RBC SURVIVAL VALIDATION IN ADULT HUMANS UNDER CONDITIONS OF NORMAL RBC SURVIVAL

NCT02757898

February 01, 2023

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Transfusion of biotinylated RBCs

Principal Investigator: John D. Roback, MD PhD

Sponsor:

Investigator-Sponsor: John D. Roback, MD PhD

Study-Supporter: National Heart, Lung and Blood Institute (NHLBI) / NIH

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The Emory University Center for Transfusion and Cellular Therapies (CTCT) studies various aspects of blood, including blood donation and blood transfusion. The purpose of this research is to study how red blood cells (RBCs) survive in a person's circulation, and how that survival may be different in red blood cells that are donated and stored prior to being transfused.

In this study we would like to collect a sample of your blood, take it to the laboratory to add a small "label" to the RBCs, then inject your RBCs back into your circulation. After this transfusion, we will draw a few additional blood samples from you and count how many labeled cells are in those samples. Any samples we collect from you are identified only with a code number. The label we will use is biotin, which is a naturally occurring vitamin that most people eat large

amounts of every day. This type of labeling, which is for investigational purposes, has been used for many years and has been shown to be very safe even when used in very young babies. We anticipate that over the course of this study we will enroll 8 people in this study.

What will I be asked to do?

A health history will be done before you donate to see if you are eligible to participate in this study. If you are pregnant or planning to become pregnant you will not be eligible to participate.

If you are eligible, we will draw up to 500 milliliter of blood from you (1/2 liter); this is the amount of blood you would normally donate if you were a blood donor. That blood will be taken to the laboratory, where it will be processed into packed red blood cells. In some cases, the packed red blood cell unit will be stored for 40-42 days in the refrigerator; you will be asked to return on day 40-42 to receive transfusions of your stored blood. In other cases, after we process your blood into packed red blood cells, we will transfuse it back to you on the same day.

In either case, prior to transfusing the blood back to you, we will perform a simple 2-3 hour procedure to add biotin to the outside of the RBCs in your blood sample. After the labeling procedure is performed, we will inject the blood back into your arm. Then, within a few minutes we will draw a 5 milliliter sample of blood from you (1 teaspoon). You will then be completed for that day. We ask that you come back the next day to have another 5 milliliter blood sample drawn, and do the same thing once a week for approximately the next 22 weeks. Should you have to miss occasional blood draws over those 22 weeks, please let us know; even under these circumstances you may still be an acceptable volunteer for this study.

The process to donate blood for this project is the same as when a lab collects blood for testing or for use in transfusion. A sterile needle will be placed into one of your veins and blood will be collected in a sterile tube. After the blood is collected, we will remove the needle and hold pressure. A bandage will be applied to stop further bleeding. The bandage should be left on 1- 2 hours after you donate. The process for donating blood will last about 30 minutes. We will briefly check you and you will be free to go.

While you are in the study, you should not use biotin or raw-egg-containing supplements.

After You Have Donated:

- Do not leave until a staff member releases you.
- If you feel faint or dizzy, either lie down or sit down with your head between your knees.
- Drink an extra 1- 2 cups of fluids over the next four hours.
- If you were given an elastic pressure bandage and it becomes too tight, loosen it up and re-wrap it.
- Bandages should be kept dry and can be removed after 1-2 hours. You should not have to put on another bandage.
- If there is bleeding from the needle site, apply pressure and raise your arm until the bleeding stops.
- If you have any questions or problems about the donation, please call Shannon Bonds, RN, at [redacted]

If you participate in the full study, and depending on the results we find in your blood, you may be asked whether you want to participate in a follow-up study. It will be your choice as to whether to participate or not. If you are interested, you will be presented with a separate consent at that time.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

Many volunteers and patients in other centers have participated in a similar study, and they have not noted any adverse effects. The main risk is that you may develop an immune response to the biotin label on your RBCs. We will be monitoring regularly for this response. While there have not been any cases of people having adverse effects from the development of this antibody response, we will not be able to accept you for future studies that involve injection of your biotin-labeled RBCs.

The risks for giving blood may include feeling queasy, throwing up, chills or feeling cold, fainting, feeling light in the head, seizures, discomfort around the needle, bruising, infection, swelling around the needle site, blood loss, and red cell destruction. Other risks could include skin rashes and hives. Since you will only be giving a small amount of blood these risks are probably minimal. You may potentially get a blood infection when we transfuse your blood back to you, although we take a large number of precautions in the lab when we label your RBCs with biotin to minimize the chances of this problem, which would be a very rare occurrence.

There may be side effects from the study or procedures that are not known at this time.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about how RBCs survive in circulation. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

There are no costs to you for being a part of this study. You will receive between $5 and $40 when we collect the first sample of blood (depending on the volume we collect); $10 when we inject that blood back into you; and then $5 when we take another blood sample a few minutes later. Thus, on the first day of the study, if you go through with all 3 of these procedures, you will receive $20 - $55. You will receive $5 each time you return to donate blood. If you do not finish the study, we will compensate you for the visits you have completed. You will get up to $170 total, if you complete all study visits.

What are my other options?

Participation in this study is voluntary. You do not have to participate in this study.

How will you protect my private information that you collect in this study?

Emory will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other

identifying information will not appear when we present or publish the study results. Study records can be opened by court order.

They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

Your samples, genomic data and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

Medical Record

Information from the study, including your signed consent form, will not go into your Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Roback at telephone number [redacted] You should also let any health care provider who treats you know that you are in a research study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs)and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Dr. John Roback is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.

- Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
- Public health agencies.
- Research monitors and reviewer.
- Accreditation agencies.

Expiration of Your Authorization

Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact Shannon Bonds, RN at: [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Shannon Bonds, RN at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted] or [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**