

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Multi-Center Pilot Study to Assess the Safety and Efficacy of A Selective Cytopheretic Device (SCD) In Patients with Acute Renal Failure (ARF)

PROTOCOL NO.: ARF-002
WIRB® Protocol #20100069

SPONSOR: CytoPherx, Inc
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**STUDY-RELATED
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202-715-4570

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, “you” always refers to the subject. If you are a legally authorized representative, please remember that “you” refers to the study subject.

Statement of Research

You, or your family member, are being asked if you want to take part in a research study using an experimental (investigational) medical treatment called the Selective Cytopheretic Device - or SCD, for short. An investigational device is one that is not approved by the U.S. Food and Drug Administration (FDA). You may decide to be in the study or decide not to take part at all. It is your decision. If you decide to be in the study, you may withdraw from the study at any time.

No matter what you decide, your decision will not lead to any penalty or affect your regular medical care. This consent form describes the procedures that will be followed and any risks that might be involved in this study. It is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

Information about the Research

You have been diagnosed with a very serious and often fatal disease known as acute renal failure (ARF). Acute renal failure is a condition where the kidneys are not capable of clearing your body of poisons (toxins) by producing adequate urine. Therefore, another way to remove waste from the body is needed to hopefully allow time for the kidneys to heal. One method of removing waste from the body is called Continuous Renal Replacement Therapy (CRRT) or variations of that therapy, and your study doctor has recommended this therapy for you. This therapy is similar to kidney dialysis.

Acute renal failure is an imbalance of the systems that protect our body from illness caused by kidney cell injury or necrosis (kidney cell death). Proteins are released by leukocytes (white blood cells) and an imbalance between these proteins and normal white blood cells can result in a high risk of death. White blood cells, especially neutrophils - a specialized type of white blood cell, are major contributors to this imbalance. A large number of treatment approaches are under investigation to limit the release of leukocytes during inflammation in order to minimize tissue destruction and disease progression.

The study device, combined with regional citrate anticoagulation (a dialysis fluid that thins your blood), can limit harmful neutrophils (Blood thinning is a normal part of dialysis). Regional citrate anticoagulation treatment prevents blood clots from forming inside the SCD. The citrate anticoagulation is administered and monitored carefully to avoid too much thinning of the blood. Citrate is not toxic and is also produced in small amounts in the human body. The SCD has been studied in preclinical animal models and in a multicenter clinical study in humans.

Purpose Of Research And Length Of Participation In Study

The purposes of this study are:

1. To evaluate the safety of the SCD and any side effects that might be associated with it;
2. This study will also see if the SCD works normally when changed daily and used for as long as 7 days; and
3. To see if the SCD will provide added benefits to normal CRRT therapy.

There will be approximately 35 subjects in this study.

Information about your health and your kidney function will be collected periodically for up to 28 days after the end of treatment and/or while you are in the hospital. Health and kidney function information will also be collected up to 60 days after your hospital stay.

This Is What Will Happen If You Decide To Be In This Research Study

Your study doctor, or one of his associates, will talk to you about your disease, ask you questions about your health, and give you a physical exam.

The study device is connected to the CRRT tubing so there are no extra needle sticks or extra tubes that need to be inserted in your body. When the study therapy is actually started, you shouldn't feel anything, although there is a risk that your blood pressure may decrease when your blood first runs through the study device (see RISKS section). At all times the study device is running, trained medical personnel will be at your bedside to make sure the SCD is functioning properly. The nurses will take your blood pressure frequently, and check your heart rate, weight and body temperature. Each day the study device is running you will have an ECG done (tracing of the electrical activity of the heart). You will be asked to report any side effects you think you may be having. Frequent blood tests for safety measurements will be drawn from your body.

The study device may be connected for a maximum of 7 days. It will be stopped earlier if your kidneys have recovered, or if your study doctor thinks it is necessary, or if there is any evidence that the study device is not working properly. You will be asked to come see your study doctor or his associate in his office for follow up appointments at least 28 days and 60 days after the last day you were on the SCD or were discharged from the hospital. At these follow-up visits you will be asked about any adverse events you may have had. You will have blood drawn for safety tests. Your vital signs and an ECG will be done.

What are the Risks of this Study?

Possible side effects with SCD are a moderate to large decrease in your blood pressure, a decrease in the number of white blood cells and platelets in your blood (platelets are cells that help your blood clot) or bleeding. In some cases any of the side effects could be life threatening.

This study device has not been tested in pregnant females. Therefore, risks to an embryo or fetus are unknown at this time. You should not be pregnant or intend to become pregnant while taking part in this study. If you are a woman able to have children, a pregnancy test will be performed before you enter the study. If you suspect that you have become pregnant, you must notify the study doctor immediately.

There is a risk of blood clotting in the SCD. To prevent blood clotting, the calcium level in the machine is lowered. Low calcium levels prevent clotting. The medication we use to lower the calcium is called citrate. In order, to make sure that the low level of calcium in the machine does not affect you, we give extra calcium intravenously.

This type of system to prevent clotting is commonly done in the ICU, and this technique has been used safely for over 30 years.

If the calcium infusion or the citrate infusion is not in balance, a rare, potential serious risk of low blood calcium could occur. For this reason, the citrate and calcium infusions are monitored continuously, and calcium blood levels are checked frequently. In addition, we are providing dedicated study personnel as an added safeguard to make sure the blood calcium level remains at the appropriate levels.

Participating in this study could cause you some inconvenience.

Approximately 150cc of blood for tests will be taken from you during the course of the study.

There may be additional risks or discomforts that are not known at this time.
Your condition may not get better or may become worse during this study.

What if there are New Findings?

Any significant new research findings regarding the study device that might change your decision to be in this study will be provided to you as updated information. You may be asked to sign a revised consent form if this occurs.

Are there Benefits?

The SCD may help resolve or control your disease. There is, however, no guarantee that you may receive any benefit from participating in this study. Your participation may significantly help researchers find out if the SCD will help other people who have acute renal failure.

Are there Commercial Issues?

There are no plans for you to receive any compensation, or financial benefits for being in this study or as a result of any products, procedures, or other items developed from information or data obtained from research conducted under this study.

What are the Costs for Participation?

The use of the study device will be paid for by the sponsor. The cost of your standard medical care to treat your kidney failure will be billed to you or your insurance company.

There will be no additional costs to you as a result of taking part in this study. However, routine medical care for your condition (the care you would receive whether or not you were in this study) will be charged to you or your insurance company.

However, you might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

Your health insurance company may not pay for these charges because you are in a research study.

Is There Payment for Participation?

You will not be paid for taking part in this study.

What Other Options Are There?

You do not have to participate in this study and can continue with your usual acute renal failure treatments. Talk to your study doctor about your choices before you decide if you will take part in this study.

What if I am Injured?

If you are injured as a direct result of being in this study, the study sponsor, CytoPherx, Inc. will cover the costs of your medical treatment necessary to diagnose and/or treat your injury. CytoPherx, Inc. has no plans to pay for such things as lost wages, disability, or discomfort due to the injury. No other compensation is routinely available. You are not giving up any of your legal rights by signing this consent form.

You may have medical problems or side effects from taking part in this research study. If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- GWU Hospital and/or the GWU MFA or
- your physician or
- treatment center of your choice.

The study sponsor may pay the reasonable medical expenses needed to treat the research-related injury. This will be done if the study doctor and study sponsor find that the injury or illness is directly related to the study procedures **and** the injury or illness is not caused by:

- Your failure to follow study instructions,
- The failure of the study doctor or study staff to follow the study plan;
- The normal progression of your disease or condition; and/or
- A pre-existing condition.

You should contact the study doctor as soon as possible about any illness or injury.

There are no plans for GWU, GWU Hospital and/or the GWU MFA to pay you for any injuries or illnesses. By signing this form you will not give up any legal rights.

Who will provide Funding?

Funding for this research study will be provided by CytoPherx, Inc.

Authorization to Use and Disclose Information for Research Purposes

Access to study records will be limited to those who need the information for purposes of this study, as well as your health care providers should they need access to the information. All records are kept in a secure location and access is limited to research study personnel.

Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed, unless you give the appropriate authorization.

Federal law requires hospitals, researchers and other healthcare providers (like physicians and labs) to protect the privacy of health information that identifies you. This kind of information is known as “protected health information” or “PHI.” This section tells you your rights about your protected health information in the study. This section also lists who you let use, release, and get your protected health information. You are free to not allow these uses and releases by not signing this form. If you do that though, you cannot participate in the study.

Protected health information that may be used and released (disclosed) in this study includes information such as:

- Your history of chronic conditions such as heart, lung and kidney disease, or other significant conditions such as previous surgeries;
- Your vital signs, ventilator settings, and medications you are given during the study;
- Results of physical examinations, blood and urine tests related to your medical condition;
- Admissions information such as your symptoms and complaints on arrival to the hospital.

By signing this form, you allow the use, sharing, copying, and release of your protected health information to carry out the study by:

- Your healthcare providers (like doctors and hospitals) which are not part of the study;
- The study doctor and his research team.

You also allow the study doctor and the research team, and other healthcare providers that are part of the study to release your health information to:

- GWU Institutional Review Board (IRB) or its authorized representatives, as well as representatives of the Office for Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;
- Western Institutional Review Board (WIRB)
- The sponsor of the study and any contractors or partners it may have. (research monitors and auditors);
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care; and
- GWU, GWUH or MFA workforce who are involved with the research;

You may request to review or have a copy of your personal health information collected during this study and placed in your medical record. This right to review and copy your personal health information only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

This permission does not end unless you cancel it, even if you leave the study. You can cancel this permission any time. Such cancellation will not affect information a healthcare provider has already used in reliance on your permission to do so. Even if you cancel this authorization, the researchers may still use and disclose protected health information they already have obtained about you as necessary to maintain the integrity or reliability of the research. However, no new PHI will be collected from you after you revoke your authorization.

To cancel your authorization, you will need to send a letter to your study doctor. This letter must be signed and dated and sent to this address: Dr. Lakhmir Chawla, 900 23rd Street, NW, Suite G-105, Washington DC, 20037. A copy of this revocation will be provided to the study doctor and his or her research team. Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits.

Your protected health information will be treated confidentially to the extent permitted by applicable laws and regulations. Federal law may allow someone who gets your health information from this study to use or release it in some way not discussed in this section and no longer be protected by the HIPAA Privacy Rule.

By signing this form you authorize the study doctor and members of the research team to use and share with others (disclose) your PHI for the purpose of this study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

Voluntary Participation/Withdrawal

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

You may withdraw from the study at any time. Leaving the study will not affect your current or future medical care at GWUH and/or MFA.

The study doctor or sponsor can decide to stop your participation in this study at any time without your consent for any of the following reasons:

- not following study-related directions from the study doctor,
- circumstances that may develop and offer alternatives, or a serious reaction,
- because the entire study is stopped,
- the sponsor may also decide to stop the study doctor's involvement in this study,
- if you don't follow instructions,

- for medical reasons,
- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason

If you decide to stop participating in the study early for any reason, your study doctor may ask you to return for one or more study visits to complete the final study activities for safety reasons.

Whom to Contact to Ask Questions About Your Rights as a Research Subject

If you have any questions, concerns or complaints about the study, your participation in the study or if at any time you feel you have had a research-related injury, please contact

Dr. Lakhmir Chawla at 202-715-4570 during regular business hours.

If you have questions about your research rights or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
Email: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, the research team will provide you with a signed and dated copy of this consent form for your records. Please keep a copy of this consent form in case you want to read it again.

Subject's Consent to Participate

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

If you agree to participate in this study, please sign below:

DOCUMENTATION OF CONSENT

Consent and Assent Instructions:

Consent: Subjects able to provide consent must sign on the subject line below

Consent is provided by the Legally Authorized Representative for subjects unable to consent

Assent: Is required for subjects able to provide assent

Subject's Name (printed)

Date

CONSENT SIGNATURES:

Subject's Signature (if no Legally Authorized Representative is used)

OR

Name of Legally Authorized Representative (printed)

Date

Signature of Legally Authorized Representative

Date

Authority of Subject's Legally Authorized Representative or Relationship to Subject

Name (printed) of Person Conducting Informed Consent Discussion

Date

Signature of Person Conducting Informed Consent Discussion

Date

