THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Feasibility of Digital Thermal Monitoring to assess endothelium-dependent vasodilation in patients undergoing hematopoietic cell transplantation (HCT)
2020-1309

Study Chair: Keri Schadler

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

If you are reading and signing this form on behalf of a potential participant, please note: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant.

The goal of this research study is to learn if the Vendys II device can be used to measure blood vessel (the endothelium) health in children and young adults that are having hematopoietic cell transplantation (HCT) and stem cell donors.

This is an investigational study. The Vendys II device is FDA approved and commercially available for detecting cardiovascular disease. Using the device in patients who are having HCT or stem cell donors is investigational. Using the device in patients under 18 years of age is also investigational.

Future patients and/or stem cell donors may benefit from the Vendys II device because it may help predict an increased risk of developing blood vessel problems. There are no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may choose not to take part

in this study because of the additional time required to use the device or the possible discomfort associated with the use of the device.

You can read a list of potential side effects below in the Possible Risks section of this consent.

Your participation in this study will be over after your blood vessel health is measured 1 time with the Vendys II device. Your participation in research may be longer based on the companion studies (described below) you are enrolled in.

There is no cost for taking part in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 50 participants will be enrolled in this study. All will take part at MD Anderson.

If you agree to take part in this study, you will need to fast (do not eat or drink anything except water) for at least 2 hours before your study visit.

For the Vendys II scan, you will be asked to lie flat on your back for 15 minutes and rest (stay still). Then, you will sit up and place your hands on a flat surface. A temperature monitor and an inflatable cuff will be placed on your index finger. This cuff is similar to a blood pressure cuff but is smaller and designed to fit around your finger.

There are 3 parts to the blood vessel measurement. Each part is about 5 minutes long. During the first part, the Vendys II will take the temperature of your finger. For Part 2, the blood pressure cuff on your finger will inflate for 5 minutes, blocking blood flow to your finger. During that time, your finger may tingle and feel as if it fell asleep. However, the feeling in your finger will return to normal after the cuff deflates. For Part 3, the cuff will deflate, and the Vendys II will continue to measure temperature changes in your finger for 5 minutes.

If you agree to take part in this study, information will be collected from your medical record for use as part of this study. Information collection will stop after the measurements are taken.

Additional Research

In addition to the study visit above, HCT candidates only will take part in another MD Anderson study (PA19-0756) titled “A Prospective Registry of Pediatric Cellular Therapy Patients at Risk for Endothelial Dysfunction, Sinusoidal Obstruction Syndrome, and/or Multi-Organ Dysfunction Syndrome.” This study will collect information about you, your medical information, and potential complications related to your HCT. You cannot take part in this study if you do not agree to enroll in the other study.

You will also be asked to take part in 1 other optional MD Anderson study (PA18-0130) for HCT candidates and donors titled “Pediatric Energy Balance Front Door Protocol.” This study measures your physical activity levels using a Fitbit, your eating habits using email questionnaires, your physical function using tasks such as standing up from a chair and walking, and your vitamin levels using a blood test. Each component of the study is optional. For example, you may choose to participate only in wearing a Fitbit or only in answering questions about the food you eat but not in the other study parts.

The study doctor will discuss all of the studies with you, and you will sign a separate consent document for each study you agree to join.

You do not have to join this or any study. You will still receive the treatment or procedure that is clinically needed.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

The **Vendys II procedure** may cause a short period of discomfort in your finger while the cuff is being used. You have the right to stop the study if you are uncomfortable.

Although every effort will be made to keep **study data** safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson’s IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary

manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Keri Schadler, at 713-794-1035) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Reasons for early stopping may include if you cannot follow study directions or if the doctor thinks it is not safe for you to participate in the study.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research. The device maker, Endothelix, will not receive any data or personal information about you.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Your data will be de-identified (all identifying information removed) during this study. The de-identified data will be stored in a password-protected, encrypted computer at MD Anderson. The study doctor and members of the study team will have access to this data and the key linking you to your data. The data will be stored indefinitely (without time limit) at MD Anderson.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION
(Adult Participants Only)

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE

_____
PRINTED NAME OF PARENT/GUARDIAN

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE
Signature of Other Parent (Optional, unless required by the IRB.)

_____
PRINTED NAME OF PARENT/GUARDIAN

____The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

____Other parent is deceased, unknown, incompetent, or not reasonably available.

____Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

_X__ The IRB has determined that the signature of both parents is NOT required.

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.

____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.

____ 3.) Other: _____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____

SIGNATURE OF MINOR (Age 13-17) DATE

_____

PRINTED NAME OF MINOR