MCC-17-13299
NCT03613727
Therapeutic Use of Intravenous Vitamin C in Allogeneic Stem Cell Transplant Recipients
Approved: 09/18/2019

RESEARCH PARTICIPANT INFORMED CONSENT FORM

TITLE:	Therapeutic Use of Intravenous Vitamin C Followed by Oral Vitamin C in Allogeneic Stem Cell Transplant Recipients
PROTOCOL #:	MCC-17-13299
VCU IRB #:	HM20013111
SPONSOR:	Virginia Commonwealth University Massey Cancer Center
PRINCIPAL INVESTIGATOR:	Gary L. Simmons, DO Virginia Commonwealth University Box 980157 Richmond, VA 23298 804-827-7952

YOUR PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY

This consent form will tell you about this research study, which is also called a clinical trial. Your study doctor or study team will explain the research study to you. Research studies only include people who choose to take part. You have the option to not participate. You may take home an unsigned copy of this consent form so that you can discuss the study with your family or friends before making your decision. You may also discuss it with your health care team. If you have any questions, ask your study doctor or study team for more explanation. Please take your time to make your decision about taking part in this study.

WHAT IS THE USUAL APPROACH TO TREATING MY CANCER?

You are being asked to take part in this study because you and your study doctor have agreed that you will be undergoing a stem cell transplant for a type of cancer that affects your blood and bone marrow.

You have already received standard treatments, if available, for your type of cancer, but your disease returned or is progressing. People who are not in a research study may be treated with stem cell transplant or with drugs, radiation, or a combination of drugs and radiation without a transplant, if available for their type of cancer.

WHY IS THIS STUDY BEING DONE?

Many of the problems that can happen after stem cell transplant are related to inflammation. Vitamin C is a nutritional supplement that can help fight inflammation. The researchers doing this study have found that most patients who have stem cell transplants have lower than normal levels of vitamin C in their blood. The purpose of this study is to look at any good and bad effects of giving high doses of vitamin C supplements after stem cell transplant, including effects on inflammation. Up to 81 people will take part in this study.

WHAT TREATMENT WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

If you take part in this study, most of the treatment you receive will be the usual approach in treating patients with your type of cancer who have a stem cell transplant. Starting on the day after your transplant, you will be given vitamin C intravenously, which means by vein (IV), three

times a day for two weeks while you are in the hospital. After that, you will take vitamin C by mouth twice each day until 6 months after your transplant.

HOW LONG WILL I BE IN THIS STUDY?

You will take vitamin C until about 6 months after your transplant procedure. You will continue to receive care that is standard after stem cell transplant for about 1 year. Your doctor will continue to check on your response to the transplant until about 2 years after the transplant.

WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?

If you decide to take part in this study, most of the exams, tests, and procedures you will have are the usual approach in treating patients with your type of cancer who have a stem cell transplant. Your study doctor or study team will tell you about these.

This study includes research using blood samples to study the effects of giving vitamin C after transplant. Results of the research using your samples will not be provided to you. The samples are collected only for the research study. There will be no benefit to you.

Three tubes of blood, each measuring about 1 teaspoon, will be collected for research purposes at each of the following times: before the transplant, on the day of your transplant, and at about 2, 4, and 14 weeks after your stem cell transplant.

This study does not plan to use your blood samples to sequence all or part of your DNA. If any inventions or discoveries result from the use of your samples, there are no plans to share any money or profits with you.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?

If you decide not to take part in this study, you have other choices. For example:

- You may choose to have a stem cell transplant without being in the study or to have another type of treatment, if any are available for your type of cancer
- You may choose to take part in a different study, if one is available
- Or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms

WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

You will be receiving many drugs and treatments as part of your care before and after the stem cell transplant. Your study doctor or study team will tell you about the side effects of those treatments, and you will be asked to sign a consent form that describes the risks of the stem cell transplant.

You will have finished your standard chemotherapy before you are given vitamin C. The researchers doing this study think this will limit any problems the vitamin C might cause with your chemotherapy. However, vitamin C has not been studied as a supplement in stem cell transplant patients, and all the possible side effects cannot be known for sure.

When you are given IV vitamin C, you may feel faint or dizzy for a short time. Other side effects associated with vitamin C include:

- nausea
- vomiting
- heartburn
- stomach cramps
- diarrhea
- kidney stones

There is a risk that being given high doses of vitamin C may cause an Accu-Chek glucose monitor to show your blood sugar level as higher than it really is. While you are in the hospital and at follow-up visits, your blood sugar level will be checked with a lab test as part of your regular stem cell transplant care.

We will watch you and other patients in this study very closely to see if there is an increased risk of any of the following serious problems that occasionally happen in stem cell transplant patients:

- life-threatening blisters or sores in your mouth, throat, or intestines
- kidney injury or failure
- lung failure
- liver failure
- severe, life-threatening infection
- engraftment failure, which is when your donor's stem cells do not successfully replace your blood cells

If too many patients in this study have these problems we will stop the study and inform you.

Here are important points about side effects:

- Your study doctor does not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may be serious and may even result in death.

Here are important points about how you and your study doctor can make side effects less of a problem:

- Tell your study doctor if you notice or feel anything different so they can see if you are having a side effect.
- Your study doctor may be able to treat some side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

If important new side effects are found, your study doctor will discuss these with you.

Let your study doctor know of any questions you have about possible side effects. You can ask your study doctor questions about side effects at any time.

Reproductive Risks

You should not get pregnant, breastfeed, or father a baby while in this study. The effects of high doses of vitamin C on a pregnancy are not known. The usual treatment before, during, and after a stem cell transplant could be damaging to an unborn baby and could cause a miscarriage. If you are able to become pregnant, you will be asked to have a pregnancy test before you begin the stem cell transplant procedures. You will also be asked to use a reliable method to prevent pregnancy for at least one year following your transplant. Check with the study doctor about what methods of preventing pregnancy are acceptable for you.

Risks Associated with Collection of Blood Samples

You may feel brief pain or have some bleeding or bruising at the puncture site used to collect the blood sample. There is also a small risk of infection, light-headedness, and fainting.

Non-Physical Risks

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

It is not possible to know at this time if the study approach is better than the usual approach, so this study may or may not help you. This study may help people in the future.

CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information for the purposes of the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available and the study is no longer in your best interest
- If you do not follow the study rules
- If the study is stopped by the sponsor, the FDA, or the institutional review board (IRB), which is a group of people who review the research with the goal of protecting the people who take part in the study.

WHAT ARE MY RIGHTS IN THIS STUDY?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Vitamin C will be supplied at no charge to you for the first six months after your stem cell transplant. This includes both the IV vitamin C you will receive in the hospital and the vitamin C you will take by mouth. You will not be charged for any costs related to the blood samples that are collected for research purposes. These samples are not used for testing that affects your care.

You and/or your health plan/insurance company will be billed for all standard costs of treating your cancer, including the cost of tests, procedures, or medicines to manage any side effects.

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

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. Your study doctor or study team will talk with you about your options for medical treatment.

Fees for such treatment may be billed to you or to your health plan/insurance company. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. The study will not pay for medical treatment.

To help decrease the risk of research-related injury or illness, it is very important to follow all study directions.

WHO WILL SEE MY MEDICAL INFORMATION?

Your privacy is very important to us. The researchers will make every effort to protect it. However, some of your medical information may be given out if required by law. If this happens, the researchers will do their best to make sure that any information that is released will not identify you.

Your research information and your personal identifying information will be kept private through the use of password-protected electronic files, locked research areas, and study identification numbers. The blood samples obtained for research purposes will be stored with the same safeguards. The results of this research may be presented at meetings or in publications, but you will not be identified by name.

It will be noted in your protected electronic medical record that you are in this study. Information about the study, including any medications you may receive, will be noted in the record. This information is protected just as any of your other medical records are protected.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- Virginia Commonwealth University (VCU)
- VCU IRB
- FDA
- National Cancer Institute (NCI)

In the future, the identifiers (like your name and birthday) could be removed from the information and samples you provide for this study. After that removal, your information and samples could be used for new studies without asking for your consent again. Those possible new studies could be done by this study team or other researchers and might involve sequencing all or part of your DNA.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

The Health Insurance Portability & Accountability Act (HIPAA) of 1996 provides for the protection of your health information from unauthorized use and disclosure. This section tells you what health information about you may be used and given out in the study and who may give and receive the information. By signing the consent form for this study, you agree that health information that identifies you may be used and disclosed as needed for this research.

Authority to Request Protected Health Information

The following people and/or groups may request your protected health information:

- Principal investigator and research staff
- Study sponsor
- Research collaborators
- VCU IRB
- Data and Safety Monitoring Committee
- Government/health agencies
- Others as required by law

Authority to Release Protected Health Information

The VCU Health System (VCUHS) may release the information identified in this authorization from your medical records and provide this information to:

- Health care providers at the VCUHS
- Principal investigator and research staff
- Study sponsor
- Research collaborators
- Data coordinators
- VCU IRB
- Data and Safety Monitoring Committee
- Government/health agencies
- Others as required by law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Types of Information That May Be Released

The following types of information may be used for the conduct of this research

- Complete health record
- Diagnosis and treatment codes

- Discharge summary
- History and physical exam
- Consultation reports
- Progress notes
- Laboratory test results
- Imaging reports (eg, X-ray reports)
- X-ray films/images
- Information about Hepatitis B, Hepatitis C, and HIV tests
- Complete billing record
- Itemized bill

Expiration of This Authorization

This authorization will expire (end) when the research study is closed, or when there is no need to review, analyze, and consider the data generated by the research study, whichever is later.

Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this authorization you may no longer be allowed to participate in the research study. To revoke this authorization, you must write to the principal investigator at the address on page 1 of this consent form.

WHERE CAN I GET MORE INFORMATION?

You may visit the NCI website at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.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.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?

You can talk to your study doctor about any questions or concerns you have about this study or to report side effects or injuries. You can also contact a study team member at 804-828-1292.

The Office of Research can answer your general questions or concerns about your rights as a participant in this or any other research. Also, if you would like to speak to a person who does not work directly with your study doctor and the study team or if you cannot reach your study doctor or a member of the study team, you may contact the Office of Research.

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
804-827-2157; https://research.vcu.edu/human_research/volunteers.htm

MY SIGNATURE AGREEING TO TAKE PART IN THIS STUDY

I have been given the opportunity to carefully read this consent form. All of the questions that I wish to raise concerning this study have been answered.

By signing this consent form, I have not given up any of my legal rights or benefits. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the signed consent form.

_____

Participant Name (*Printed*)

_____ _____

Participant Name (*Signature*) Date

_____

Person Conducting Informed Consent Discussion/Witness (*Printed Name*)

_____ _____

Person Conducting Informed Consent Discussion/Witness (*Signature*) Date

_____ _____

Signature of Investigator (*If different than above*) Date