

Northwell Health
Comprehensive Wound Healing & Hyperbaric Center
1999 Marcus Avenue
Suite M6
Lakes Success, NY 11042
Consent for Participation in a Research Study

Study Title: Examining the Use of Three-Dimensional Ultrasound in the Assessment of Vascular Pathologies

Principal Investigator: Alisha Oropallo, M.D.

About this research

You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	We are conducting this study to determine whether 3D images created by a device attached to the ultrasound machine (a device that uses sound waves to create a 2-dimensional image of someone's blood vessels) will help give patients a better understanding of their vascular disease (problems with your blood vessels, typically seen as either narrowing or ballooning) in the hopes of improving patient outcomes. The device is the PIUR Infinity tUS (PIUR Imaging GmbH, Vienna) and has NOT been approved for use by the Food and Drug Administration (FDA, a government agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human drugs, biological products, and medical devices).

What will happen to me during the study?	You will undergo the standard ultrasound testing that has been prescribed for you by your doctor. The experimental device is an attachment to the ultrasound machine and will collect data and images from the machine to be able to produce a 3D image of your blood vessels. You will not be subjected to any additional and/or alternative ultrasound testing for participating in the study.
How long will I participate?	If you choose to take part in this study, the study procedures will last for 30 minutes. The research team will continue to follow your progress by accessing your medical records for 6 months after the ultrasound.
Will taking part expose me to risks?	Participation in this study will only expose you to minimal risks, meaning that the probability of harm or discomfort anticipated in the research does not exceed what you would face during routine standard medical treatment. The imaging system we are evaluating is non-invasive and works simply by attaching to the ultrasound probe itself. You will not feel any difference between this and a standard ultrasound study of your blood vessels.
Are there any benefits to participation?	Participants may benefit directly from enrolling in the study because you will be able to view your blood vessels in a 3-dimensional image. Your doctor will then be able to show you areas of concern that may require additional testing and/or intervention.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction

You are being asked to join a research study. The purpose of a research study is to answer specific questions.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?

The purpose of this study is to determine whether viewing 3D images created by a novel device attached to the ultrasound machine will help in your understanding of your vascular disease and whether or not it will promote greater understanding of your medical issue and if that understanding will help you adhere to the treatment recommended by your doctor. You will then review these images with your doctor. The device has NOT been approved for use by the Food and Drug Administration (FDA, a government agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human drugs, biological products, and medical devices). You are being asked to participate in this study because your doctor has prescribed for you to undergo vascular ultrasound testing to diagnose and/or assess your vascular disease.

How many people will take part in this study?

This research study hopes to enroll 270 participants. 135 of these participants will be recruited from the group of patients like yourself who are about to undergo ultrasound testing. We will then compare outcomes to 135 patients who have had similar tests performed in the past but were only shown 2D hand-drawn sketches of their ultrasound results.

How long will you be in this study?

If you choose to take part in this study, the study procedures will last for 30 minutes and you will be followed for another 6 months. The use of the PIUR Infinity tUS (3D ultrasound probe) will not increase the length of the ultrasound test. We will not ask you to return to the clinic for study purposes.

What will happen in this research study?

Once we obtain your consent and you are enrolled in the study you will undergo the standard vascular ultrasound testing that was prescribed for you by your doctor. The only difference is that there will be a small sensor attached to the ultrasound probe that will collect additional information. This probe will not come into contact with you in any way. The sensor will then relay information to the 2nd part of the 3D device that is attached to the ultrasound machine. This small black box will use the data obtained from the sensor as well as the images captured by the ultrasound machine to generate a 3D model of the blood vessels that were examined. This image will then be loaded onto a laptop that has software specially designed to view the 3D imaging. Additionally, we will obtain certain de-identified data from your medical chart.

What are the risks of the research study? What could go wrong?

The only risk if you choose to participate will be a risk of a breach of confidentiality. All standard precautions will be taken to ensure the safety and security of your Personal Health Information (PHI, any information that can potentially identify an individual, that was created, used, or disclosed in the course of providing healthcare services, whether it was a diagnosis or treatment).

Incidental Findings

Although some of the imaging you will have in this study is being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. Although not likely, it is possible that the doctors may notice something that may be very serious and could immediately affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

What are the benefits of this research study?

The possible benefits you may experience from the procedures described in this study include the ability to visualize your vascular disease processes and gain a better understanding of why your circulation may be compromised. Your doctor will be able to highlight areas of vascular disease and explain what effect that is having on your overall health.

Will I receive my results?

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. Certain results may dictate the speed as to which further treatment should be undertaken if any is warranted.

Are there any costs for being in this research study?

You will not have any added costs from being in this study.

Will you receive any payments for participating in this research study?

You will not receive any form of compensation for participating in this study.

What are your rights as a research participant?

Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?

You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?

If you agree to be in this study, we will collect health information that identifies you. We will collect the results of your ultrasound test. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?

Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:

- other researchers,
- clinical staff not involved in the study who may be involved in participant's treatment, billing,

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from Federal and state government oversight agencies, such as the Department of Health and Human Services
- Representatives from Northwell Health's Human Research Protection Program (a group of people that oversee research at this institution)

We will do our 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 the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?

If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?

There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?

If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Alisha Oropallo
Clinical Director,
Northwell Health Comprehensive Wound Healing & Hyperbaric Center
1999 Marcus Avenue
Suite M6
Lake Success, NY 11042

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will my information be used for research in the future?

Information or specimens collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified data to be used by future researchers without additional consent.

Does the investigator of this study receive money if you take part?

The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?

If you have any questions about the study, you may call Dr. Alisha Oropallo at (516) 233-3780. If you have questions about side effects or injury caused by research, you should call Dr. Alisha Oropallo at (516) 233-3780. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

Subject: Name (Print) **Signature** **Date**

Signature

Date

Signature

Date

(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement

In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

Investigator/: Name (Print) **Signature** **Date**
Person obtaining consent