RESEARCH CONSENT FORM

Basic Information

Title of Project: Monitoring and Predicting Breast Cancer Neoadjuvant Chemotherapy Response Using Diffuse Optical Spectroscopic Imaging (DOSI)

IRB Number: H-33188 **NCT02510456**

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Background

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family. The National Cancer Institute (NCI) booklet "Taking Part in Clinical Trials: What Cancer Patients Need to Know" is available from your treating doctor.

You are being asked to be in this research study because you have breast cancer. We want to test the effectiveness of an experimental imaging method known as Diffuse Optical Spectroscopy Imaging (DOSI) in predicting the success of chemotherapy treatment (shrinkage of tumor). The DOSI device, which has no known side effects, uses laser beams or LED lights, which do not contain x-rays. Experimental imaging devices are being developed to monitor and predict breast cancer response to chemotherapy, both before and as early as possible during the course of treatment. It will be compared to other standard of care imaging techniques usually taken during the treatment.

DOSI is relatively simple to perform and interpret compared to other imaging methods. Because it is smaller and more portable, DOSI can be administered in the clinic, rather than going to the Radiology Department. You will not have a direct benefit from being in this study, but will be contributing to the knowledge that may benefit future breast cancer patients.

All participants in this research study will undergo DOSI scanning with a wearable probe. More detail about this process is available later in this form.

Your doctor is also an investigator of this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

Purpose

We are conducting this study to evaluate the usefulness of imaging using an investigational experimental device in determining patient response to chemotherapy (shrinkage of tumor) and thus determining success of chemotherapy treatment in individual breast cancer patients.

What Happens In This Research Study
We expect about 37 subjects to participate in this research study at the time points outlined below. The research will take place at Boston Medical Center.

Before you begin the study
You will need the following exams, tests or procedures to find out if you can participate in this study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Physical examinations and medical history
- Vital signs (temperature, blood pressure, heart rate and blood oxygen level)
- Pregnancy test (standard for all women of childbearing potential undergoing chemotherapy)

Study Plan
If you agree to take part in this study, you will have up to four (4) DOSI measurements at up to four (4) different time points during the course of your standard treatment. A measurement includes the scanning of the affected breast as well as the opposite breast for comparison. Both the affected breast and the opposite breast will be measured with a separate probe. The probe is flexible and bends to adapt to the natural curve of the breast and will be kept in place with a transparent dressing. You will be able to wear clothes or a hospital gown after the probes are in place. Below are the 4 potential DOSI time points:

DOSI 1: Baseline and Drug Infusion Time point
One DOSI measurement will be performed at least two weeks after your standard biopsy and within two weeks before you start your first standard chemotherapy cycle. This measurement will take about 30-60 minutes.

DOSI 2: Early-Therapy Time points
During early-therapy you will have up to two DOSI measurements within the first 10 days of starting your first standard chemotherapy cycle. These DOSI measurements will typically take place at days 1, and 2 after infusion. Early-therapy time points are adjustable based on your availability and ongoing analysis.

DOSI 3: Mid-Therapy Time point
A mid-therapy DOSI measurement will take place, and will be scheduled based on your ongoing standard treatment plan.

DOSI 4: Post-Therapy Time point
The post-therapy DOSI measurement will be performed after you finish your last cycle of standard chemotherapy.

What happens in the scanning?
You will be scanned in a private area in the oncology clinic. Upon your consent you will be asked a question to determine your skin type. You will be scanned by a research associate trained for this study. Only the research associate will have physical contacts with you for this study. A transparency film will

be placed on your affected breast and the research associate will use a surgical marker on the film to mark the proposed scanning points around the area of your tumor using your nipple as a landmark. The markings will then be transferred from the film onto your breast and used to mark the location of the scanning probe. A similar mapping will be done on the opposite breast for comparison. The same master grids will be used at each visit. The surgical marks on the breasts can be removed by using an alcohol wipe and/or soap and water after each visit.

Each measurement will start with an initial period of up to 5 minutes, during which you will breathe normally. Then, you will do "paced breathing" where you 1) inhale for 3-15 seconds, 2) hold your breath for up to 20 seconds, and then 3) exhale for 3-15 seconds. The paced breathing steps will be repeated up to 20 times, followed by a recovery period with natural breathing for about 5 minutes. A single DOSI measurement, which includes placement of the probes and the paced breathing measurements, is expected to take from 30-60 minutes.

At the time of the scanning, there will be present a second operator, a graduate student of Biomedical Engineering associated with this study, to run the device laptop during scanning. The second operator will have all the necessary trainings required for studying and doing human research. If you request, a curtain will be used to separate the second operator from the scanning location.

Will I know my results?
NeoDOSI study results will not be shared with you or your treating doctor. Your treating doctors will have access only to standard of care imaging results taken during study. As DOSI remains investigational, these early imaging results are not yet fully understood. The DOSI imaging results should not and will not change your treatment course and will not be part of your medical record.

How long will I be in the study?
Your participation in this study will last throughout the course of your chemotherapy treatment and is predicted to take between 3-9 months, depending upon the length of your planned cancer treatment. Your direct participation will consist of a screening visit for confirming your eligibility for this study and in total up to 6 visits for DOSI measurement time points.

Can I stop being in the study?
Yes. You can decide to stop at any time. Tell the study doctor, Dr. Naomi Ko if you are thinking about stopping or decide to stop. She will help about through the stopping process. It is important to tell the study doctor if you are thinking about stopping so any risks from associated with this study can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you. The study doctor may stop you from taking part in this study at any time if she believes it is not in your best interest; if you do not follow the study rules; or if the study is stopped.

Risks and Discomforts
There are no known side effects from the use of DOSI. Each of the DOSI measurements will take about 30-60 minutes of your time depending on the number and size of the locations imaged. Tape remover spray will be applied to help remove the tape from your skin. The smell could be unpleasant although the solvent is skin safe.

There is a small possibility that two of the visits may not coincide with a clinically scheduled visits, thus requiring two visits solely for the research which may have associated costs for parking or travel. However the study will pay for this additional cost in the form of Stop & Shop gift cards.

There is always a risk of release of information from your health records. We will protect your records so that your name, address, and phone number will be kept confidential. Only the investigators and the project manager will have access to your identifiable information.

Reproductive risks:
It is unknown if the investigational DOSI scan can affect an unborn baby

There is always a risk of release of information from your health records. We will protect your records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

What are my responsibilities?

- Keep your study appointments. If you cannot keep an appointment, contact your study doctor or study staff to reschedule as soon as you know that you will miss the appointment.
- Tell your study doctor if you have been in a research study in the last 30 days or are in another research study now. While participating in this research study, you should not take part in any other research project without approval from your study doctor. This is to protect you from possible injury arising from such things as extra drawing of blood samples, possible reaction between research drugs, or other hazards.

Potential Benefits
This is not a treatment study and you will not receive any medical benefits from your participation in this imaging study. The information learned from this study may lead to a better identification of treatment response to chemotherapy in future for patients with breast cancer.

Alternatives
You may choose not to participate in this research study.

Subject Costs and Payments
All the DOSI sessions are free of charge for this study. There will be no charges to you for any visits or tests related solely to the imaging research study. You or your insurance will be billed for any treatments or procedures that are a part of the standard of care for your cancer (these are the costs that you would have whether or not you participated in this research study).

You will receive a $25 Stop & Shop gift card for each visit and will be paid at the completion of each visit. There will be no other reimbursements. If you withdraw from the study, you will be paid only for the number of visits you made.

Confidentiality
We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who see your medical records. Please ask us if you have any questions about what information will be included in your medical records.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information

The people and groups that may use or share your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research

- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study.

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org.

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep. If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Campus and Boston Medical Center at 617-358-5372. The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact Naomi Ko, MD at (617) 638-8265 during the day and the on-call Oncologist via the hospital's page operator at (617) 6387423 after hours.

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such

as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Where Can I Get More Information?

For any concerns or questions please contact the following persons:

Study Contacts

Naomi Ko, MD, Co-Investigator Phone:
617-638-8265

Darren Roblyer, PhD, Co-Investigator
roblyer@bu.edu
Phone: 617-358-1554

Elizabeth Pottier, Research Associate
Elizabeth.Pottier@bmc.org
Phone: 617-638-8260

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.

SIGNATURES

Subject: _____

Printed name of subject

By signing this consent form, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study and authorize the use and release of your Protected Health Information.

_____ _____
Signature of subject Date

Researcher: _____

Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that s/he understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

To be completed by **witness** if researcher reads this form to the subject

This consent form was read to and apparently understood by the subject in my presence.

_____
Printed name of witness (a person not otherwise associated with the study)

_____ _____
Signature of witness Date