Feasibility Study for Electroacupuncture for Chemotherapy- Induced Peripheral Neuropathy (CIPN) Using a Point-Of-Nerve Conduction Device (NeuroMetrix) and the Rydel-Seiffer Tuning Fork

NCT04092764

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CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Study Title:	**Feasibility study for Electroacupuncture for chemotherapy-induced peripheral neuropathy (CIPN) using a point-of-nerve conduction device (NeuroMetrix) and the Rydel-Seiffer tuning fork**
Protocol Number:	**MCC 20022**
Sponsor:	**Moffitt Cancer Center**
Principal Investigator: **(Study Doctor)**	**Hye Sook Chon, MD** **Andrea L Buras, MD** **Robert Wenham, MD, MS**
Telephone: **(24 hour number)**	**813-745-7205** **800-456-3434**
Address:	**Department of Gynecologic Oncology** **Moffitt Cancer Center** **12902 Magnolia Drive** **Tampa, FL 33612**

You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate.

The purpose of the study is to determine the validity of a point-of-care nerve conduction device (NeuroMetrix) and Rydel-Seiffer tuning fork in assessing the level of peripheral neuropathy in patients with chemotherapy-induced peripheral neuropathy (CIPN). Chemotherapy-induced peripheral neuropathy (CIPN) is a common, persistent toxicity among patients who receive chemotherapy. It is characterized by a variety of sensory and motor symptoms such as numbness, tingling, reduced sense of touch, reduced proprioception (awareness of your limb and body position in space), pain, weakness, balance disturbances, and deficits in motor skills. Studies have reported a positive effect of acupuncture on CIPN.

Your participation in the study will require a total of 5 session(s) including a screening visit, 3 electroacupuncture treatments and 1 follow up visit. The screening and follow up visit will last approximately 45 minutes. The 3 electroacupuncture treatments will each last approximately 30 minutes and will take place once a week for 3 weeks. During the acupuncture treatments, needles will be placed in the webs of your toes, on the top of your foot, and the sole of your foot, for a total of 12 needles. The devices used in this study have been tested in humans and are not investigational.

You are being asked to take part in this study because you have received treatment with a taxane or platinum chemotherapy agent at least 3 months ago, and since receiving the treatment, you have been experiencing numbness, tingling, loss of deep tendon reflexes, or other symptoms in your lower extremities that were absent prior to treatment with

chemotherapy.

About 6 subjects will participate in this study.

Your participation is voluntary, and you may stop your participation at any time. There will be no penalties or loss of benefits or opportunities, if you do not participate or decide to stop once you start. Since this is not a treatment study, your alternative is to not participate.

We do not know if you will receive any benefit from your participation. The most common and most serious risks that may be related to taking part in this research include bruising or bleeding, however these side effects are uncommon. Additional possible side effects include nearby tissue injury or damage and infection which are also uncommon.

Any new important information that is discovered during the study, and which may influence your willingness to continue participation in the study, will be provided to you.

Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

WHAT WILL HAPPEN DURING THIS STUDY?

Screening:

Before any study-related tests and procedures are performed, you will be asked to read, sign and date this consent document. The following screening procedures will then be performed to determine if you qualify to take part in this study:

- Health and Medication Questions – you will be asked questions about your health, medical history, any symptoms you may be experiencing, and the medications you are taking
- A Physical Exam will be conducted
- Vital Signs: your blood pressure will be checked by putting a band around your arm (this will squeeze your arm for about a minute), your pulse will be checked, we will listen to you breathe in and out and your temperature will be taken
- Height and Weight – we will measure how tall you are and how much you weigh
- Your chemo-induced peripheral neuropathy (CIPN) will be assessed utilizing a point-of-care nerve conduction device The nerve conduction device is a handheld device consisting of biosensors and stimulating probes. The probes will be applied to the side of your ankle, the nerve will be stimulated for up to 20 seconds, and the response will be recorded by the biosensor. The procedure will be completed within 1 minute. This will then be repeated on your opposite ankle.
- Your chemo-induced peripheral neuropathy (CIPN) will be assessed utilizing standard of care nerve conduction studies
- Your chemo-induced peripheral neuropathy (CIPN) will be assessed utilizing a tuning fork Vibration that will be initiated in the tuning fork. It will then be placed on your toe and allowed to continue to vibrate until you can no longer feel the vibration. Neuropathy causes a loss of sensation that you would typically feel from a tuning fork placed on your foot.

- Questionnaires: you will be asked to fill out questionnaires about your CIPN and quality of life

Study Treatment:

You will receive acupuncture treatment once a week for 3 weeks. During the study treatment needles will be placed in the webs of your toes, on the top of your foot, and the sole of your foot. A total of 12 needles will be used. Each treatment will last approximately 30 minutes.

After Study Treatment/Follow up Assessments:

- Your chemo-induced peripheral neuropathy (CIPN) will be assessed utilizing a point-of-care nerve conduction device using the same procedure as in the screening assessment.
- Your chemo-induced peripheral neuropathy (CIPN) will be assessed utilizing standard of care nerve conduction studies
- Your chemo-induced peripheral neuropathy (CIPN) will be assessed utilizing a tuning fork using the same procedure as in the screening assessment.
- Questionnaires: you will be asked to fill out questionnaires about your CIPN and quality of life
- Health and Medication Questions – you will be asked questions about your health, medical history, any symptoms you may be experiencing, and the medications you are taking

WHO IS PAYING FOR THIS STUDY?

Moffitt Cancer Center, the sponsor of the study, is paying for this study

WILL IT COST ANYTHING TO BE IN THIS STUDY?

You and/or your insurance company will be financially responsible for hospital inpatient, outpatient and follow-up visits that would normally or routinely occur in the management of your disease. Inpatient and outpatient visits could include charges for treatments, medications, physician visits, laboratory tests and procedures. You and /or your insurance company will be responsible for paying for the charges which are considered routine, since you would have received these services even if you were not participating in this study. You will be responsible for any costs not covered by your insurance company, including deductibles, co-payments and all out-of-pocket expenses. Before you agree to be in this study, you should contact your health insurer to see if your plan will cover the costs required as part of your participation.

You and/or your insurance company will not be responsible for paying for study related items and services that are specifically required for this research study and are not considered part of the routine management of your disease, if these procedures are performed at Moffitt Cancer Center.

If you would like more information on the costs of being on this study or have other insurance related questions then please let your clinical trial coordinator know or contact our Business Office at 813-745-8422.

WILL BEING IN THIS STUDY HELP ME?

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

Although rare, the following potential risks may occur as a result of acupuncture:

- Infection
- Damage to surrounding organs
- Bruising
- Bleeding
- The treatment may cause psychological effects, such as distress, in some individuals

It is possible that you could have other problems or side effects that nobody knows about yet.

DPNCheck (NeuroMetrix) is a safe and non-invasive device.

The most common risk of standard of care nerve conduction tests is temporary discomfort at the site of testing.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you need emergency care:

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

If you do NOT need emergency care:

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

MOFFITT CANCER CENTER INJURY STATEMENT

If you believe you have been injured as a result of your participation in this study or if you have questions about your rights as a person who is taking part in a research study, you may call the Moffitt Cancer Center Risk Manager at 813-745-7882. Moffitt Cancer Center and its investigators have made no provision for monetary compensation in the event of physical illness or injury resulting from this study. Likewise, Moffitt Cancer Center and its investigators have made no provision for payment of lost wages, disability, or discomfort in the event of physical

illness or injury resulting from this study. Florida law (Statute 768.28) limits the liability of Moffitt Cancer Center. This statute provides that damages are available only to the extent that negligent conduct of a Moffitt Cancer Center employee caused your injuries, and are limited by law.

WILL I GET PAID?

You will not get paid for being in this study. You will not be reimbursed for expenses for travel and/or lodging while taking part in this study.

WHILE YOU ARE IN THE STUDY, YOU MUST:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Give correct and accurate information about your medical history and current medical condition.
- Tell the study doctor about any health problems you have during the study.
- Tell the study doctor about any new medicine or drug you take during the study.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

DO I HAVE TO REMAIN ON THIS STUDY ONCE I JOIN?

If you want to stop being in the study, tell the study doctor or study staff. If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in more tests or return for a final study visit.

ARE THERE REASONS THE STUDY DOCTOR OR SPONSOR MIGHT TAKE ME OUT OF THE STUDY LATER?

Even if you want to stay in the study, there may be reasons the study doctor or study staff will need to take you out of it. Your study doctor has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons, including the following:

- If the study doctor believes, for any reason, that it is in your best interest.
- If other causes prevent you from continuing in this study.
- If the Sponsor decides to end the study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing and dating this form, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care

arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

Your private information collected during this study will not be used or distributed for future research studies, even if identifiers are removed.

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?

Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: Moffitt Cancer Center
- Any federal, state, or local governmental agency that regulates the study such as The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants

finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?

By signing and dating below, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study doctor listed on the first page of this form.

Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You will receive a signed and dated copy of this form.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Participant Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00034331.

WHERE CAN I GET MORE INFORMATION?

You may call the National Cancer Institute's (NCI) Information Service at:
1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

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.

STATEMENT OF CONSENT AND AUTHORIZATION

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant Date Time

STATEMENT OF PERSON OBTAINING INFORMED CONSENT / RESEARCH AUTHORIZATION

I attest that the participant above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Date Time