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Supplementary information

Quantitative magnetic resonance imaging and tumor forecasting of breast cancer patients in the community setting

In the format provided by the authors and unedited

The University of Texas at Austin

Consent to Participate in Research

Basic Study Information

Title of the Project: MRI evaluation of breast tumor growth and treatment response
Principal Investigator: Thomas E. Yankeelov, Ph.D., University of Texas at Austin

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to find the best ways to take images of breast cancer that can be used to improve clinical decision-making.
- In order to participate, you must be a woman with breast cancer.
- If you choose to participate, you will be asked to undergo 4 MRI scans. This will take place over the course of approximately 6 months, depending on your treatment.
- Risks or discomforts from this research include discomfort in the MRI scanner and side effects from the MRI contrast agent.
- There is no direct benefit for participating in this study.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

The purpose of the study is to improve imaging of breast cancer and its response to treatment. You are being asked to take part in this research study because you are a woman with breast cancer. We are trying to find the best ways to take images that can be used to improve clinical decision-making. We are using a scanner called the Siemens 3.0 Tesla Magnetic Resonance Imaging (MRI) scanner. No medical decisions may be made based on the results of the scan. Magnetic resonance imaging (MRI) is a way to take pictures of organs inside the body. We will scan you in a number of ways using this scanner and compare the results. The purpose of this study is to test advanced MRI methods to improve early detection of breast cancers and monitor their responses to therapy. We would like to determine whether MRI exams will be able to provide more information about breast cancer. We will enroll a maximum of 100 participants in this study at the University of Texas at Austin.

What will happen if you take part in this study?

You will be asked to participate in up to a total of four MRI scanning sessions, each lasting approximately 60 minutes over the course of your neoadjuvant therapy (first step of treatment before surgery). If you agree to be in this study, images will be taken using a Siemens 3.0 Tesla Magnetic Resonance Imaging (MRI) scanner. The MRI scanner is a machine that enables us to acquire images by manipulating magnetic fields. Magnetic resonance scans are taken only for research purposes. Results of the MR scan will ***not*** be provided to you.

During each MRI scanning session you will be asked to do the following:

- Be screened for magnetic material by the MRI technician
- Receive information on how to alert the staff in need of assistance
- For the MRI scan, you will need to lie still for 30-60 minutes
- Lie on your stomach on top of a breast coil
- Wear earplugs (and headphones if desired)
- Receive an injection of MRI contrast agent (Gadolinium-based contrast agent, Gadavist)

If you have a medical device implanted in your body, its serial number will be checked to ensure that you can safely take part in this study. If it is rated "safe" you are free to take part in the study. If it is rated "unsafe" you will not be allowed to take part in the study. If it is rated "conditional" you will not be allowed to take part in the study, unless it is a certain chest port that can tolerate a magnetic field gradient up to 720 Gauss/cm. We will confirm this tolerance with your devices specifications prior to your participation and so that you do pass through any unsafe magnetic fields during the procedure.

How long will you be in this study and how many people will be in the study?

Participation in this study will last 6 months and we anticipate enrolling 100 subjects in this study.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study. There are no known major risks with an MRI scan. But it is possible that harmful effects could be found in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

MRI SCAN

Common:

- You may feel uncomfortable while being scanned.
- You may feel the fear of enclosed space while being scanned.
- MRI scan noises may bother you (ear plugs will be provided).

CONTRAST AGENT (Gadolinium-based contrast agent, Gadavist)

Uncommon:

- Headache and nausea.
- Generalized itchy rash or reddening of the skin.
- Local pain and tenderness at the injection site due to irritation of the vein

Rare:

- Mild asthma type attack consisting of chest tightness and some difficulty breathing.

Rare (serious):

- Severe difficulty breathing
- Severe swelling of the face, mouth, or airways.
- Severe kidney damage

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

Although you will not directly benefit from being in this study, others might benefit because we may learn new things about breast cancer.

What will happen to the samples and/or data we collect from you?

As part of this study, we will collect health information related to your disease and MRI scans. This data will be analyzed to determine what new MRI techniques can tell us about breast cancer.

How will we protect your information?

We will protect your information by using a code to identify your MRI scan data. Only the study personnel with have access to this code. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

Information about you may be given to the following organizations:

- Representatives of UT Austin and the UT Austin Institutional Review Board
- Officials of the Department of Health and Human Services

We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify you. We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future research. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

What if we learn something about your health that you did not know?

If you volunteer for this research study, the MRI scans that we will perform are NOT necessarily equivalent to MRI scans used to diagnose medical problems. Potentially serious problems may be undetectable on these scans. These scans are in addition to your standard of care scans. A negative MRI should not be used to avoid a visit to your primary care physician. If you are having physical symptoms that you are concerned about, you should see your primary care physician and oncologist, who will determine the examinations required to arrive at a proper medical diagnosis. Because the images obtained in this study do not comprise a standard clinical MRI study, these images will not be made available to you or your physician.

How will your health information be used and shared during the study?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or

questionnaires. This type of information is considered “Protected Health Information” that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

	☐ Complete health record	
☐ Information about sexually transmitted diseases	☒ Diagnosis & treatment codes	☐ Discharge summary
☐ History and physical exam	☐ Consultation reports	☐ Progress notes
☒ Laboratory test results	☒ X-ray reports	☐ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	☐ Information about mental health
☐ Other physical or mental health information (specify):		

Where will you get my records?

For this study, we will obtain records from the following healthcare providers:

- Texas Oncology
- Seton Hospital

Who will use or share protected health information about me?

The covered entities listed above are required by law to protect your identifiable health information. By signing this document, you authorize them to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at UT Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law

If your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

If you later decide that you do not want to share your medical information any longer, please contact the study team in writing to withdrawal your authorization. Contact information for the study team can be found at the end of this form.

How will we compensate you for being part of the study?

You will receive $250 for each MRI scan in which you participate. Payments will occur via prepaid gift card. You will be responsible for any taxes assessed on the compensation.

You will receive $1000 for your participation in this study if you complete a total of 4 MRI scans. You can stop participation at any time and still receive the compensation for the visits you have completed.

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin.

You are not waiving any of your legal rights by participating in this study.

What are the costs to you to be part of the study?

To participate in the research, you may need to pay for parking at the MRI center location.

Who can profit from study results?

Your samples may be used for commercial profit and there is no plan to share those profits with you.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin, your doctor, or healthcare provider. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you decide to withdraw before this study is completed, we will retain data that has already been collected.

Is it possible that you will be asked to leave the study?

You may be asked to leave the study if it is determined by your doctor or the research team that it is unsafe for you to continue. If any of the following issues come up, we will have to ask you to stop participating: progression of disease; reaction to MRI scan.

Is it safe to start the study and stop before you are finished?

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect your standard medical care or any other benefit you would receive if you were not in a research study.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

Thomas E. Yankeelov, Ph.D.
Phone: 512-471-1733
Email: thomas.yankeelov@utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date

_____ By initialing here you are confirming that you have received a medication guide regarding Gadolinium (Gadavist).