Cold Stored Platelet Early Intervention in Hemorrhagic Shock (CriSP-HS) Trial

NCT 04667468

Approved 07/25/2023

CONSENT FOR CONTINUING PARTICIPATION IN RESEARCH

PRINCIPAL INVESTIGATOR: Lucy Kornblith, M.D.

STUDY TITLE: LITES TASK ORDER 4
Cold Stored Platelet Early Intervention (CriSP)

SOURCES OF SUPPORT: This study is being funded by the Department of Defense (DoD)

The word "YOU" throughout this document refers to the person injured. In cases where the injured person is unable to read and understand this form for themselves, this form is being provided to the legally authorized representatives acting on the injured person's behalf.

KEY INFORMATION

This is a clinical research study. Your study doctor Lucy Kornblith, MD and her study staff from the UCSF Department of Surgery, will explain this study to you. You are being asked to continue to participate in a research study that is being done to see if giving cold stored platelets early in the course of treatment is feasible and if it would help improve outcomes in injured patients that lose a lot of blood. Due to the nature of the emergency, it was not possible to obtain informed consent before enrolling you in this study. This consent provides you with information so you can decide if you want to continue in this study.

As a result of your injury, you have received either cold stored platelets soon after arriving at the Zuckerberg San Francisco General hospital or usual care, which could include blood or blood components. We also obtained data about the incident from pre-hospital reports and your hospital records.

We would like to continue to collect information from your medical records to follow up on your health during your hospital stay and the care that you receive while in the hospital. If you choose to continue to participate, we will collect information from your hospitalization up to thirty days. If you are discharged before thirty days, we may call you to check on your status.

Please note that due to your injury, you would have received whole blood or component therapy as part of your medical care. The risks of being enrolled in this study are related to receiving cold stored platelets early in the course of treatment instead of standard therapy. The risks of continuing to participate in this study are from blood collection and a risk to confidentiality.

We are unsure if there are benefits to one method of blood replacement therapy over another. There is a potential benefit to you from increased monitoring during your care and your participation may help us better understand treatment of trauma injuries in the future.

Since continuing to participate in this research only involves the collection of your medical information, the only alternative is to decide not to continue in this study.

If you are interested in learning more about this study, please continue to read below.

INTRODUCTION

You are being asked to continue to participate in a research study. Before you make this decision, you need to understand the risks and benefits of this study. This is known as informed consent. This consent form provides information about the research study that has been explained to you. Once you understand the study and what is required to participate, you will be asked to sign this form if you would like to continue in the study. Your decision to continue to take part in this study is voluntary. This means you are free to choose if you will continue in the study. This research study will enroll 200 patients across the country.

PURPOSE OF THE STUDY

This study is being done to see if giving cold stored platelets early in the course of treatment is feasible and if it would help improve outcomes in injured patients that lose a lot of blood. Room temperature platelets or whole blood, which contains platelets, may have been given to you even if you were not a part of this research study as part of usual care for patients that lose a lot of blood. The cold stored platelets used in this study have been stored longer and are given earlier in the course of treatment than room temperature platelets that are part of usual care. Cold stored platelets are less likely than room temperature to have bacteria that could cause an infection. There is some information that suggests that severely injured people who are given platelets soon after arriving at the hospital may have improved survival.

As a result of your injury, you have received either cold stored platelets soon after arriving at the hospital or usual care, which could include blood or blood components. A randomization process (like flipping a coin) was used to determine which you would receive.

Depending on the randomization, you may or may not have been given cold stored platelets. All other medical care provided to you for your injury was standard medical care for your condition. In addition, we also obtained data about the incident from the pre-hospital reports and your hospital records. Due to the nature of the emergency, it was not possible to obtain informed consent before enrolling you in this study. This consent provides you with information so that you can decide if you want to continue in this study.

This study is only done in emergencies. The Food and Drug Administration (FDA) has special rules that allow studies looking at emergency treatments to be done without consent. One of these rules is that we can only use treatments that we think could help people. Another rule is that the study team must talk to members of the community where the study will happen to get their opinions on the research.

We would like to continue to collect information from your medical records to follow up on your health during your hospital stay and the treatment that you receive while in the hospital. The reason for getting this additional information is to better understand how the type of blood replacement

used to treat your injury impacted your recovery. The information may include time spent in the hospital and the type of care you got, information such as date of birth, age, gender, test results and any illnesses or set-backs you experience while you are in the hospital. We will collect information about how each of your body systems is doing by recording lab values and procedures that are done as part of your care. Your permission to access your health records for the purposes of this study will expire in 15 years.

We will collect information from your hospitalization up to thirty days. If you are discharged before thirty days, we may call you to check on your status. If you are discharged to another facility, we may contact that facility for an update on your condition. If we are unable to get in touch with you or with the facility you were discharged to, we will check your survival status on a public access database using some of your personal identifiers such as your name, date of birth, and SSN.

POTENTIAL RISKS AND DISCOMFORTS

Participation in this study has exposed you to certain risks and discomforts. Please note that you have already been exposed to some of these risks, but due to the seriousness of your injury, blood or blood component therapy would have been performed on you anyway as part of your medical care. Risks of receiving platelets in any form include infection, allergic reaction, fever, and respiratory distress (shortness of breath). The risks of being enrolled in this study are related to receiving cold stored platelets early in the course of treatment instead of standard care. We don't know if receiving cold-stored platelets increases your risk of thrombosis (clotting). We don't know if receiving cold stored platelets makes other risks better or worse.

The only risk of continuing participation in this study is a risk to confidentiality, which is discussed in a paragraph below.

ANTICIPATED BENEFITS TO SUBJECTS

We are conducting this study to compare giving cold stored platelets early in the course of treatment to usual care and are unsure if there are any benefits to one method over another. There is some information that suggests that severely injured people who are given platelets soon after arriving at the hospital may have improved survival. The risk of infection from bacterial contamination may be lower with cold stored platelets than with platelets given as part of standard care. Whether or not you receive the study product, there is a potential benefit to you through increased monitoring during your care. Ultimately your participation may help us better understand treatment of trauma injuries in the future.

ALTERNATIVES TO PARTICIPATION

Since continuing in this study only involves the collection of your medical information, no alternative treatments are available. The only alternative is to decide not to continue in this study.

PAYMENT FOR PARTICIPATION

You will not be paid for participation in this study.

COSTS OF PARTICIPATION

Two types of procedures were done during this study. Some were part of your standard medical care and others were only for research. You or your insurer will be billed for the standard medical care.

You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research were not charged to you or your insurer

MEDICAL CARE FOR RESEARCH RELATED INJURY

It is important that you tell your study doctor, Lucy Kornblith, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at 628-206-6946.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

CONFIDENTIALITY

We make every effort to keep the information about you confidential. You have been assigned a study code number. This code number, and not your name, is used on all of the data we collect. Your data may be shared with other doctors and research scientists outside of UCSF Health. A key linking you to the code number is kept locked in a secure location and will be available only to the investigators and their research teams. The data will be retained indefinitely and used for future studies. Data from this study, without your identity, may be reported in scientific meetings, articles, or other appropriate communications. We will notify the community of the results through scientific papers, presentations at scientific meetings, and through local media.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. The principal investigator and other study personnel will ensure that your confidentiality will be maintained. Subject name and other identifiable information will be kept in a secure, locked, limited access area such as a password protected database.

If you sign this document, you give permission for continued access to your health information that identifies you for the research study to the investigators listed on the first page of this consent form and their research staff. In addition, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office, the Data Safety Monitoring Board, the Department of Defense, the University of California, and the FDA may access your research

records as part of their responsibility to protect human subjects in research. This information can also be requested by and provided to courts or legal authorities.

If you do not have a UCSF medical record, one will be created for you.

SUBJECT ACCESS TO RESEARCH RESULTS
In accordance with the Zuckerberg San Francisco General Hospital and UCSF Health Notices of Privacy Practices document that you have been provided, you are permitted access to research results contained within your medical records filed with your health care provider. Please note that such access may be limited to the end of the research study.

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

PARTICIPATION AND WITHDRAWAL
Your continued participation in this research is voluntary. If you choose not to continue to participate, that will not affect your relationship with your providers or your right to health care or other services to which you are otherwise entitled. If you decide to continue to participate, you are free to withdraw your consent and discontinue further participation at any time without prejudice.

CONSEQUENCES OF WITHDRAWAL
This study involves randomization to receive early cold stored platelets or not, and data collection. Withdrawing from this study means we will no longer continue to access your medical records to collect data. However, any data already collected will be retained.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR
The investigator may withdraw you from participating in this research if they feel it is best for you. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made to protect your health and safety.

NEW FINDINGS
During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation. If new information is provided to you, we will ask for your consent to continue participating in this study again.

IDENTIFICATION OF INVESTIGATORS
In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact Dr. Lucy Kornblith at 628-206-6946.

RIGHTS OF RESEARCH SUBJECTS
You may withdraw your continuing consent at any time and discontinue further participation without penalty. You are not waiving any legal claims, rights or remedies because of your

participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Human Subjects Protection Advocate University of Pittsburgh (1-866-212-2668).

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SIGNATURE OF RESEARCH SUBJECT
VOLUNTARY CONSENT

The study has been explained to me and all of my questions have been answered. I understand that, throughout my participation in this research study, I am encouraged to ask questions about any aspect of this research study including the use and disclosure of my identifiable medical record information. Any additional questions or concerns about any aspect of this study will be answered by the investigators listed on the first page of this form.

Any questions I might have about my rights as a research participant or the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh at 1-866-212-2668.

By signing this form, I agree to participate in this research study. I will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about me. I have been given a copy of this consent form and the Experimental Subjects Bill of Rights to keep.

_____	_____	_____	_____
Participant's Signature	Printed Name of Participant	Date	Time

SURROGATE CONSENT

_____ is unable to provide direct consent for study participation
Participant's Name (Print)

Therefore, by signing this form, I give my consent for his/her continued participation in this research study.

_____	_____
Representative's Name (Print)	Relationship to Participant

_____	_____	_____
Representative's Signature	Date	Time

PARENTAL PERMISSION

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my permission to enroll my child and authorize the research team's access to my child's medical records. I will be asked to sign a separate form authorizing access, use, creation, or disclosure of

health information about my child. I have been given a copy of this consent form and the Experimental Subjects Bill of Rights to keep.

_____	_____	_____	_____
Signature of Parent	Printed Name of Parent	Date	Time

ASSENT of a Minor Participant

This research has been explained to me and I agree to participate.

_____	_____	_____	_____
Participant's Signature	Printed Name of Participant	Date	Time

INVESTIGATOR'S CERTIFICATION

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the subject or their representative or family member and any questions about this information have been answered.

_____	_____	_____	_____
Research Staff Signature	Research Staff Name (Print)	Date	Time

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CONSENT FOR CONTINUED RESEARCH PARTICIPATION

I am currently participating in a research study in which consent for my participation was initially obtained from my legally authorized representative as a result of my inability to provide consent at the time. I have now recovered to the point where the study doctor believes that I am able to consent to continued participation in this research study.

I have read the information in this consent form. The study has been explained to me, and all of my current questions have been answered.

I agree to continue my participation in this research study. I will be asked to sign a separate form to continue authorizing access, use, creation, or disclosure of health information about me. I have been given a copy of this consent form and the Experimental Subjects Bill of Rights to keep.

_____	_____	_____	_____
Participant's Signature	Printed Name of Participant	Date	Time

CONSENT FOR CONTINUED PARTICIPATION (adolescent turns 18)

I understand that I am currently participating in a research study. I further understand that I gave assent for my participation in this research study because I was a minor at the time I was asked to be in the study. I have now turned 18 years old, and I am able to provide direct consent for continued participation in this research study.

The study has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns, or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing below, I agree to continue my participation in this research study and authorize the research team's continued access to my medical records. I will be asked to sign a separate form to continue authorizing access, use, creation, or disclosure of health information about me. I have been given a copy of this consent form and the Experimental Subjects Bill of Rights to keep.

_____	_____	_____
Participant's Signature	Date	Time

INVESTIGATOR'S CERTIFICATION

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the subject and any questions about this information have been answered.

_____	_____	_____	_____
Research Staff Signature	Research Staff Name (Print)	Date	Time