Evaluation of Breast CT

NCT00584233

Consent document for IRB # 214750

Consent Version Dated November 17, 2021

Title of research study: Evaluation of Breast CT

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Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have been identified as having suspicious lesions on your mammogram and are being scheduled for a breast biopsy. About 624 female patients who have been identified as having suspicious lesions on their mammograms and who are scheduled for a breast biopsy will take part in this study at UC Davis.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.
  - Medical treatment, if any, that is available for complications.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document**.**

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (916)734-3101 (Study Coordinator) or (916)734-0521 (Dr. Shakeri).

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to Radiologist on duty. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-

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admin/.You may talk to a IRB staff member at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

We hope to learn more about the diagnostic performance of the Breast computed tomography (CT) scanner and to see if the new imaging technique can be used in the early detection of breast cancer in women. We will compare this imaging to the standard magnetic resonance imaging (MRI) imaging.

How long will the research last?

You will be asked to participate for Breast CT scanning with contrast and Breast MRI scanning with contrast and these two scans will take approximately 45 minutes each. We will also monitor your medical record for any follow-up breast pathology results (typically 2-3 months).

How many people will be studied?

We expect about 624 women here will be in this research study.

What happens if I say yes, I want to be in this research?

If you decide to take part in this study, you will be asked to come to the UC Davis Medical Center Ambulatory Care Center.

Prior to your biopsy appointment, we will ask you to come in for the breast CT and MRI scans. Depending on the clinic schedule, they may take place on the same day just prior to your biopsy appointment, or we may ask you to come in on a separate day for one of the scans.

For the Breast MRI visit:

The MRI technologist will first confirm with you whether you can safely have an MRI, which involves laying inside a large magnet.

We will place a thin plastic needle, called an “IV,” into a vein in your arm. To this IV we will connect a tube to the contrast injector machine. We will then have you lie face down on a large table (which is covered by a foam pad), and you will place both breasts into separate holes in the table. We will then perform the pre-contrast scanning. After this, we will inject the MRI contrast (about 1-5 teaspoons). Then, the final post-contrast scanning will be done. After that, your participation in the study visit will be complete.

For the Breast CT visit:

We will place a thin plastic needle, called an "IV," into a vein in your arm. To this IV we will connect a tube to the contrast injector machine. (If you are unable to tolerate X-ray dye injection, or cannot have an IV placed, you may still participate in the non-contrast portion of the CT scanning). We will then have you lie face down on a large table (which is covered by a foam pad), and you will place the breast to be scanned in a small hole in that tabletop. The hole is surrounded by a soft neoprene "hammock," which will allow your entire upper torso to slump into the scan plane of the device. After positioning of the breast by a female mammography technologist, you will be instructed to hold your breath (for approximatey 15 seconds) and a pre-contrast scan will commence. Then we will inject the contrast (about 7 tablespoons). If you have lesions in both breasts, we will split the contrast dose into two injections, one prior to scanning each breast. The radiation dose will be the same. We will then take two quick X-ray pictures before starting the scan. After this, you will be instructed to hold your breath again (for approximately 15 seconds) and the post-contrast scan will commence. There will be no breast compression (as in mammography), and other than the sound of the relatively noisy x-ray system in the room, you will not feel or sense any aspect of this scan. After the scans have finished, you will be given a questionnaire to fill out about your experience during the study. In addition, you will be given post contrast instructions verbally and in writing. After that, your participation in the study visit will be completed.

Note: If you are pregnant or breast-feeding, please tell the investigators because you will not be eligible to participate. If you are unsure if you are pregnant, we will provide you with a simple urine pregnancy test at no charge.

Parts of this study may involve standard medical care. Standard care is what is normally done to prevent, diagnose, or treat a certain condition or illness. Other parts of this study may involve devices that are being tested for a certain condition or illness. When a device has not been approved by the U.S. Food & Drug Administration (FDA), or has not been approved for the use intended in a study, it may be called experimental or investigational.

The following procedures are part of standard of care and may be done even if you do not join the study: Your standard of care Breast Biopsy.	**The following procedures WILL ONLY BE DONE IF YOU JOIN THE STUDY:** Breast CT scan and breast MRI scan (if eligible), both with and without contrast.

WHEN I AM FINISHED

After the scans have finished, you will be given a questionnaire to fill out about your experience during the study.

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What are my responsibilities if I take part in this research?
If you take part in this research, you will need to follow the procedures outlined in the previous section.

What happens if I do not want to be in this research?
You may decide not to take part in the research and it will not be held against you. Taking part in this study is your choice and completely voluntary.

What happens if I say yes, but I change my mind later?
You can leave the research at any time and it will not be held against you. If you decide to take part in this study, you can decide to stop at any time. Leaving the study will not affect your medical care here at UC Davis. Tell the Researcher if you are thinking about stopping or decide to stop so any risks can be managed safely. Another reason to tell the Researchers that you are thinking about stopping is to discuss what follow-up care and testing may be important for you.

The Researcher may withdraw you from this research if circumstances arise which warrant doing so even if you would like to continue.

We will tell you about new information or changes in the study that may affect your health or willingness to continue in the study.

Is there any way being in this study could be bad for me?
You may have side effects while on this study. Everyone taking part in the study will be watched carefully for any side effects. However, the Researcher may not know all the side effects or risks. Side effects may be mild or very serious. This study involves a small amount of radiation exposure that is typical of other diagnostic tests involving the use of radiation exposure (such as a mammogram). The amount of radiation exposure received in this study is below the levels that are thought to result in a significant risk of harmful effects.

The risks associated with CT scan IV contrast injection are listed below:
Minor/Common risks:

- Bruising and/or infection at IV site
- Nausea & vomiting
- Urticaria (hives)
- Pruritis (itching)
- Diaphoresis (sweating)

Moderate/Uncommon risks

- Faintness
- Facial edema (swelling)
- Laryngeal edema (swelling of the airway in the throat)
- Bronchospasm (tightening of the airways in the chest)

Severe/Rare risks

- Pulmonary edema (fluid in the lungs)
- Respiratory arrest (loss of breathing)
- Cardiac arrest (loss of heartbeat)
- Seizures

The risks associated with MRI IV contrast injection are listed below:

Minor/Common risks:

- Bruising/infection at the IV site

Severe/Rare risks:

- Nephrogenic Systemic Fibrosis (NSF) (a disease involving stiffening of the skin, joints, and sometimes internal organs that can happen with patients with severe kidney disease)

Risks associated with MRI scans are as follows:

Minor/Common risks:

- Claustrophobia

A doctor will be present during each contrast-enhanced breast CT and MRI scan to monitor you for signs and symptoms of adverse reaction to the contrast injection.

Since this is a research study and this procedure is relatively new, there may be additional side effects which are not known or predictable at this time but which may occur at the time of the procedure or later. For more information about risks and side effects, ask the Investigator.

There may also be risks to your privacy. The Researchers will store study records and other information about you in a secure location and will grant access only to those with a need to know. However, just like with other personal information kept by your health care providers, your banks, and others, even these safeguards cannot guarantee absolute protection of the data. If private information gets into the wrong hands, it can cause harm. Although rare, there are reported cases of breaches that have resulted in discrimination in insurance or employment. For more information about risks and side effects, ask the Researcher.

Will my information be kept confidential?

We will do our best to make sure that your personal information will be kept confidential. However, we cannot guarantee total privacy. Your personal information may be released if required by law. If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government

agencies or other groups associated with the study. Designated University officials, including the Institutional Review Board, the Food & Drug Administration and the research sponsor have the authority to review research records. If information from the study is published or presented at scientific meetings, your name and other personal information will not be used.

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. If necessary for your care, this information will be provided to you or your physician.

It is important that you promptly tell the Researcher if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. You do not lose any legal rights by signing this form.

Will being in this study help me in any way?

You may not personally benefit from your participation in this study. We hope that this new Breast CT technique will benefit future women who need diagnostic imaging of the breast. Since the breast CT scanner has not been FDA approved, the images from your breast CT scan will not be released to you or your physician. These images may not be processed for several weeks. The results of your Breast CT scan will not affect your regular health care in any way.

The results of your Breast MRI scan will be evaluated by a Radiologist and will be entered in your medical record the same as if your doctor had ordered it as part of your regular care. Your doctor will have access to these results.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

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.

The CT scans of you collected for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. Your identity will not be

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recorded if your CT scans are re-used for other research. You will not share in any commercial value or profit derived from the use of your CT scans and/or information obtained from them.

This research has received a Certificate of Confidentiality from the Federal government that will help protect the privacy of the research records. The Certificate of Confidentiality allows the Researchers to refuse to disclose identifying information on your participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself and your involvement in this research. If you have given your consent for an insurer or employer to obtain information about you, the Researcher may not use the Certificate of Confidentiality to withhold this information. A Certificate of Confidentiality also does not prevent a Researcher from disclosing information about you to prevent serious harm to yourself or others, such as reporting to the authorities' incidents of child abuse, elder abuse or spousal abuse.

What else do I need to know?

This research is being funded by the U.S. National Institutes of Heath (NIH), also called the sponsor. Sponsors may change or be added.

There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department. You will not be paid for taking part in this study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

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