STUDY INFORMED CONSENT

ARFI, VisR AND DDAI ULTRASOUND FOR IMPROVING DISCRIMINATION OF MALIGNANT AND UNRESPONSIVE BREAST CANCER

Arm 2

NCT number NCT 03785782
Document Date October 26, 2020

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants – Arm 2

Consent Form Version Date: October 26, 2020
IRB Study # 17-0949
Title of Study: ARFI, VisR, and DDAI Ultrasound for Improving Discrimination of Malignant and Unresponsive Breast Cancer
Principal Investigator: Caterina Gallippi
Principal Investigator Department: Biomedical Engineering
Principal Investigator Phone number: (919) 843-6647
Principal Investigator Email Address: cmgallip@email.unc.edu
Study Contact Telephone Number(919)-966-4431; (919) 966-6957; (919) 966-9284
Study Contact Email: Emily_ray@med.unc.edu; shanah_kirk@med.unc.edu; doreen_steed@med.unc.edu

---

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 to determine whether a special ultrasound technique is useful to evaluate the response to chemotherapy of malignant lesions in the breast with ultrasound. The study also aims to use this ultrasound technique to determine if it can detect which types of tumors respond to chemotherapy. The use of this device is investigational and is not FDA approved. The settings being used fall within what the FDA considers to be safe.

You are being asked to be in the study because you will undergo neoadjuvant chemotherapy for breast cancer.

Are there any reasons you should not be in this study?
You should not be in this study if you cannot remain still for 15 minutes, you have had a surgical excision of the biopsy-proven lesion of interest, you are pregnant or lactating, you have had a mastectomy, or you have breast implants.

How many people will take part in this study?
There will be approximately 80 people in this research study, including a total of 40 people in this arm of the study.

How long will your part in this study last?
You will have several research ultrasound scans done in coordination with your clinical treatment schedule. It is anticipated that each visit will last approximately 45 minutes to 1 hour. At a minimum, you may undergo 3 ultrasounds. At a maximum, you may undergo 8 ultrasounds.

What will happen if you take part in the study?
If you decide to participate, you will be escorted by the research coordinator to a dressing room, where you will change into a gown. Then, you will receive the research ultrasound exam in conjunction with your breast biopsy. Imaging will be performed by a trained medical or research personnel using mild compression to eliminate motion, similar to when you received your breast ultrasound. The total imaging time is estimated to be less than 15 minutes.

Your imaging appointments will coincide with your treatment plan. You will be imaged prior to starting a new chemotherapy treatment, at the start of each chemotherapy type, and at the completion of the treatment.

We will also continue to follow your medical treatment to assess how well you respond to treatment, including pathology reports and other treatment information.

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?
There may be uncommon or previously unknown risks. You should report any problems to the researcher.

There is a minimal risk of a breach of confidentiality. To lessen this risk, we will not identify your information by name in this study. Instead, you will be given a unique study ID and only the research team members will know who you are.

The likelihood of pain or discomfort from ultrasound imaging is rare. One aspect of this study that is different from conventional ultrasound imaging is the application of very short high-intensity impulses of ultrasound. However, the settings that we use are within what the FDA considers to be safe.

If you choose not to be in the study, what other treatment options do you have?
You do not have to be in this research study in order to receive treatment. The other procedures or treatments that are available include your previously planned clinical imaging and biopsy.

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?
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 not receive anything 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.

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