Informed Consent

Transcutaneous ARFI Ultrasound for Differentiating Carotid Plaque with High Stroke Risk

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

Consent Form Version10/11/2021

IRB Study # 17-2700
Title of Study: Transcutaneous ARFI Ultrasound for Differentiating Carotid Plaque with High Stroke Risk
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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.

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 to develop a new ultrasound method, called 'Acoustic Radiation Force Impulse (ARFI)' ultrasound, for imaging the structure and composition of carotid atherosclerotic plaque so that the plaque's risk for causing stroke may be assessed. Improved knowledge about stroke risk could help to avoid unnecessary carotid endarterectomy (CEA) surgeries for patients such as you in the future.

You are being asked to be in the study because your doctor has determined that you are in need of CEA to prevent stroke.

Are there any reasons you should not be in this study?
You should not be in this study if you have any of the following: 1) prior CEA or carotid stenting, 2) carotid occlusion, 3) vasculitis, 4) malignancy, 5) prior radiation therapy to the neck, 6) treatment with immunomodulating drugs, or 7) oncological disease.

How many people will take part in this study?
There will be approximately 80 people in this research study.

How long will your part in this study last?
Your part in this study will last less than 30 minutes. This is the amount of time needed to collect ultrasound images of your carotid artery that will undergo surgery.

What will happen if you take part in the study?
If you participate in this study, the following will happen.

- ***Overall design***: ARFI ultrasound imaging will be performed on your surgical carotid plaque.
    - First, ultrasound gel will be applied on your neck above your surgical carotid artery. This may feel a little cool, like lotion being applied to your skin.
    - Second, the sonographer (the person acquiring the ultrasound data) will place the ultrasound transducer (the probe attached to the ultrasound machine) on your neck to determine the proper position for ARFI imaging.
    - Third, ARFI ultrasound imaging will occur.
    - Your participation will be over once ARFI imaging is completed.
- ***Specimens***: The remnants of your surgically extracted carotid plaque specimen will be collected for additional imaging and histological processing. We will compare what our ARFI images describe in regard to the plaque's composition and structure to the true composition and structure of the actual plaque. This one-to-one comparison will help us to understand if our ARFI imaging methods are working properly or if additional improvements are needed.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?
Overall, this research study is deemed to be of minimal risk to study participants.

ARFI ultrasound is performed using conventional ultrasound machines. Conventional ultrasound uses only sound waves to generate images of tissue, so ARFI imaging also uses only sound waves to create images. Sound is non-ionizing, which means it does not carry enough energy to ionize atoms or molecules. Other examples of nonionizing sources include radio waves and visible light. No ionizing radiation will be transmitted into your body during ARFI imaging.

ARFI is different from conventional ultrasound because it uses higher intensity sound waves to very softly push on tissue. The pushes are very short (much less than a second long) and very small (much smaller than the pushes your arteries receive from flowing blood). You will not feel the pushes at all.

The only aspect of the procedure that may be considered minimally unsafe is the pushing force the sound wave delivers inside the body. This pushing that occurs is much less forceful than the push your heart puts on your blood vessels each time it beats.

The series of sound waves that will be used to push on your carotid plaque are similar to those that are commonly used for routine therapeutic ultrasound treatments. Therapeutic ultrasound is often used in physical therapy to generate heat in muscle tissue and joints to promote healing (like an internal heating pad). The degree of warmth (if any) that you feel during this research procedure should be no more than that experienced by placing a heating pad on your leg. The possibility of tissue injury from the ultrasound technique in this examination is felt to be no different from that normally encountered in any diagnostic examination using ultrasound. These risks are minimized because the high intensity ultrasound waves will be applied in very short time bursts (much less than 1 second), shorter than those normally used in therapeutic procedures (greater than 5 minutes).

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

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.

How will information about you be protected?
Your private information will be protected in the following ways:

- Only authorized study personnel will have access to your private information.
- All data will be stripped of identifying information. The data coming from you will be stored using a study number that in no way reveals your identity or any other private information.
- The file linking your study number to your identity will be secured with password protection on a computer or locked in a filing cabinet in paper form.
- The electronic data files will be kept for five or more years after completion of the study, at which time they will be securely deleted.

A copy of this consent form will go in to your medical record. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study.

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 one-hour parking voucher for the UNC Hospitals visitor parking deck for taking part in this study.

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

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the 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.

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.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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