UNITED STATES ARMY INSTITUTE OF SURGICAL RESEARCH

CONSENT TO PARTICIPATE IN RESEARCH

RESEARCH SUBJECT CONSENT FORM

TITLE: Plasma Resuscitation without Lung Injury (PROPOLIS)

PROTOCOL NO.: CNTR-2020-001

 IRB Protocol #20210893

SPONSOR: Coalition for National Trauma Research (CNTR)

INVESTIGATOR: Name

 Address

 City, State Zip

 Country

STUDY-RELATED

PHONE NUMBER(S): Phone Number

 Phone Number (24 hours)

 [24 hour number is required]

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| --- |
| RESEARCH SUMMARY |
| VoluntaryParticipation | You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study. |
| Purpose | The purpose of this research is to better understand why some patients develop acute lung injury after being severely burned and others do not. It might be that there are certain resuscitation treatments and blood products reduce the likelihood of acute lung injury. |
| Duration | Admission to six months post discharge from hospital. |
| Procedures | Like flipping a coin, you will be randomized into one of two groups.* Participants in one group will receive lactated ringers as part of fluid resuscitation during the first 24 hours after injury.
* Participants in the other group will receive pathogen-reduced plasma a as part of fluid resuscitation during the first 24 hours after injury.
* Blood will be drawn at study enrollment, 12, 24, and 48 hours after injury and will be analyzed for markers.
* Information from your medical record will be collected hourly up to 48 hours in the burn center at 72 hours, and on a weekly basis until you are discharged from the hospital will be reviewed by study team.

After your discharge, study staff will contact you at six months and ask you to take a short survey about how your recovery is progressing. |
| Risks | Risks include edema formation in the tissues which may cause injury to vital organs especially the lungs and kidneys and even in death.* The resuscitation products used in the study are approved for this purpose by the Food and Drug Administration. The experimental part of the study is to compare them.
* All blood draws will be taken from catheters already in your artery or veins that were placed as part of the treatment for your injuries.
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| Benefits | There is intent to benefit all participants of this study regardless of randomization group. Possible benefits to you include lower complications related to fluid resuscitation. |
| Payment | You will not be paid for your participation in this study. |

You are being invited to take part in a research study, conducted at the [Site (burn center)] by [Name]. You are asked to participate in this research because you have a burn injury and have been admitted to the [Site (burn center)]. A person who takes part in a research study is called a research subject or research participant.

Your participation in this research is voluntary. It is important that you read what is written below and ask questions about anything you do not understand. You may want to talk with your family, friends or others to help you decide if you want to be part of this study. When you feel that your questions have been answered. You will be asked if you agree to be part of the research or not. If you agree, you will be asked to sign this consent form. You will be given a copy of this form to keep. You will be given a copy of this form to keep. You can find additional study information using the following QR code



In this consent form “you” generally refers to the research subject. If you are being asked as the legally authorized representative to permit the subject to take part in the research. “you” in the rest of this form generally means the research subject.

What should I know about this research?

* Someone will explain this research to you.
* This form sums up that explanation.
* Taking part in this research is voluntary. Whether you take part is up to you.
* You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
* You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
* If you don’t understand, ask questions.
* Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to better understand why some patients develop acute lung injury after being severely burned and others do not. It might be that there are certain resuscitation treatments and blood products reduce the likelihood of acute lung injury. You are being asked to take part in this study because you have been severely burned and are being cared for at the [Site (burn center)]. As a result of your injury, you are at risk for the development of acute lung injury. The experimental part of this study is to randomly assign subjects to different approved treatments and to compare them.

This study is being funded by the Department of Defense/Peer Reviewed Medical Research Program through the Coalition for National Trauma Research because many injured civilians and/or soldiers develop acute lung injury after burn injury.

This study is being conducted in five - six major burn centers. 94 participants will take part in this research. We anticipate enrolling 19 participants at this burn center over three years.

How long will I be in this research?

We expect that your taking part in this research last for the time that you are in the hospital plus six months after your admission (for follow-up).

What happens to me if I agree to take part in this research?

If you consent to take part in this study, you will be put into a study group by chance (like a coin toss/ like drawing straws). You have a 1 out of 2 chance of being placed in each group. You cannot choose your study group. Participants in one group will receive lactated ringers as part of fluid resuscitation during the first 24 hours after injury. Participants in the other group will receive pathogen-reduced plasma a as part of fluid resuscitation during the first 24 hours after injury.

Both fluids are approved by the Food and Drug Association for resuscitation after injury. Resuscitation for both groups will be monitored by a Burn Navigator every hour to be sure that the participants are receiving the right amount of fluids. The Burn Navigator is approved by the Food and Drug Administration for guiding resuscitation.

During the study, small amounts of blood will be drawn (taken from the catheters that are already in your artery or veins) and will be tested for markers that may predict who will develop acute lung injury. The amount of blood taken each time (at study enrollment, 12, 24, and 48 hours after injury) is a very small amount (about 2.5 teaspoons each time, totaling 3.5 tablespoons).

The study team will collect information from your medical record hourly up to 48 hours in the burn center and at 72 hours, and on a weekly basis until you are discharged from the hospital. However, no additional procedures will occur for this study after the first 48 hours. Before your discharge, study staff will ask you for contact information (phone, address and email) for you and a person who could help us contact you.

After your discharge, study staff will contact you at six months and ask you to take a short survey about how your recovery is progressing. The survey is called the Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10. It has 10 questions that will measure your health and functioning. The research staff will try to reach you by phone, email and regular mail.

The blood drawn during the study will be analyzed for markers.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to provide contact information so that we can reach you for the follow-up surveys and to complete the surveys (either over the phone or in writing via email or regular mail) at 6 months after you are discharged from the hospital.

Could being in this research hurt me?

The resuscitation products used in the study are approved for this purpose by the Food and Drug Administration. There may be risks associated with either arm of the study. Based on available data, patients in the crystalloid arm may be at higher risk for volume overload (infusion of a large volume of fluid during the resuscitation phase of care), to include acute respiratory distress syndrome (ARDS). Patients in the plasma arm may be at higher risk of transfusion-related complications such as TRALI (transfusion-related acute lung injury). In brief, both groups of patients may be at risk of lung injury. It is not possible to determine which group is at higher risk; ascertaining this risk is a major aim of the study.

There is a very small risk of disease transmission in the plasma arm.

All blood draws will be taken from catheters already in your artery or veins that were placed as part of the treatment for your injuries. The amount of blood taken out of your body for this study amounts to two tablespoons, which will be of no consequence to your health and recovery.

There is a small risk that a breach of confidentiality could occur; however, every member of the research team is trained on maintaining research records and your confidentiality. We will keep records on password protected computers and restrict access to your records to make sure this doesn’t happen. We will also remove your name and all other identifiable information from your study data as soon as we can.

There may be unknown risks.

Will it cost me money to take part in this research?

Taking part in this research may lead to added costs to you, such as treatment from any injury resulting from the study. In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. The Department of Defense will not provide payment, reimbursement or compensation for research-related injuries. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

Will being in this research benefit me?

There is intent to benefit all participants of this study regardless of randomization group. Possible benefits to you include lower complications related to fluid resuscitation. One other possible benefit of being in this study is that aside from the close monitoring you would receive from the bedside nurses and physicians you will have additional monitoring by research nurses, and research investigators. Possible benefits to others include improved resuscitation and outcomes after burn injury in the future.

What other choices do I have besides taking part in this research?

Your alternative is to not take part in the research. You can receive either treatment without taking part in this research study. There may be another study you could enroll in.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

* The research sponsor: The Coalition for National Trauma Research
* The funding organization: The Department of Defense
* People who work with the research sponsor
* Government agencies, such as the Food and Drug Administration
* The Institutional Review Board (IRB) that reviewed this research
* U.S. Army Human Research Protections Office and other DOD offices charged with oversight of human research

Data use agreements will be established between each data collection center and the University of Washington data center. These data use agreements will be approved by all institutional review boards, and will establish systematic and agreed upon uses of data, including for research purposes, representatives of the DOD, and reporting sensitive data to state and local authorities when applicable.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

The information and/or data specimens that we obtain from you for this study might be used for future studies. After we remove anything that might identify you from the information and specimens that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you.

There may be whole genome sequencing in future research.

The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

Incidental or unexpected findings will be communicated in writing to the clinical team for inclusion in the patient’s medical record (to include in the discharge summary or equivalent document). This information will be disclosed verbally and in writing to the patient, no later than at the time of discharge from the hospital.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818­2289, researchquestions@wcgirb.com if:

* You have questions, concerns, or complaints that are not being answered by the research team.
* You are not getting answers from the research team.
* You cannot reach the research team.
* You want to talk to someone else about the research.
* You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If at any time you believe you have suffered an injury or illness as a result of participating in this research, please contact the Principal Investigator, [Name] at [Number] (24 hours). The investigator will treat you or refer you for treatment.

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

No compensation is routinely available for research-related injuries. You are not waiving any legal rights to bring a claim in the legal system.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

* You are or become ineligible to participate
* It is in your best interest
* You have a side effect that requires stopping the research
* You need a treatment not allowed in this research
* The research is canceled by the FDA or the Coalition for National Trauma Research (study sponsor)

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, you are being asked to contact the research team so that the investigator can stop collecting your data and blood samples.

Will I be paid for taking part in this research?

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

Statement of Consent:

* All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
* If consent from a legally authorized representative is obtained, have the person obtaining assent document assent on the consent form.

Your signature documents your permission for you or the individual named below to take part in this research.

Signature of adult subject capable of consent or adult subject’s Date

legally authorized representative

Printed name of subject Date

(not required if subject personally provided consent)

Signature of person obtaining consent Date

* I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.

OR

* The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining assent Date

**\*\*For Sites in California\*\***

**AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

**What information may be used and given to others?**

The study doctor will get your personal and medical information. For example:

* Past and present medical records
* Research records
* Records about phone calls made as part of this research
* Records about your study visits.

**Who may use and give out information about you?**

The study doctor and the study staff. [They may also share the research information with [enter SMO company name]*,* an agent for the study doctor. delete if the site does not have an SMO]

**Who might get this information?**

The sponsor of this research. “Sponsor” means any persons or companies that are:

* working for or with the sponsor, or
* owned by the sponsor.

**Your information may be given to:**

* The U.S. Food and Drug Administration (FDA),
* Department of Health and Human Services (DHHS) agencies,
* Governmental agencies in other countries,
* The institution where the research is being done,
* Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
* Institutional Review Board (IRB)

**Why will this information be used and/or given to others?**

* to do the research,
* to study the results, and
* to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

**What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study.

**May I review or copy my information?**

Yes, but only after the research is over.

**May I withdraw or revoke (cancel) my permission?**

This permission will be good until December 31, 2070*.*

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

**Is my health information protected after it has been given to others?**

There is a risk that your information will be given to others without your permission.

**Authorization:**

I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

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.

**AUTHORIZATION SIGNATURE:**

**Signature of Subject Date**