MCC-14-10739
NCT02593123
Adoptive Immunotherapy in Patients with Relapsed Hematological Malignancy: Effect of Duration and Intensity of Early GVHD Prophylaxis on Long-Term Clinical Outcomes
IRB Approval Date: 12/17/2021
Document Date 11/24/2021

RESEARCH PARTICIPANT INFORMED CONSENT FORM

TITLE: Adoptive Immunotherapy in Patients with Relapsed Hematological Malignancy: Effect of Duration and Intensity of Early GVHD Prophylaxis on Long-Term Clinical Outcomes

PROTOCOL #: MCC-14-10739

VCU IRB #: HM20005586

SPONSOR: Virginia Commonwealth University Massey Cancer Center

INVESTIGATOR: Amir A. Toor, MD
Virginia Commonwealth University
PO Box 980157
Richmond, VA 23298
804-828-4360

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

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, for example, leukemia, lymphoma, or multiple myeloma.

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?

A common problem that may occur after a stem cell transplant is a condition known as graft versus host disease (GVHD). The word “graft” refers to the stem cells that are transplanted from a donor into you, the “host”. GVHD occurs when the donor graft attacks the tissues in the host. GVHD can cause skin rash, intestinal problems such as nausea, vomiting, or diarrhea. It may also damage the liver and cause hepatitis or jaundice. GVHD may increase your risk of infection and cause other health problems. Treatment with drugs that can decrease the chance of having GVHD or decrease the severity of GVHD is a standard part of patient care following stem cell transplant. One of these drugs is mycophenolate mofetil (MMF). MMF is approved by the Food

and Drug Administration (FDA) as a treatment for preventing GVHD after organ and tissue transplant.

The purpose of this research study is to compare any good and bad effects of giving MMF for 15 days following stem cell transplant instead of the usual 30 days. Researchers believe that giving MMF for a shorter period of time after transplant may help the transplanted stem cells become engrafted sooner, which could increase the chance of a successful transplant.

Another standard treatment after stem cell transplant is a drug that helps support bone marrow function until your bone marrow can produce enough white blood cells to fight infection. One of the drugs used for supporting bone marrow function is granulocyte-colony stimulating factor (G-CSF). G-CSF will be given to patients who will be taking MMF for 30 days. A drug similar to G-CSF called granulocyte macrophage-colony stimulating factor (GM-CSF) will be given to patients who will be taking MMF for 15 days. The researchers believe that GM-CSF will be more helpful than G-CSF in supporting bone marrow recovery in patients who will be taking MMF for 15 days. Both drugs are FDA-approved for treating patients who have had stem cell transplant or other cancer treatments that affect bone marrow function.

There will be about 60 people taking part in this study.

What will happen if I participate?

If you decide to take part in this study, most of the treatments and procedures you will have are the usual approach in treating patients with leukemia, lymphoma, or multiple myeloma who have a stem cell transplant. Your study doctor or study team will tell you about these.

After your stem cell transplant, you will take MMF pills for either 15 days or 30 days. You will also receive GM-CSF or G-CSF until about 2 to 3 weeks after your transplant procedure. A computer will decide which group you are in. We tell you more about this in the “Study Treatment” section of this consent form.

This study also includes research using blood samples to study the effects of giving MMF for fewer days on bone marrow recovery after transplant. Blood samples, each measuring about 1 teaspoon, will be collected for research purposes before the transplant and at about 2, 4, 6, 10, and 14 weeks after your stem cell transplant. A blood sample will also be collected if you develop GVHD.

This study plans to use your blood samples to sequence all or part of your DNA. Deoxyribonucleic acid (DNA) is the “blueprint” or “recipe” that gives the body’s cells instructions on how to do their jobs. Scientists use sequencing to determine the order of the molecules that make up your DNA, like reading all the letters in a book. Sequencing is usually done to look for changes in the molecules of DNA that may cause health problems.

Individual 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. If any inventions or discoveries result from the use of your samples, there are no plans to share any money or profits with you.

You will continue to receive care that is standard after stem cell transplant for about 1 year. Your doctor will continue to check you for side effects and follow your cancer response to the transplant until about 5 years after the transplant.

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 are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "Risks and Discomforts" section.

Risks

- There may be possible risks of giving MMF for 15 days instead of the usual 30 days that researchers do not yet know about. For example, there may be a greater risk that GVHD will occur or will be more severe when MMF is given on fewer days. The risk of engraftment syndrome may also be increased. Engraftment syndrome includes fever that is not due to infection, skin rash, diarrhea, weight gain, and fluid in the lungs, which is called pulmonary edema.
- You should not get pregnant, breastfeed, or father a baby while in this study. The treatment used in this study, which is part of the usual care following a stem cell transplant, could be damaging to an unborn baby and could cause a miscarriage.
- 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.
- 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.

Benefits

- 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.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

STUDY TREATMENT

This study has two study groups.

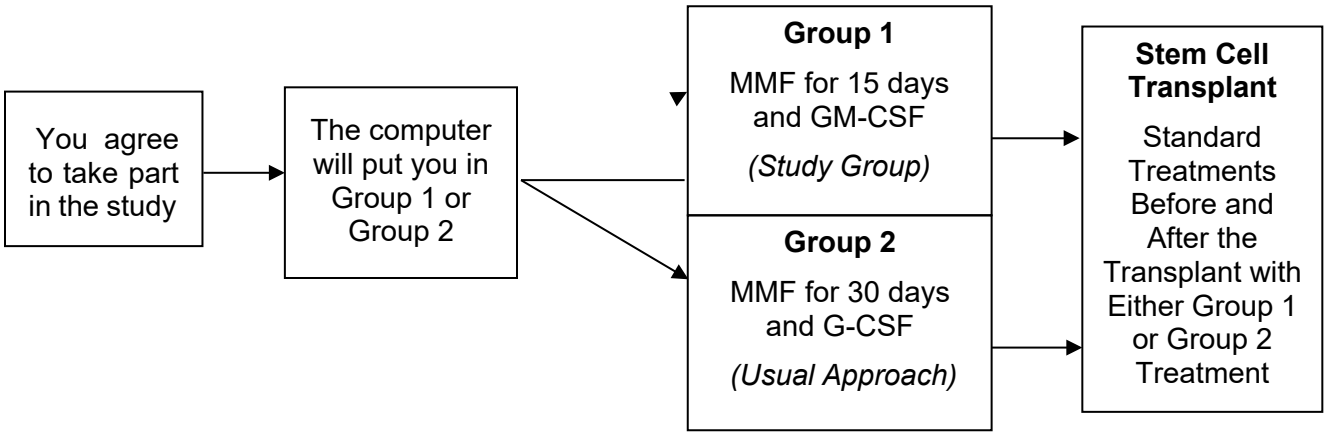
Group 1 – Study Treatment

If you are in Group 1, you will take MMF pills by mouth twice each day for 15 days beginning on the day of the transplant. Also, you will be given GM-CSF intravenously, which means by vein (IV), or by a shot once each day beginning 4 days after your transplant and continuing until your bone marrow is able to make enough white blood cells to be able to fight infection. You will also be given all of the drugs and treatments that are usually included in the care of patients who have had a stem cell transplant.

Group 2 – Usual Treatment

If you are in Group 2, you will take MMF pills by mouth twice each day for 30 days beginning on the day of the transplant. Also, you will be given G-CSF intravenously, which means by vein (IV), or by a shot once each day beginning 4 days after your transplant and continuing until your bone marrow is able to make enough white blood cells to be able to fight infection. You will also be given all of the drugs and treatments that are usually included in the care of patients who have had a stem cell transplant.

A computer will assign you to one of the treatment groups in the study. When the study begins, participants will have a 50:50 chance of being assigned to Group 1 or Group 2. The computer will keep track of which treatment group might be doing better. As time goes on, a larger proportion of participants could be assigned to the group that seems to be doing better. The chart below shows the treatment groups at the very beginning of the study. Start reading at the left side and read across to the right.



RISKS AND DISCOMFORTS

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. MMF and G-CSF or GM-CSF are all drugs that will be included in your care even if you decide you do not want to participate in this study. Your study doctor or study team will talk with you about the side effects of these drugs and you will be given drug information sheets.

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

The treatment used in this study, which is part of the usual care following 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.

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
- 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?

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, but your information may be given out if required by law. However, 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.

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, identifiers (like your name and birthday) might 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.

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.

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
804-827-2157

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