Intraoperative evaluation of axillary lymphatics for breast cancer patients undergoing axillary surgery

NCT05094102

IRB Approval Date: 12/5/2022
University of Wisconsin – Madison

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: Intraoperative evaluation of axillary lymphatics for breast cancer patients undergoing axillary surgery

Lead Researcher: Heather B. Neuman, MD, MS.

Where Lead Researcher works: University of Wisconsin School of Medicine and Public Health

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Invitation

We invite you to take part in a research study about how to better see lymph nodes and lymphatic channels under your arm during breast cancer treatment surgery. We are inviting you to participate because you have been diagnosed with breast cancer and will be undergoing an axillary lymph node surgery related to your breast cancer.

The purpose of this consent and authorization form is to give you the information you need to decide whether you'd like to be in the study. It also explains how health information will be used for this study, and requests your authorization (permission) to use your health information. Please ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all of your questions, you can decide whether or not you'd like to participate in this study. This process is called "informed consent."

Why are researchers doing this study?

The purpose of this research study is to assess the feasibility of using fluorescence imaging through the Asimov Imaging Platform to perform "axillary reverse mapping" (ARM). Axillary reverse mapping is a way for your surgeon to see the lymphatic channels that travel from your arm. Saving those lymphatics may decrease your risk of developing lymphedema – or arm swelling – after surgery. Most surgeons use blue dye to guide axillary reverse mapping. Although the use of fluorescence imaging for axillary reverse mapping has been described in research studies, there are limitations with the currently available fluorescence-imaging platforms that make them difficult to use for this purpose. We are doing this research to test the feasibility of a new technology

platform (Asimov Imaging) that we think will address some of the limitations of prior techniques and improve our ability to perform axillary reverse mapping.

This study is being done at the University of Wisconsin-Madison (UW-Madison). Approximately 25 people will participate.

Funding for the Asimov Imaging Platform for this study is provided by the National Cancer Institute. The medical device company OnLume is providing the device to be used during this study.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to sign and date this consent form. If you do not sign this consent form, you will continue to receive care, but not as part of this study.

In this study, Dr. Neuman will perform axillary reverse mapping with isosulfan blue dye using standard procedures. This involves injecting the blue dye in the upper arm; the dye then will track into the lymphatic channels to mark where the lymphatic channels are that are draining the arm. Dr. Neuman will look for these lymphatic channels during surgery and try to save them, if possible. Dr. Neuman will make decisions during surgery using information from the blue dye alone. For patients who are also undergoing the sentinel lymph node biopsy for their cancer, the mapping of the breast lymphatics will be performed with the radioactive protein (technetium TC 99M sulfur colloid) alone; no blue dye would be used to map the lymphatics draining the breast.

For this research, Dr. Neuman will also use indocyanine green (ICG) fluorescence dye during your surgery. She will inject the ICG fluorescence dye in the upper arm in the same location as the isosulfan blue dye as well as between your fingers. She will then image the axilla with the Asimov Imaging Platform to look for the lymphatics draining the arm. Dr. Neuman will collect information about whether the lymphatic channels draining from the arm were able to be seen, and whether they were seen by blue dye or the ICG fluorescence dye (or both or neither). She will also collect information related to the ICG fluorescence and the Asimov Imaging Platform.

Demographic data (such as age and race), information about your tumor, and any later axillary surgeries or complications will also be collected from your medical record up to 1 year after your surgery.

Adding the ICG-fluorescence with the Asimov Imaging Platform may extend the length of your surgery by up to 20 minutes.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, such as your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results from tests or procedures done as part of the study.
- Things you tell the researchers about your health.
- Information currently in your medical record as well as information added to your medical record during the course of this study. This information could include demographics (such as age and race), type of axillary surgery, cancer stage and receptor status, and prior cancer treatments. Operative data will also be collected, such as the number of lymph nodes removed and whether the lymph nodes were radioactive, blue, or fluorescent.

How long will I be in this study?

Your active participation in the study will take place on one day (the day of your lymph node surgery). However, researchers may review your chart for up to 1 year after surgery.

How is being in this study different from my regular health care?

- People with breast cancer usually have axillary surgery as part of the cancer treatment. Axillary reverse mapping is a technique used by breast surgeons as a way to potentially decrease the risk of lymphedema resulting from the axillary surgery. It is most commonly used for patients undergoing an axillary lymph node dissection. The mapping is most commonly performed using blue dye (such as isosulfan blue).
- In this study, patients will undergo either an axillary lymph node dissection or a sentinel lymph node biopsy per their surgeon's recommendations. Patients will also undergo the axillary reverse mapping procedure. Axillary reverse mapping would be performed with both blue dye and ICG-fluorescence during the surgery.
- If you take part in this study, the main difference between your regular care and the study is that the axillary reverse mapping procedure would definitely be performed. This procedure is performed sometimes in regular care. The other difference is that the axillary reverse mapping would be performed with both blue dye and ICG-fluorescence (most commonly done at the UW using just the blue dye). The Asimov Imaging Platform will be used to distinguish the arm vs. breast draining lymph nodes.
- Using the indocyanine green (ICG) fluorescence with the Asimov Imaging Platform may lengthen your surgery by less than 20 minutes.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with your healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is complete. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the study.
- If you take back your authorization, information that was already collected may still be used and shared with others; however, the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study. To take back your authorization, you will need to tell the Lead Researcher by writing to, Heather B. Neuman, K6/142 CSC, 600 Highland Ave, Madison, WI 53792-7375.

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get care for your breast cancer. If you decide not take part in the study, you have other choices. For example, you may choose to get the regular care described above for breast cancer.

Will being in this study help me in any way?

You are unlikely to benefit directly from participation in this study. However, your participation may help other people in the future by helping us learn more about how to best perform axillary surgery to decrease the risk of lymphedema.

Will I receive the results of research tests?

Information related to the ICG imaging is being collected for research purposes only and no imaging findings from the ICG fluorescence are being used to make clinical

decisions. Because the imaging can only visualize the lymphatics, it is unlikely that there will be any unexpected findings. Dr. Neuman will describe whether the lymphatics draining the arm were visible during the surgery upon your request.

What are the risks?

There is a risk that your information could become known to someone not involved in this study. There is a very small risk of an allergic reaction (1 in 42,000 people) to the ICG-fluorescent dye. An allergic reaction could range from something as small as hives to cough or difficulty swallowing. If you were to develop an allergic reaction, you would be treated with medicines in the operating room. Using the indocyanine green (ICG) fluorescence with the Asimov Imaging Platform may lengthen your surgery by less than 20 minutes. Extension of the operation and the anesthesia represents no foreseeable risk to your health.

Will being in this study cost me anything?

- There will be no cost to you for any of the study activities or procedures.
- You or your insurance company will have to pay for all costs for medical care related to your treatment for your breast cancer, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.

Will I be paid or receive anything for being in this study?

- We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.
- Researchers may develop products from the information you provide for this study. Some of these products may have commercial value. If the research team or others use your information to develop products of commercial value, you will not receive any profits from products created from your samples or information.
- A member of this research team has a personal interest in or might profit financially from the results of this study. This is called a “conflict of interest.” The University of Wisconsin-Madison manages conflicts of interest so that they do not affect study participants or the quality of the data collected. We are telling you about the conflict of interest in case it affects whether you want to take part in this study.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services – as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact the UW Breast Center.
- Call the Lead Researcher, Dr. Heather Neuman, at 608-266-6400 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

The study has a Certificate of Confidentiality from the National Institutes of Health (NIH). A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and the National Cancer Institute responsible for monitoring this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health

information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

Members of the research team

Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

U.S. Office for Human Research Protections

The study sponsor, National Cancer Institute

Collaborating researchers outside UW-Madison, including researchers at OnLume, Inc.

OnLume Inc. will receive participant data that is collected through the Asimov Imaging Platform.

The U. S. Food and Drug Administration (FDA)

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.

Will information from this study go in my medical record?

Some of the information we collect for this study will go in your medical record. This includes a description of the operative procedure in the medical record; this operative procedure will also state that you participated in the research study. Both you and your UW Health providers will be able to see these results. No imaging pictures will be added to your medical record.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Dr. Heather B. Neuman, at 608-262-2025. If you have any questions about your rights as a research subject or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____
_____ Printed Name of Research Participant

_____
Signature of Research Participant Date

_____
Signature of Person Obtaining Consent and Authorization Date

****You will receive a copy of this form****