are the parent/guardian of a child who is being invited to participate in this study, the word "you" or "I" in this document refers to your child. As the parent/guardian, you are asked to read and sign this document to give permission for your child to participate.
- If you are a patient, 18 or older, you are asked to read and sign this document to indicate your willingness to participate in this study.

INTRODUCTION

We are asking for your permission to be in a research study so that we can learn new information that may help others. If you decide not to give your permission to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In this research study, we want to learn more about the effects of a new device that is similar to a dialysis filter used in the treatment of Acute Kidney Injury (AKI). Because of your kidney injury, continuous renal replacement therapy (CRRT) is being used to help your kidneys recover. This research involves using an investigational device or filter on the CRRT machine which is called a selective cytopheretic device (SCD). The SCD works by allowing cells that cause kidney injury to be desensitized, inactivated, or stopped from causing more harm.

We are asking you and other people with AKI and requiring CRRT to be in the research, to understand the safety and effectiveness of the dialysis filter, selective cytopheretic device (SCD). We are asking 30 people to participate in this research.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Stuart Goldstein is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study. CCHMC is being paid by the National Institutes of Health to do this study.

WHO SHOULD NOT BE IN THE STUDY?

You cannot be in this study if you have any of the following:

- Older than 22 years old
- Not receiving care in an intensive care unit

- Pregnant or lactating
- Heart support devices like, LVAD, RVAD, BiVAD
- History of End Stage Kidney Disease
- History of previous dialysis treatments during this admission
- Severe chronic liver failure
- Cancer
- Chronic immunosuppression
- HIV or AIDS.
- Weigh less than 15 kilograms (33 lbs)
- Concurrent enrollment in another interventional clinical trial. Patients enrolled in clinical trials where only measurements and/or samples are taken are allowed to participate.
- Use of any other Investigational drug or device within the previous 30 days.

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain each visit to you. You will be able to ask questions to make sure that you understand what will happen to you. These are the things that will happen to you while in the study:

- CRRT prescribed by your doctor with the addition of the SCD filter for up to 7 days
- SCD will be changed once every 24 hours (See below the description of SCD)
- Daily blood work for safety monitoring
- In addition to daily blood work, a blood sample for Complete Blood Count will be done in daily in the evening from an existing catheter for safety monitoring (extra 1 mL/day)
- Every other day blood samples for biomarkers (for this and future research) will be drawn from an existing catheter (total amount 4 mL/during the study period)
- Data collection from your medical record for every day of the SCD is used and up to 60 days later
- If you still need dialysis after 7 days, you will be treated per standard of care without the SCD filter as prescribed by your doctor.

The SCD is a synthetic membrane similar to filters used for hemodialysis to filter unwanted substances from the blood. The SCD will be connected to existing CRRT system. Blood from the CRRT machine flows through the SCD, is returned back to the CRRT machine, and then returned back to the patient.

To keep the blood from forming clots in the circuit, a solution of citrate is put in the CRRT and SCD. Citrate is a medication that keeps blood from forming clots when the blood is outside the body. Citrate is used with CRRT as part of normal care at CCHMC.

FUTURE RESEARCH:

Researchers in this study are dedicated to researching biomarkers of kidney disease related to AKI. The data and blood samples collected during this study are important to this study and to future AKI research. With your additional consent, blood collected during this study (will be kept in an outside laboratory for an indefinite period of time with samples from other children who have enrolled in this study. All identifying information will be removed from the samples. They will be identified only by a unique study number.

These samples may be used in the future in ongoing research related to biomarkers involved in AKI and other kidney conditions. They will only be studying kidney disease, which you have already been diagnosed as having. They will not be researching non-kidney related disease.

These samples will be sent to an outside laboratory chosen by the sponsor, CytoPherx, Inc, but we will not give them any information that would personally identify you. We will not put the results of any tests conducted on these samples in your medical record. You may still participate in this study even if you do not agree to participate in the sample repository.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this study may have potential benefit of improved outcome in terms of survival, improved blood pressure stability and shorter ICU course; however, this cannot be guaranteed. Being in this study may not help you right now.

When we finish the study, we hope that we will know more about the effects of the new dialysis filter on patients with AKI. The results from this study may help others with AKI later on.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

	Mild	Serious	Life Threatening
Common	• General aching • Skin Rash • Nausea/Vomiting • Low blood pressure • Low white blood cell counts		
Uncommon	• Changes in temperature • Confusion • Pain	• Infections • Electrolyte disorders	• Irregular heart rate
Rare		• Pneumonia • Bleeding • Low platelet count • Low or high calcium levels	

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it. If you choose not to participate, will receive CRRT as standard of care.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you remains private is important to us. To protect your privacy in this research study we will:

- Identifiable data will have limited access, only the appropriate study staff will have access.
- Store all study information in a locked cabinet or password protected file
- Enter de-identified data into a secure password protected system
- Ensure only appropriate study staff will have access to patient information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

The Food and Drug Administration (FDA) may choose to inspect your records since you are a subject in this investigation of an unapproved device.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

You will be told of any new information that might affect your health, welfare, or willingness to continue to participate in this study.

WILL IT COST YOU ANYTHING EXTRA FOR YOU TO BE IN THE RESEARCH STUDY?

There will be no extra costs to you because you are participating in this study. You or your health insurance will pay for all the things you or your insurance would have paid for even if you were not in the study, including the ICU stay, CRRT, and other hospital related health costs. The SCD study device will be provided at no cost to you or your health insurance provider.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will not be paid for participating in the study.

WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?

If you believe that you have been injured as a result of this research you should contact Dr. Stuart Goldstein as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in a research study. If possible, you should give them a copy of this permission form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document. If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

CCHMC will need to use and share your PHI as part of this study. This PHI will come from:

- Your CCHMC medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications

- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your medical care be impacted?

By signing this document you agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

☐ _____ **I AGREE** to allow my blood samples to be saved for future biomarker studies. (check box and initial)

_____

Printed Name of Research Participant

_____ _____

Signature of Participant / Parent / Legally Authorized Representative Date

_____

* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____ _____

Signature of Individual Obtaining Consent Date Time