

UNIVERSITY OF CALIFORNIA LOS ANGELES CONSENT TO PARTICIPATE IN RESEARCH

NCT03202472

Pilot trial evaluating a miniature radiofrequency tag for localization of non-palpable breast lesions for surgery

INTRODUCTION

Maggie DiNome, MD and associates from the Departments of General Surgery and Radiology at the University of California, Los Angeles are conducting a research study.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because you have a breast lesion that cannot be felt on examination but requires surgery for removal.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate a new radiofrequency marker for localizing breast lesions. Currently, patients who have breast lesions that require surgery but are not able to be felt on examination need a wire placed on the morning of surgery that guides the surgeon toward the lesion in the breast. This is a standard procedure performed by the breast radiologists.

We are evaluating a new, FDA-approved radiofrequency tag that would take the place of the wire. The tag is not radioactive in any way and does not emit a signal. It is inactive. The LOCalizer probe used to locate the tag in the operating room emits the signal that then completes a circuit with the tag that allows for detection. This technology called radiofrequency identification (RFID) is already widely in use for microchipping pets. The primary benefit of the radiofrequency tag for our patients is that it resides entirely within the breast so that patients can go home with the marker in place, and there is no concern for dislodgment. The marker can be placed up to 30 days before surgery.

The following definitions may help you understand how this research study is designed: this is a non-randomized, single arm, open label study, which means that all study participants will undergo the same intervention and that the intervention will be known to you. It is a pilot study, which means that it is a preliminary exploratory study to assess the feasibility of using this new device.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the study:

Before you begin the study, you will need to sign an informed consent.

During the study:

By agreeing to participate, you have agreed to the placement of this new FDA-cleared device instead of a wire to localize your breast lesion for surgery. This will be arranged for a date within 30 days of surgery. The localization procedure for placement of the wire and the radiofrequency tag are similar. Both are performed by the breast radiologist in the Breast Imaging department. Your breast skin and tissue will be anesthetized with local anesthesia. The lesion and/or clip that was placed in the breast following your biopsy will be identified by either mammogram or ultrasound, and the radiofrequency tag will be placed under imaging guidance into the site. Unlike the wire, which resides partially outside of the breast, the tag is entirely within your breast (similar to the metallic clip that was placed after the biopsy). You are then discharged to home. You may drive yourself to and from the procedure. Separating this procedure from the surgery itself allows you to forego the requirement of not eating and drinking prior to the procedure, which should lead to less episodes of lightheadedness and fainting. In addition, you will not have to be transported from the imaging center to the surgery center outside in your gown on the morning of surgery.

Following your procedure, you will be asked to complete a brief questionnaire in a private room about your experience. This will help us to assess whether this is a suitable alternative to wire placement. You will then undergo your regular surgical procedure as planned, and then return for a follow-up post-operative visit.

If the RFID tag is not able to successfully guide removal of the intended lesion, you may need a second localization procedure with the wire and a second surgery. This would be considered a study failure.

HOW LONG WILL I BE IN THIS STUDY?

This study will last for 3 visits. The first visit is the localization procedure, which occurs within 30 days of surgery. The surgery is the second visit, and the third visit is the post-operative visit, which occurs ~5-7 days after surgery. The study will end for you after the post-operative visit.

This study is asking for permission to prospectively collect data from your medical record in a de-identified fashion. Data will be collected during these routine visits that would have occurred regardless of participation in this study. No additional research visits or procedures are required for this study.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:

The possible risks and/or discomforts associated with the procedures described in this consent form are mild and temporary. Patients may experience pain with the injection of the local anesthetic but once anesthetized, less than 10% of patients will experience pain during the remainder of the procedure. Bruising occurs more commonly in ~25% of patients but bleeding and infection occur < 1% of the time.

Localization procedure:

- Pain
- Bruising, bleeding
- Swelling
- Infection
- Lightheadedness, dizziness
- Clamminess, anxiety

Less common (< 1%) risks include:

- Implant rupture
- Lung puncture (pneumothorax)
- Migration of marker after placement
- Unsuccessful placement of marker

Unknown risks and discomforts:

The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:

You may or may not receive a benefit from participation in this study.

Possible benefits to others or society:

This study will help the researchers learn more about the radiofrequency tag and RFID technology. Hopefully this information will help in the treatment of future patients with breast lesions who also require localization and surgery.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, the following alternative procedures or courses of treatment are available: You will undergo the standard wire localization procedure and surgery as planned.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:

When you enroll in the study, you will be given a unique code. This code is put on all study materials. The key to connect you to the unique code is kept on a password protected computer in a private office with limited access. Only the Principal Investigator (PI) has access to the key with the codes to your personal information. It is necessary for someone to have access to your information so that we can continue to collect medical information.

How information about you will be stored:

Research results and stored data are kept confidential. They will not go into your medical record. They will not be given to you, your study doctor, or your insurance company. These results will not be released in a way that does not protect your identity.

People and agencies that will have access to your information:

The research team, authorized UCLA personnel, and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

There will be no additional cost to you or your health plan as a result of your participation in this study. Items and services described in this consent form would have occurred regardless of your participation in this study or, if research-related, will be provided to you at no cost.

WILL I BE PAID FOR MY PARTICIPATION?

You will not receive any compensation from your participation in this study. Participation in this study is voluntary.

Researcher Financial Interests in this Study

None

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 10889 Wilshire Blvd, Ste 830, Los Angeles, CA 90095-1406.

Public Information about this Study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on <http://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.

The National Cancer Institute (NCI) keeps a database about all the clinical trials it supports. The database helps NCI set priorities for clinical research. NCI requires us to

put information about this study in the database. We'll provide general information about how many subjects enroll in the trial and how the trial turns out. We also need to provide information about you as a subject. This includes information about your cancer, your study identification number, the month and year of your birth, as well as your gender, country of origin, race, ethnicity, and zip code. NCI limits access to this database and has many safeguards to help keep your information secure and confidential.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime prior to placement of the tag
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

SIGNATURE OF THE PARTICIPANT

Name of Participant

Signature of Participant

Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent

Contact Number

Signature of Person Obtaining Consent

Date