THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent/Authorization for Participation in Research

TITLE: Vapocoolant Analgesia for Breast Scintigraphy

PROTOCOL NO: 2022-0454

INVESTIGATOR: Sanjit Tewari

STUDY-RELATED PHONE NUMBER(S): 832-729-1874
713-792-2121 (24 Hours)

_____ _____
Participant's Name Medical Record Number

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you are scheduled to have a routine breast scintigraphy scan with Technetium (Tc-99m sestamibi) at MD Anderson.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

A breast scintigraphy scan involves an injection in the breast with a small amount of radioactive imaging agent such as Tc-99m sestamibi. This injection is often described

as being painful and can cause anxiety in patients because typically no form of anesthesia or numbing medications are given before the injection.

The goal of this research study is to learn if applying vapocoolant anesthetic spray ("Nüm") on the surface of the intended injection site will reduce the pain/anxiety associated with breast injections.

Nüm is FDA approved and commercially available as a vapocoolant anesthetic spray (a spray that cools and numbs the skin) to control pain during minor surgical procedures (such as lancing boils, incisions, injections and IV placements) and minor sport injuries. The doctor can explain how Nüm is designed to work.

How long will the research last and what will I need to do?

As part of this study, Nüm will be used on your skin before your injection of Tc-99m during your standard-of-care breast scintigraphy scan. After that, you will complete a questionnaire. Your active participation in the study will be over after the questionnaire is done. Your medical records will continue to be reviewed for 6 months.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

Before choosing to take part in this study, you should discuss with the study investigator any concerns you may have, including side effects.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no guaranteed benefits to you from taking part in this research. However, receiving Nüm may lessen your feelings of pain, discomfort, and/or anxiety before and during the scintigraphy scan. Future patients may benefit from what is learned.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of being in this research study, you may choose to receive a standard of care breast scintigraphy scan without Nüm. Your alternative to participating in this research study is to not participate.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 832-729-1874.

This research has been reviewed and approved by an Institutional Review Board (IRB - an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected that about 200 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

If you agree to take part in this study, your breast (or the area that will receive the injection of Tc-99m) will be sprayed with Nüm (the vapocoolant) for about 4-6 seconds. Nüm should cool and numb the area before the injection. After Nüm is applied, you will receive your injection of Tc-99m sestamibi and have your scintigraphy scan.

After the scan, you will complete a quick questionnaire about your feelings of pain. This should take less than 1 minute to complete.

Your breast surgeon may choose to perform routine follow-up tests/procedures at future clinical visits, but this will be done as part of your standard care.

Information from your medical record, such as your treatment diagnosis, information about follow-up visits, imaging scans, and follow-up results, will be collected for research purposes. Identifiers (such as your name, medical record number, and date of birth) will be collected, but will be replaced with a code so that you cannot be linked to the data. Data will be stored on institutionally approved and protected databases.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

Nüm may cause skin irritation, redness, itching, burning, and/or discoloration.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

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.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

Nüm will be provided at no cost to you. You and/or your insurance provider will be responsible for the cost of your standard of care T-99m injection and breast scintigraphy scan.

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 health care plan 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 health care plan 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 health care plan 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.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data or samples be used future research?

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

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- call the study doctor (Dr. Sanjit Tewari, at 832-729-1874)

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson 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.

What else do I need to know?

This research is being funded by Gilero, LLC.

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

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

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

A. During the course of this study, MD Anderson and the Harris Health System 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

   - Gilero, LLC., who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology

- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

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 by sending or faxing your request in writing. For MD Anderson participants, instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP). You may contact the Chief Privacy Officer of MD Anderson at 713-745-6636 with questions about how to find the NPP. 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.

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 researcher 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 this protocol.

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

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
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.)