Official Title: A Randomized Single-Center Superiority Trial of Radioactive Seed Localization Versus Needle Localization for Malignant Breast Disease
IRB-Approved Date: 6/9/2015
NCT02522468

CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title: **Levine Cancer Institute, A Randomized Single-Center Superiority Trial of Radioactive Seed Localization versus Needle Localization for Malignant Breast Disease**

Protocol Number: **LCI-BRE-BCS-RSL-001**

Principal Investigator: (Study Doctor) **Lejla Hadzikadic Gusic, MD**

Telephone: [redacted] **(24 Hours)**
[redacted] **(24 Hours)**

Address: **Levine Cancer Institute**
[redacted]

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. Accordingly, when the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject rather than the person (legally authorized representative) who is signing this form for the subject. In cases where the subject's representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent should be completed and the subject offered the ability to leave the study if desired.

INTRODUCTION

Study doctor (Principal Investigator) and the study associates (the investigators/study staff) are asking you to participate in a research study at Levine Cancer Institute (LCI) and Carolinas HealthCare System (CHS) comparing radioactive seed localization (RSL) and wire-guided localization (WL) for breast conservation surgery. You are being asked to take part because you have a malignant breast lesion that you are planning to have removed by breast conservation therapy.

Taking part in this research study is entirely voluntary. Your study doctor will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You have also been told that you have the option not to participate. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

This study is being carried out under the sponsorship of Levine Cancer Institute (LCI).

WHY IS THIS STUDY BEING DONE?

This is a research study that is being completed to determine whether RSL is superior to WL for removal of breast lesions that require image-guided localization. We would like to compare the two localization procedures based on surgical outcome, cost, subject satisfaction, interdisciplinary doctor satisfaction, and other variables.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

You will be one of approximately 400 people involved in this research study at CHS. The length of your participation will depend upon your personal treatment and care. The study is expected to be open for approximately 5 years.

HOW THE STUDY WORKS

It is already recommended by your surgeon that you receive breast conservation surgery (BCS). Both RSL and WL are approved methods of localization for benign and malignant breast abnormalities that cannot be felt on physical exam but are apparent on imaging studies.

If you agree to be in the study, you will be randomized to one of two localization procedures. Being randomized means that you are put in a group by a chance process, like flipping a coin. In order to remove as much of the abnormality as possible from your breast, a radiologist will use mammogram, ultrasound, or MRI to insert a wire or radioactive seed (depending on which group you are randomized to) into the lesion. This is standard practice so that your surgeon can more easily locate the lesion in the operating room. Due to the nature of the surgery, you will be informed of which study procedure you have been randomized to. We are using this method to determine whether one study procedure is superior to the other. Your chance of being randomized to either study treatment is 50%.

At the time of placement of the wire or seed(s), you will be asked to complete a survey to indicate your pain level, anxiety level, and satisfaction with the study procedure.

Once the lesion has been removed, we will get opinions from the radiologist, surgeon, and pathologist regarding their satisfaction with the process. We will collect data about each study procedure, whether or not your breast abnormality was completely removed during surgery, whether or not you need to go back for re-excision, any complications that may have occurred at any point in the process, etc.

At your post-operative visit with your surgeon (approximately one week after surgery), you will be asked to complete another survey to indicate your satisfaction as a whole, your pain level, and your cosmetic outcome after surgery.

RISKS

This study has equivalent risks inherent to standard-of-care localization of palpable or non-palpable abnormalities in breast conservation surgery. The risks specific to each study group are as follows:

Wire localization group:

- The wire may move or become dislodged during transportation from radiology to the operating room
- The wire may break
- The wire may be difficult to place
- An additional wire may need to be placed due to any reason

Radioactive Seed Localization group:

Radiation exposure from the radioactive seed is a known risk. Safety studies have shown that the average radiation dose is similar to a 2-view mammogram.

Other risks to the RSL group include:

- The seed may move
- The seed may not be placed correctly on the first try
- The seed being moved during the removal
- The seed capsule may open
- If the seed is not retrieved or left in for more than 5 days

Other possible risks related to breast conservation surgery may include the following:

- Any difficulties for surgeon during the surgery
- Pain at the site
- Bruising at surgical site
- Breast tenderness
- Swelling and inflammation
- Bleeding
- Deformity at or in the biopsy area
- Infection

There may be additional risks that are unknown at this time. Please discuss any side effects you experience with your study doctor.

REPRODUCTIVE RISKS

You may not take part in this study if you are breastfeeding, are pregnant, think that you may be pregnant, or are trying to get pregnant. If you are pregnant or breastfeeding, there may be risks to you and the baby that are not known at this time.

WILL I BENEFIT FROM PARTICIPATING IN THIS STUDY?

You will receive no direct benefit from your participation in this project. However, your participation may help the study doctors determine the best way to treat health problems in the future.

Through this trial, we hope to determine whether or not radioactive seed localization is superior to wire-guided localization. Both methods have been proven effective in localization of breast abnormalities for surgical excision.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your alternative is to not participate in this study.

The standard procedure for localization of breast abnormalities at our institution is currently wire-guided localization. If you choose not to participate in this study, the recommended course of treatment would be wire-guided localization with subsequent breast conservation surgery. The study doctor will discuss the risks and benefits of other treatments with you.

STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

None of the study doctors asking you to participate in this study has received or will receive money or other benefits for personal use from the company that developed the localization treatment used in this study. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the study doctor or study staff is associated.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not receive payment for taking part in this study. For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this web site. Another way to get the information is to call [redacted] and ask them to send you a free copy.

You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

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

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

In the event that you are harmed because of your participation in this study, inform your study doctor immediately so you can access medical treatment. You and/or your health plan will be charged for this treatment in the usual manner. The study will not pay for standard medical treatment.

You still have the right to make a claim through the legal system even if you sign this form, accept medical care, or accept payment for medical expenses.

WHAT IF I WANT TO QUIT THE STUDY?

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, your decision to not participate will not in any way harm your relationship with your study doctors or with Carolinas HealthCare System (CHS). You are free to stop being in the study if you change your mind after entering it. This would not harm your relationship with your study doctors or CHS. Information contributed to the study will remain in the study even if you choose to withdraw. If you choose to withdraw from the study, please notify the study doctor in writing at the address on page 1.

There will be no penalty or loss of benefits to you if you decide not to be in the study or to withdraw from the study.

The study doctor may choose to involuntarily withdraw you from the study for any reason.

If you wish to withdraw after randomization and have undergone placement of a radioactive seed, you must still undergo radioactive seed removal.

NEW INFORMATION

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

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Your record for this study may, however, be reviewed and/or photocopied by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other regulatory/governmental agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location. Your privacy is very important to us and we will use multiple safety measures to protect your privacy. However, in spite of all the safety measures that we will use, we cannot guarantee that your identity will never become known.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Carolinas HealthCare System (CHS)
- Levine Cancer Institute (LCI)
- Government and/or other regulatory agencies, like the Food and Drug Administration (FDA) that are involved in keeping research safe for people

A description of this clinical trial will be available on 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.

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor (LCI) and the study doctor to collect and process any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

Throughout study participation, data from your medical record will be collected, including but not limited to tumor characteristics, subject demographics, surgical parameters, and longitudinal follow-up data. This data will not be shared outside the study staff unless required by law. In the instance that this data is published, it will only be published about the overall cohort; all personal information will be de-identified.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the study doctor, study colleagues in the Breast Surgery Clinic at Levine Cancer Institute and research staff
- regulatory or other governmental authorities of the United States and other countries
- Carolinas HealthCare System employees
- other persons or agencies as required by law or allowed by federal regulations

You have been told that your personal data is being collected and processed to:

- check your suitability to take part in the study
- monitor activity with the treatment under study
- compare results with those of other subjects in the study
- support the development of other study protocols

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you will be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At the conclusion of the study, your research record will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed, it will be kept confidential and secure to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study sponsor - study doctor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain until the study is terminated. If you wish to revoke authorization to use your personal information, you will notify the study doctor in writing at the address on page 1.

Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study or at any time during the study). Questions may include:

- Who to contact in the case of a research-related injury or illness.
- Any payment for being in the study.
- Your rights and your responsibilities as a study subject.
- Other questions.

Contact the study doctor or study staff at Carolinas HealthCare System with any questions or concerns. Their telephone number is printed on the first page of this form. If you have any questions or complaints about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00012559.

CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form. The study doctor, one of the study associates, or their study designee, will give me a copy of this signed and dated form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

_____ ____/____/____ _____
Signature of Legally Authorized Representative (if applicable) Date Time

_____
Printed Name of Legally Authorized Representative (if applicable)

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent