Does Plasma Reduce Bleeding in Patients Undergoing Invasive Procedures

NCT02637427

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RUTGERS
Robert Wood Johnson
Medical School

Department of Medicine
Division of General Internal Medicine

I. SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Does Plasma Reduce Bleeding in Patients Undergoing Invasive Procedures

Principal Investigator: Jeffrey L Carson, MD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Dr. Jeffrey Carson is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Carson may be reached at:

Clinical Academic Building
125 Paterson St., Suite 2300
New Brunswick, NJ 08901-1962

732-235-7122

The principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: National Institutes of Health

The National Institutes of Health is the sponsor of this research study. They are providing the support for study doctor to conduct this study according to a budget that will cover the costs of collecting all of the information required by the study.

Why is this study being done?

The length of time that it takes for blood to clot (thicken to stop bleeding) differs among people. Doctors measure this clotting time with a blood test they call an INR. Normal INR values are between 0.8 and 1.2. There are some diseases and medical conditions that cause patients to have a higher INR value (longer time to clot). Sometimes the higher INR value is because doctors give patients medication to thin the blood. Patients whose blood takes a longer time to clot may be at risk for bleeding when they have a medical procedure that involves puncturing, opening, or cutting the skin (an invasive procedure). Doctors may decide to give these patients a transfusion of fresh frozen plasma (liquid portion of donated blood contains the clotting factors) before the procedure. They hope it will decrease the amount of bleeding. However doctors do not truly know if fresh frozen plasma has any effect on this bleeding. This study will compare two treatment plans; 1) fresh frozen plasma is transfused before the medical procedure, and 2) no fresh frozen plasma before the procedure. This study is being done to see if fresh frozen plasma transfusion does help to reduce bleeding.

Why have you been asked to take part in this study?

You are being asked to take part in this study because you are either scheduled to have a medical procedure, or likely to need a medical procedure, and your blood test shows that you may be at increased risk of bleeding.

Who may take part in this study? And who may not?

You may take part in this study if you 21 years or older and, your INR is between 1.5 and 2.5, and you will be having a medical procedure that might cause some bleeding.

You may not take part in this study if your procedure will take place in the operating room, you are already bleeding at the time of the procedure, your procedure will involve your spinal cord or head, or if you are having a procedure that looks at the heart blood vessels. You may not participate if you are not willing to receive a blood transfusion, if you are taking medications to thin your blood that has not been stopped, if you have been diagnosed with a condition that affects your blood clotting, or if your blood tests show that you have a very low platelet (part of blood that causes clotting) count. If you are female, you may not participate if you are pregnant.

How long will the study take and how many subjects will participate?

There will be a total of 110 subjects entered into this study at 5 different hospitals. It will take 16 months to enroll the subjects. There will be about 30 subjects enrolled at Robert Wood Johnson University Hospital. The study staff will follow each subject during the hospitalization (for up to 30 days).

What will you be asked to do if you take part in this research study?
If you chose to participate in this study, your treatment plan will be set by random rules of research (like a coin flip). If the plan is for you to receive fresh frozen plasma, you will receive a transfusion before your medical procedure. If the plan is to hold off, you will undergo your procedure without prior plasma transfusion. If there is bleeding after the procedure, you are able to receive a plasma transfusion regardless of your treatment plan. Medical care other than plasma transfusion will not be influenced by participation in the study.

The study staff will collect the results of your blood count (portion of your blood that carries oxygen) and INR tests performed after the procedure and on days 1 and 2 (if you are still in the hospital). If you have been on blood thinners that have just been stopped there will be an INR level dawn approximately 4 hours after you received the last dose. These tests will usually have been ordered by your doctor. If they are not, an order will be placed in the medical record to perform the test for research purposes.

Study staff at your hospital will record medical information from your chart including plasma and blood transfusions and your medical status. If, through day 2 after the procedure, you have symptoms that might mean you have extra fluid in your blood vessels or a problem with your lungs, study staff will copy sections of the medical record related to these symptoms. These records, which will not contain identifying information, will be sent to the members of the study to team for review.

If you chose to participate but your doctors do not perform one of the procedures, you will not be included in this study. The study investigators will only keep a copy of this signed form and a notation of your INR value. They will not collect any other information about you.

What are the risks and/or discomforts you might experience if you take part in this study?

Some plasma transfusions cause problems. Plasma can transmit viral infections such as hepatitis (liver infection) which occurs less than 1 in 10,000, cause allergic reactions (for example, hives), lead to extra fluid in the lungs (1-5%), or cause injury to the lungs (1 in 5000).

While doctors commonly believe that patients with moderately elevated INR levels are at increased risk for bleeding following an invasive procedure, it is unknown if plasma transfusion will decrease risk. It is not known if you are at greater risk if you receive the transfusion or if you do not. Thus, there are no additional risks to you for participating in this study.

Are there any benefits for you if you choose to take part in this research study?

There is no direct benefit from taking part in this study. The results of this study may help doctors in deciding how to use fresh frozen plasma for patients like you.

What are your alternatives if you don't want to take part in this study?

There are no other alternative treatments. Your alternative is not to take part in this study.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There will be no cost to you for participating in this study.

Will you be paid to take part in this study?

You will not be paid for your participation in this research study.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

You will be assigned a study number that will be used to identify all the information collected about you. Other than dates, there will be no personal identifiers collected. All study data will be entered onto a secure password protected website. Staff at the study center at Robert Wood Johnson Medical School will maintain all study-wide data using password protected electronic files.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers will use this Certificate to legally refuse to disclose any information, documents or biospecimens that may identify you from disclosure, including a court order. This means that research material collected about you for this study will not be released to anyone who is not connected with this study unless:

- you request or consent to its release;
- a law requires its release (such as reporting communicable diseases or child abuse to State agencies);
- it is used for other scientific research, as allowed by federal regulations protecting subjects; or

- it is requested by the U.S. federal or state agency sponsoring the research because it is needed for auditing or program evaluation or to meet the requirements of the Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document

A description of this clinical trial will be available on 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 results. You can search this website at any time.

What will happen if you are injured during this study?

If you take part in this study, you will be exposed to certain risks of personal injury. In addition, it is possible that during the course of this study, new adverse effects of fresh frozen plasma transfusion that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment if you sustain personal injuries or illnesses as a direct consequence of participation in the research. Your health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent, but you must do this in writing to

Dr. Jeffrey Carson
Clinical Academic Building
125 Paterson St., Suite 2300
New Brunswick, NJ 08901-1962

Beginning on the date that you withdraw your approval, no new health information will collected for this research. However, the study doctor/investigator may continue to use the health information that was provided before you withdrew your approval.

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Jeffrey L Carson, MD
Department of Medicine, Division of General Internal Medicine
732-235-7122

If you have any questions about your rights as a research subject, you can call:

IRB Director
(732)-235-9806

And

Human Subject Protection Program
732-235-8578

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you

sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- Hospital discharge summaries
- Radiology records or images (MRI, CT, PET scans)
- Medical history or treatment
- Medications
- Laboratory/diagnostic tests or imaging
- EKG and/or EEG reports
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- Non-Rutgers researchers on the study team: Paul Ness, MD, Johns Hopkins University; Darrell Triulzi, MD, University of Pittsburgh; Paul C. Hébert, MD, MHSc (Epid), L'Université de Montréal; Maria Mori Brooks, PhD, University of Pittsburgh
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- National Heart, Lung, and Blood Institute, National Institutes of Health
- Data and Safety Monitoring Board

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision:

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Clinical Academic Building
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How long will my permission last?

There is no set date when your permission will end. Your health information may be studied for many years.

NOTE: SIGNATURE PAGE FOLLOWS IMMEDIATELY.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

II. SURROGATE CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Does Plasma Reduce Bleeding in Patients Undergoing Invasive Procedures

Under certain circumstances, an individual can give consent for another person to take part as a Subject in this Research Study (hereinafter "Study") because the Subject is unable to consent to this Study and the Subject has not expressed opposition either to this Study or to the determination of incapacity. This individual is called the Legally Authorized Representative, or Surrogate, and is providing Surrogate consent.

You are being asked to serve as the Surrogate for _____, who is called the Subject in this document. You are being asked to give permission for the Subject to participate in this Study. Your decision should be based on the Subject's individual health care instructions and other wishes, if known, or on your best estimation of what you believe are the Subject's personal values and what the Subject would choose for himself/herself.

Would the person for whom you are signing consent want to take part in this Study?

This form tells you about this Study. After reading this entire form and having this Study explained to you by someone conducting this Study, you can decide if you think the person for whom you are authorizing consent would want to take part in this Study. It is important to note that the person for whom you are signing consent does not have to take part in this Study in order to receive medical care outside this Study.

What will happen if you, as the Surrogate, do not enroll the Subject in this Study, or if the Subject, or you as the Surrogate, later does not want the Subject to participate in this Study?

The Surrogate can decide not to enroll the Subject. The Subject or the Surrogate can decide to discontinue at any time the Subject's participation in this Study. Any decision by the Surrogate not to enroll the Subject or by the Subject or the Surrogate to discontinue the Subject's participation shall not affect the Subject including the Subject's receipt of medical care outside the Study. The Subject may withdraw without penalty and without loss of any benefits to which s/he are entitled.

Regardless of the Surrogate's consent, the Investigator can take the Subject out of this Study at any time because it would not be in the Subject's best interest to stay in it.

NOTE: SIGNATURE PAGE FOLLOWS IMMEDIATELY.

SIGNATURE PAGE WHEN SUBJECT REQUIRES A SURROGATE (OR LAR)

AGREEMENT TO PARTICIPATE

1. Surrogate Consent:

The purpose and procedures for this Study have been described to me verbally and in writing. My questions about this Study have been answered and I have been provided with information about who to contact with additional questions.

As Surrogate, I freely give my consent to have _____take part in this Study and authorize that his/her health information as described above, be collected/disclosed in this Study. I understand that by signing this form I am agreeing for the individual named above to take part in research. I understand that I will receive a copy of this form to take with me.

_____ _____ _____
Signature of Surrogate Printed name of Surrogate Date

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

3. Signature of Consent Process Witness:

I have observed the consent process which included a description of the purposes and procedures of this Study and an opportunity for questions and answers about this Study. I attest that I am not the subject, his/her guardian or authorized representative, or a researcher on this study and can attest that the requirements for informed consent to the medical research have been satisfied.

_____ _____
Signature of Witness Printed Name of Witness Date

III. CONSENT TO TAKE PART IN A RESEARCH STUDY FOR INDIVIDUALS ENROLLED UNDER PRIOR SURROGATE CONSENT

TITLE OF RESEARCH STUDY: Does Plasma Reduce Bleeding in Patients Undergoing Invasive Procedures

Under certain circumstances, someone can give consent for another person to take part in a research study. This person is providing "surrogate consent." The surrogate can make choices for the subject, if the subject is not able to make choices for him or herself. In fact, since _____, you have been enrolled in this research study by your surrogate, _____.

Now that you can make your own decision about whether or not to participate in this research study, please carefully review this entire form, **including both Section I and Section II**, which tells you about the research study. After reading through this form and having the research explained to you by someone conducting this research, you can decide if you wish to remain in the study or to withdraw. Your decision to withdraw will not affect the medical treatment you receive at the University.

AGREEMENT TO PARTICIPATE

1. Subject Consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

_____ **I agree** **OR** _____ **I do not agree** to continue to participate.
(Initial (Initial)

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____