Study Title: 18-FLT PET/MR Imaging to Predict Graft Failure and Graft Versus Host Disease in Bone Marrow Transplant Patients

NCT03546556

Consent Form Date: September 4, 2018

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 9/4/2018
IRB Study # 17-0457
Title of Study: 18-FLT PET/MR Imaging to Predict Graft Failure and Graft Versus Host Disease in Bone Marrow Transplant Patients
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What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is explore the use of fluorothymidine (FLT)-PET-MRI, a PET tracer that goes to areas with high rates of cell division, in the evaluation of allogeneic bone marrow transplant

patients to potentially predict bone marrow transplant success, malignancy relapse, and the development of graft versus host. Even though FLT has been utilized in research studies for a number of applications, it is not an imaging agent that is approved for clinical use by the FDA.

You are being asked to be in the study because you are undergoing allogeneic bone marrow transplant or autologous stem cell transplant.

Are there any reasons you should not be in this study?

You should not be in this study if you:

- are pregnant or breastfeeding
- have a pacemaker, intracranial aneurysm clip, bladder stimulator, cochlear implant or metal near eyes or near pelvis that would create excessive imaging artifact
- unable to tolerate MRI (e.g., inability to lie flat for >1 hour)
- have an allergy to fluorothymidine
- have a Creatinine clearance < 40 ml/min
- Have poorly controlled diabetes mellitus (fasting blood glucose > 500 mg/dl)

How many people will take part in this study?

There will be approximately 15 people in this research study.

How long will your part in this study last?

You will be asked to participate in two scans on the PET-MRI system FLT-PET-MRI imaging on two separate occasions. The PET-MRI system is an FDA approved scanner that performs simultaneous PET and MRI. Each appointment will last approximately 3 hours and will involve the injection of the FLT tracer. Patients will be followed for one year for the development of acute GVHD or graft failure.

What will happen if you take part in the study?

You will be asked to review the informed consent form and then, date and sign that you understand your participation in the study. A technologist will go over your medical history briefly, with questions pertinent to both MR and PET scans.

You will be asked to change into either a gown or scrubs, provided by the facility. A technologist will attempt to access an existing central venous catheter. If necessary, however, a peripheral IV line will be placed. You will then be brought into the scanner room to initiate the scan. FLT will be injected one hour prior to imaging.

The technologist will then acquire your images. Once the scan is finished, the technologist will help you off the table and remove the IV. You will then change back into your own clothes and complete the compensation forms.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?

There may be uncommon or previously unknown risks. You should report any problems to the researcher. Pregnancy tests will be done on all females who might be able to get pregnant within 7 days prior to each PT/MR.

IV Placement

For patients, study participation may require placement of an IV for administration of the radioisotope for PET/MRI scans if we are unable to utilize existing central venous access. IV placement may result in pain, bruising or infection. The IV will be placed by a certified BRIC technologist using sterile techniques to minimize the risk of bleeding and infection. Patients will have the option of a topical anesthetic for IV placement to reduce pain and discomfort.

Radiation

This research study involves exposure to radiation from radiotracer (FLT) that is given for PET/MR scans. *The effective dose from one scan is 1216 mrem, which is equivalent to exposure in everyone receives in 4 years from background radiation*. For comparison, a person in the United States receives a radiation exposure of 0.3 rem per year from natural background sources. This radiation exposure involves only a small risk and is necessary to obtain the research information desired. The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care."

Risks arising from the imaging procedure itself including injury to the donor bone marrow and/or additional infectious complications are felt to be extremely low but theoretically possible. Notably FLT-PET scanning has been applied to both the autologous and allogeneic stem cell transplant patient population previously with no reported adverse effects on patient outcomes.[9,11] Furthermore an NCI study is currently ongoing which specifies the use of FLT-PET scanning in allogeneic stem cell transplants as early as 5 days post-transplant (NCI study NCT01338987, Pilot Study of Lupron to Improve Immune Function After Allogeneic Bone Marrow Transplantation). There is a potential risk to a fetus of radiation injury, and thus we excluded pregnant women and will verify that patient of child-bearing children are not pregnant.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

The images acquired for this study are from a clinical scanner, however, the scans are performed for research purposes. Whenever imaging is done, there is the chance of finding an unexpected abnormality. A qualified physician will review the images obtained in this study. If an important abnormality is found, then you, or (with your permission) your primary health care provider, will be notified. Such an abnormality may require further follow up or treatment. Any further follow up and costs associated with the incidental finding will be your responsibility.

There may be benefits to learning of such abnormalities (such as early detection and treatment of a disease or tumor), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

How will information about you be protected?

Clinical information will be maintained on UNC network-protected computer. All electronic files will also be password protected. All written data will be maintained in a locked cabinet in a locked office.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will be receiving a $50.00 Target gift card for taking part in this study. Parking will be provided.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on 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.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent