Myocardial Ischemia and Transfusion

NCT02981407

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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: Myocardial Ischemia and Transfusion (MINT) Trial
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. 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:

Rutgers-Robert Wood Johnson Medical School
Division of General Internal Medicine
125 Paterson Street – 2nd Floor
New Brunswick, NJ 08901
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?

This study is to be done to find the best blood transfusion plan in patients with a heart attack. Healthy people in North America have red blood cell counts above 12. The red blood cell count measures the part of the blood that brings oxygen to the organs in your body. Patients who are in the hospital with a heart attack often have low red blood cell counts. Doctors can order blood transfusion to increase the red blood cell count but it is not known if patients who receive the blood transfusion do better or worse. There is no local standard of care for when to give the blood at our hospital and doctors use different red blood cell counts to guide their decision. Some decide to order a transfusion when the red blood cell count is below 10 and others wait until the count falls to 7 or 8 before ordering a transfusion. Doctors are unsure which plan is best. The purpose of this study is to determine at what red blood cell count patients should be given a transfusion in order to lower the risk of death, heart attacks and other health problems.

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

You have been asked to take part in this study because you have had a heart attack and your doctor believes that either of the blood plans in this study would be appropriate for you. You should feel free to talk to your doctor at any time about this study.

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

You may take part in this study if you have had a recent heart attack and you have a red blood cell count of less than 10. You must be at least 18 years old. Your doctor has given us permission to tell you about the study. You may not take part in this study if your red blood cell count does not fall below 10, you plan to have heart surgery during this hospital stay, or if you will not accept blood for religious or other reasons.

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

There will be a total of 3500 patients in this study. There will be about 250 patients enrolled at Robert Wood Johnson University Hospital. Your participation in this study will last 6 months.

What will you be asked to do if you take part in this research study?

Study staff will review your red blood cell counts. If your red blood cell count is less than 10, your blood use plan will be set by random rules of research (like a coin flip) to either receive blood now or to wait. You will have an equal (50:50) chance of being in either blood use plan. If the plan is for you to receive blood now, you will receive enough blood to keep your red blood cell count to equal or above 10. If the plan is to hold off, you will not receive any blood unless your red blood cell count drops to less than 8 and your doctor feels it is in your best interest. Your doctors will follow the study blood plan as long as you are in the hospital (for up to 30 days). If you have signs or symptoms that your doctor thinks will get better with blood, you will receive a blood transfusion regardless of your red blood cell count. These may include bleeding, chest discomfort described as pressure or heaviness that does not go away with medication or

other signs or symptoms which your doctor believes is related to your heart and red blood cell count.

The study collects information about your red blood cell counts and heart studies. 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 and the study will be pay for the test. The rest of your medical care and tests are those that your doctor would have ordered for you whether or not you were in the study.

You will provide us with contact information (including your phone number and address) so that we will be able to be in contact with you for the next 6 months. We will also ask you to provide us with the name and phone number of two people who know you well but do not live with you to use if we have trouble reaching you. We will have you sign a form that gives the study doctors permission to review the medical records for any hospital admission that occurs within 30 days of your hospital discharge.

Study staff will review your chart while you are in the hospital and collect information about your health status. They will also obtain and review the medical records for any other hospital admissions you have within the next month. They will call you twice, once at 30 days and again at 6 months to see how you are doing and to find out if you have had any additional hospitalizations.

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

There are potential risks associated with each of the blood use plans. In patients with heart attacks it is unknown whether one of the plans is safer than the other. Nearly all studies in patients with other medical problems with low red blood cell counts have shown that the risk of death and other complications does not change significantly if they receive more or fewer blood transfusions. There are a few studies that suggest giving fewer blood transfusions to patients with heart problems may increase the risk of having a second heart attack or dying. However, doctors are not sure that this is correct because there are other studies that do not show an increase risk of death or heart attacks with less transfusion and the studies were too small and included too few patients with heart attacks.

The people in this study who are assigned to get blood only if their red blood cell count is less than 8 are likely to get fewer blood transfusions than the patients in the other group. Some doctors think that giving fewer blood transfusions and allowing a patient's red blood cell count to be lower increases the risk of complications such as more heart damage or another heart attack. On the other hand, the people who are assigned to get blood if their red blood cell count is less than 10 are likely to get more blood transfusions than the patients in the other group which may lead to higher risk for shortness of breath and fluid overload. Blood transfusions may sometimes cause other problems. These bad effects of blood do not happen often and most of the time get better with treatment.

The use of blood or blood products has the following general risks: Uncommon (1-5%) chance) risks include mild reactions resulting in itching, rash, fever, headaches. Rare risks (<1% chance) include: respiratory distress (shortness of breath, fluid overload) or lung injury; exposure to

blood borne micro-organisms (bacteria and parasites) that could result in an infection; possible effects on the immune system, which may decrease the body's ability to fight infection; or shock (low blood pressure). Risks that are extremely rare (approximately one in a million or less) include; exposure to blood borne viruses such as hepatitis C or Hepatitis B (inflammatory diseases affecting the liver); Human Immunodeficiency Virus (HIV, the virus that causes AIDS); death.

There may be risks from not receiving blood or having transfusion delayed or risks from transfusions that are not yet known. At this point, there is not enough information to know if transfusing patients with heart disease at a higher or lower red blood cell count will increase, decrease or have no impact on their health. This is why a study such as MINT is needed.

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

If the study finds that one of the blood use plans has a better outcome, then the patients assigned to that plan may benefit. However, we do not know if there will be any difference between the two plans. The results of this study may help doctors in deciding how to use blood for patients like you in the future.

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

If you are not in this study, your doctor will decide when you may receive blood transfusions. If you have any questions how your care would differ from that provided in the study feel free to talk to your doctor.

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. The transfusions you receive are part of routine treatment and will be billed to your insurance.

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 which will be used to identify the information collected about you for this study. This information will then be sent to the Data Coordinating Center in Pittsburgh, Pennsylvania where it will be processed. The study also collects your personal identifiers (name, address, telephone number) to be used for the study follow-up after hospital discharge. Only staff responsible for contacting you at 30 days and 6 months will have access to this file. All medical records obtained for re-admission to the hospital will be reviewed by the study staff and labeled with your study identification number and your personal identifiers will be removed. They will then forward the records to a team of study doctors who will evaluate whether or not you had problems with your heart during the hospitalization.

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?

Subjects in this study will be exposed to certain risks of personal injury. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's 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.

Beginning on the date that you withdraw your approval, no new personal health information will be used for 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. You may also decide to stop taking part in the study any time after your agreement to participate. You may also stop the treatment described in the study and receive alternative therapies if needed, but remain as a study subject to allow the study doctor to continue to collect health information that is required by the study.

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?

- Medical History
- Blood Transfusions
- Laboratory Results
- Diagnostic Testing
- Electrocardiograms & Reports
- Radiology & Imaging Reports
- Medications & Medical Treatment
- Consultations
- Medical Findings
- Hospital discharge summaries

Who may use, share or receive my information?

The research team may use or share your information (but not your identity) 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: Data Coordinating Center at the University of Pittsburgh; The Clinical Events Committee at St Louis University
- 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
- The National Institutes of Health (the study sponsor)
- 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:

Dr. Jeffrey L Carson
Rutgers-Robert Wood Johnson Medical School
Division of General Internal Medicine
125 Paterson Street – 2nd Floor
New Brunswick, NJ 08901

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.

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 to take part in this research study.

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: _____

NOTE: SIGNATURE PAGE FOLLOWS IMMEDIATELY.

II. SURROGATE CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Myocardial Ischemia and Transfusion (MINT) Trial

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: Myocardial Ischemia and Transfusion (MINT) Trial

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,
(date)

_____.
(name)

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: _____