19-008929

Cryotherapy to Prevent Taxane-induced Sensory Neuropathy of the Hands and Feet

NCT04256512

Document Date: 01/05/2022

MAYO CLINIC

Name and Clinic Number

Approval Date: **January 5, 2022**
Not to be used after: **January 4, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Cryotherapy to prevent taxane-induced sensory neuropathy of the hands and feet

IRB#: 19-008929

Principal Investigator: Pooja Advani, MD, and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research study is to investigate the effectiveness and tolerability of cryotherapy and to evaluate whether they can prevent or improve taxane-induced sensory peripheral neuropathy. You have been asked to take part in this research because you have been diagnosed with breast cancer and are about to begin 12-18 weeks of chemotherapy with a taxane-based regimen.
What's Involved	If you choose to participate in this study, you will be provided with one set of Elasto Gel® frozen mittens and foot wraps prior to your first chemotherapy infusion. These will be worn on both hands and feet at each chemotherapy infusion during your 12-18 weeks of treatment.

	Study participation also involves assessment of peripheral neuropathy, physical functioning, and quality of life prior to the initiation of taxane-based chemotherapy, immediately after completion of taxane-based chemotherapy, and again at 3 months following completion of chemotherapy.
Key Information	There are no costs to you for being in the study. The risks of this study are minor and include painful digits, cold intolerance, frostbite and ulceration of the digits. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. While our study is research and not guaranteed to offer help, you may benefit from the treatment if it works.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

MAYO CLINIC

Name and Clinic Number

Approval Date: **January 5, 2022**
Not to be used after: **January 4, 2023**

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Pooja Advani, MD **Phone:** (904) 953-7291 **Study Team Contact:** Ivy Vilches **Phone:** (904) 953-7844 **Institution Name and Address:** Mayo Clinic Florida 4500 San Pablo Road Jacksonville FL 32224
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

A description of this research study will be available on https://www.mayo.edu/research/clinical-trials. This website will not include information that can identify you. You can search this website at any time.

Why are you being asked to take part in this research study?

You have been asked to take part in this research because you have been diagnosed with breast cancer and are about to begin 12-18 weeks of chemotherapy with a taxane-based regimen.

The plan is to have 100 people take part in this study at Mayo Clinic Florida.

Why is this research study being done?

Peripheral neuropathy (PN) is weakness, numbness, and pain from nerve damage, usually in the hands and feet. Some chemotherapy drugs can cause peripheral neuropathy, which is called chemotherapy induced peripheral neuropathy (CIPN). CIPN occurs in approximately 25-35% of patients treated with chemotherapy, most notably with taxanes which are a standard chemotherapy option for treatment of breast cancer. While mild neuropathy tends to improve after completion of chemotherapy, many patients, especially those with moderate to severe CIPN, can have prolonged symptoms causing pain and limiting function including vocation.

Cryotherapy has been found to have promising results in minimizing the incidence and severity of peripheral neuropathy in patients undergoing chemotherapy. This research study is being done to investigate the effectiveness and tolerability of cryotherapy (Elasto Gel® frozen mittens and foot wraps) and to evaluate whether they can prevent or improve taxane-induced sensory peripheral neuropathy.

Information you should know

Who is Funding the Study?
Mayo Clinic is funding this study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in this study for about eight months. We will collect study-related data during your standard of care visits at three separate time points while you are enrolled in this study.

What will happen to you while you are in this research study?

If you agree to be in this study, you will be asked to answer questionnaires about your quality of life and symptoms of CIPN, and we will measure physical function, balance, and fall risk. We will also conduct monofilament sensory testing. Monofilament is a portable strand made of nylon which is used to check sensation in the limbs to assess damage to the nerve endings. These questionnaires and assessments will take about 30 minutes to complete and will be completed at three separate times throughout your participation in the study. The first time point will be during your standard of care chemotherapy education appointment prior to the start of your first chemotherapy infusion. The second time point will be during your standard of care end of chemotherapy visit with your medical oncologist. The third time point will be approximately three months after the completion of your chemotherapy regimen during your standard of care visit with your medical oncologist.

	Pre-chemo MD visit	Chemotherapy Education Appointment	End of Chemo MD visit	3 months post-chemo MD visit
Consent	x	x*		
FACT-G questionnaire		x	x	x
FACT/GOG-NTX questionnaire		x	x	x
CIPN-R-ODS		x	x	x
Timed Up and Go Test		x	x	x
Data entry		x	x	x

*If not collected during pre-chemo visit with MD

You will be provided with one set of Elasto Gel® frozen mittens and foot wraps prior to your first chemotherapy infusion. These will be worn on both hands and feet at each chemotherapy infusion during your 12-18 weeks of treatment. You will start wearing the mittens and foot wraps 15 minutes prior to each infusion, during the entire infusion, and for 15 minutes after the completion of each infusion. The research coordinator will record the time that the mittens and foot wraps are applied and the time they are removed for each infusion, and document any time and circumstances in which the mittens and/or foot wraps had to be removed.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance

What are the possible risks or discomforts from being in this research study?

Your doctor will discuss the risks of your chemotherapy as these tests and procedures are part of your standard clinical care. The risks of cryotherapy may include painful digits, cold intolerance, frostbite and ulceration of the digits.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator (PI) if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may not make your health better. However, it may prevent or improve taxane-induced sensory peripheral neuropathy, in turn providing better physical function and higher quality of life.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Questionnaires
- Physical function measurements
- Monofilament sensory testing
- Cryotherapy mittens and foot wraps

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- MD visits
- Chemo Education Visit
- Chemotherapy infusions

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

Will your information or samples be used for future research?

Your information collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Surveys and other study data will be collected and inputted into a password protected database. Only research staff designated by the PI will have access to the data. Hardcopy data will be kept in locked filing cabinets within secured department areas. All study data will be entered by a staff member designated by the PI.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

MAYO CLINIC

Name and Clinic Number

Approval Date: **January 5, 2022**
Not to be used after: **January 4, 2023**

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

MAYO CLINIC

Name and Clinic Number

Approval Date: **January 5, 2022**
Not to be used after: **January 4, 2023**

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature