THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Assessment of Outcomes Following Prophylactic Lymph Node Transfer in Patients Undergoing Autologous Breast Reconstruction
2018-0528

Subtitle:

Study Chair: Edward I. Chang

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to learn if performing a vascularized lymph node transfer (VLNT) at the time of breast reconstruction surgery can lower the risk of arm swelling (lymphedema) in patients with breast cancer.

Researchers want to find ways to lower the risk of lymphedema in those patients who are at high risk of developing it after their breast removal surgery.

The VLNT procedure involves transferring lymph node(s) from an unaffected area in your body to replace those removed as part of treatment. It is usually done after a diagnosis of lymphedema.

This is an investigational study the ICG dye that is injected is FDA approved for human use. Performing a VLNT with the goal of lowering the amount of future swelling is being done for research purposes only.

The VLNT procedure may lower the risk of future swelling. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects and time commitment. It is possible you may never develop lymphedema even without the surgery. The surgery may not have very much benefit for you.
You can read a list of potential side effects below in the Possible Risks section of this consent.

Your participation on this study will be over after you complete the visit 2 years after your surgery.

There will be no additional cost to you to take part in this study. You and/or your insurance provider will be responsible for the cost of your surgery.

You may choose not to take part in this study. You may choose to have your lymph node surgery without taking part in this study. You may choose to receive other investigational therapy, if available. You may choose not to have treatment at all. In all cases, you will receive appropriate medical care.

1. STUDY DETAILS

Screening
If you can become pregnant, the results of your most recent standard-of-care pregnancy test will have been checked. To take part in this study, you cannot be pregnant.

Baseline Procedures
If you agree to take part in this study, the size of your arms will be measured during a routine clinic visit before your surgery. It should take about 10 minutes to complete.

Up to 30 participants will be enrolled in this study. All will take part at MD Anderson.

Surgery
You will be scheduled for your breast reconstructive surgery as part of your standard care. During the surgery, a dye (contrast drugs) will be injected into your foot to help the doctors to see the lymph nodes and know which lymph nodes to remove and which to avoid. You will sign a separate consent form that explains the surgery in more detail, including its risks.

For the VLNT, lymph node(s) with a blood supply from an artery and a vein will be surgically moved from an unaffected area in your body to replace those removed as part of treatment. The lymph node(s) are part of the tissue flap used to reconstruct the breast and if the doctor thinks it is needed, may be surgically attached to the breast area to help improve lymph drainage.

The study procedures should not increase the length of time your surgery takes, or change your recovery from surgery.

There are no alternative options that exist in terms of performing an operation to reduce their risks of lymphedema when patients present for breast reconstruction with high risk factors for developing lymphedema.

Before surgery, you will also have routine care as recommended by your doctor, such as imaging to check for lymphedema.

Follow-up
After your surgery, you will have follow-up visits as part of your standard care. These visits will be at about 2 weeks after surgery and then at 3 and 6 months and then 1 and 2 years after your surgery. At each visit, both arms will be measured as they were before your surgery.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with your study doctor. The known side effect are listed on this form but they will vary from person to person.

VLNT may rarely cause an abnormal collection of fluid at the area of the breast surgery. A pocket of fluid may develop in the area, which may be related to the surgery and/or the VLNT. Although VLNT is being given to see if it can prevent lymphedema in the area of the breast surgery, it is possible that VLNT may cause lymphedema in that area.

Contrast drugs may cause a feeling of warmth or pain at the injection site. They may cause nausea, vomiting, headache, dizziness, and/or heart of kidney complications. They may cause hypersensitivity reactions which may cause breathing and/or skin problems (rash, redness, blisters, itching, and/or local swelling) and may appear either immediately or up to a few days after the injection. It may cause water to collect in the lungs and/or anaphylactic shock (a severe allergic reaction that can cause breathing difficulty and/or a drop in blood pressure). It may cause changes in the way you move or changes in your senses.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a loss of confidentiality. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Edward I. Chang, at 713-794-1247) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your

consent at any time by the study chair, U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Your personal information is being collected as part of this study. This information, or data, may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information

   Individuals who put all the study information together in report form Only the study chair and collaborator(s) will be participating in the collection and analysis of data. If PHI is collected, it will not be disclosed to any other person or entity for other research without IRB approval. Data will be strictly stored only on password-

protected, institutional computers and servers behind the MD Anderson firewall and accessible only to the study doctor and collaborator(s). Participants will be identified by their medical record numbers in order to collect data for study-releated research, but these identifiers will be kept separate from the data collection form. Data will be stored indefinitely as a research project created within REDCap for future use only in IRB-approved research.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

•

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2018-0528.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION