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Fred Hutchinson Cancer Research Center

Consent to take part in a research study:

Pilot study of oral cryotherapy vs. oral cryotherapy plus acupuncture and acupressure to decrease chemotherapy-induced peripheral neuropathy from oxaliplatin-based chemotherapy for GI cancers

[**Short title: Acupuncture for GI cancer neuropathy**]

Principal Investigator: Stacey Cohen MD. University of Washington; Fred Hutchinson Cancer Research Center. (206) 606-6725

Emergency number (24 hours): (206) 598-6190

Ask the UW operator to page the on-call medical oncologist.

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to test whether acupuncture and acupressure reduces the side effects from chemotherapy containing oxaliplatin, especially neuropathy.

People who agree to join the study will be randomized to either standard-of-care practice for managing symptoms from chemotherapy or additionally have acupuncture over the 3 months of the study. After the initial 3 months, subjects enrolled in the standard-of-care arm will also be given the option to receive acupuncture therapy. They will be given a coupon for up to 6 visits, to be redeemed within a maximum of 6 months after their initial study participation.

Cryotherapy (using ice chips and ice packs) is currently used to minimize neuropathy symptoms. This will be included for all patients on this study as it is part of standard-of-care. Acupuncture is a traditional Chinese medical treatment which involves the use of very small, thin needles to stimulate specific points in the body. Acupuncture will be given during regular clinic appointments for chemotherapy. Participants receiving acupuncture will also be taught acupressure techniques to do at home in between sessions. All participants will be asked to fill out surveys about their symptoms 3 times over the 3 months of the study.

We do not know if acupuncture and acupressure would help minimize neuropathy from oxaliplatin, but it is unlikely to make your condition/disease worse. Acupuncture could cause discomfort at the sites of the needles, as described below in this form.

You do not have to join this study. You can choose to receive standard methods to manage symptoms with oxaliplatin-containing chemotherapy instead of participating in this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We invite you to join this research study.

We invite you to join this research study because you have a gastrointestinal (GI) cancer of the esophagus, stomach (gastric), pancreas, biliary tract (cholangiocarcinoma), liver, small bowel, appendix, colon, rectum, anus, or GI/pancreatic neuroendocrine tumor) and your doctor has recommended treatment with oxaliplatin chemotherapy. Up to 60 people will join this study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

You do not have to be in the study. You are free to say "yes" or "no", or to drop out after joining. If you say "no," you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

Why are we doing this study?

We are doing this study to examine neuropathy from chemotherapy. This is when the chemotherapy causes dysfunction of the nerves, often leading to pain, tingling, and/or numbness. Most often this affects the hands or feet. With oxaliplatin, this can also affect the mouth and throat. We want to know if acupuncture and acupressure can decrease this symptom if they are started at the same time as the chemotherapy.

In this study, we want to compare acupuncture and acupressure to the standard treatment, which includes cryotherapy, to learn which works better for people with neuropathy from oxaliplatin chemotherapy in GI cancers. If you join this study, we would watch carefully for any side effects.

There are 2 groups of participants in this study. We will give different treatments to different groups, and compare the results. This is how we hope to find out if acupuncture and acupressure is helpful for neuropathy.

In this study, we use a computer program to decide which treatment to give. If you join this study, you would not be allowed to choose the treatment. You would have a 1-in-2 chance of receiving acupuncture and training in self-administered acupressure during the 3-month treatment. However, even if you are enrolled in the standard-of-care arm and don't receive acupuncture during the initial 3 months of the study, you will be provided an opportunity to receive acupuncture later. All subjects enrolled in the standard-of-care arm will be provided with 6 acupuncture coupons, to be redeemed within 6 months after their initial study participation.

What research tests, procedures, and treatments are done in this study?

If you join this study, we would do these tests and procedures:

- **Questionnaire.** We would ask you to fill out three questionnaires—one when you join the study, another one six weeks later, and a final one at 12 weeks (the end of the study). Each questionnaire has questions about your symptoms from chemotherapy. Some of the questions may be sensitive. Questions that make you feel uncomfortable would not have to be answered.
- **Cryotherapy.** All participants would receive standard-of-care management of neuropathy. This includes cryotherapy to minimize the development of neuropathy. You would be given ice chips to keep in your mouth and ice packs for your hands and/or feet to keep on during the oxaliplatin infusion. We will ask you (by phone, in person, and/or by in clinic questionnaire) questions about the approximate time you used the cryotherapy.

If you are in **Group 1**, we would additionally do these tests and procedures:

- **Acupuncture.** You would have a 30-45 minute acupuncture therapy session during your chemotherapy infusion on day 1 of each cycle and at the time of your chemotherapy pump disconnect on day 3 of each cycle. You would receive a total of 12 treatments, which will each take approximately 30-45 minutes

- **Acupressure.** During the first acupuncture session, you would be taught acupressure techniques. These would be aimed at decreasing pain, fatigue, nausea, changes in oral sensation, and anxiety from your treatment and/or cancer. You would be asked to perform the acupressure techniques on your days in between treatments and record your sessions in a diary.

If you are in **Group 2**, you will receive six coupons for complimentary acupuncture treatment which you may decide to use after the study is over. At the time of these visits, limited exams may be completed, including a physical exam, vitals and some questionnaires.

How long would you stay in this study?

If you join this study, you would stay in this study for about 3 months if you enroll into Group 1, or up to 9 months if you enroll into Group 2.

Doctors could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- You are not able or willing to follow study procedures.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

What are the side effects (risks)?

In this part of the consent form, we describe the side effects we expect from the tests and treatments in this study. Acupuncture and acupressure could cause side effects we do not know about yet. We carefully watch everyone in the study for side effects.

If you join this study, we would tell you if we discover new side effects that could affect you. Side effects may be mild or very serious. Medicines could be given to help lessen side effects. Many side effects go away soon after you stop taking acupuncture and acupressure. In some cases, side effects can last a long time or never go away.

For participants receiving acupuncture, you will have a minor risk of bruising, bleeding, pain at the insertion site, redness, or an allergic reaction. There is a very rare chance of fainting, infection, and organ puncture.

Acupuncture may involve unknown risks to an embryo or fetus (unborn baby). Therefore, you could not join this study if you are pregnant or if you are planning to become pregnant.

If you join this study, you would have to use an effective method of birth control from the time this form is signed after the last treatment of acupuncture. If you are already using a method of birth control, you would have to check with the study doctor or a member of the study staff to make sure it is acceptable.

If you became pregnant after joining this study, you would have to notify the study doctor immediately. Participation in this study would end, and you would receive counseling and follow-up throughout the pregnancy and for about 6 months after the child is born.

Non-physical risks

If you join this study, non-physical risks are:

- You might not be able to work.
- You may feel uncomfortable, embarrassed, or self-conscious about answering the study questions.
- The visits for your chemotherapy appointments may be slightly longer due to the need for the acupuncture therapy/waiting for your treatments, as well as the time required to fill out surveys.

What are the benefits?

We do not know if this study would help you. We are testing acupuncture and acupressure for the management of chemotherapy side effects, including neuropathy, by comparing it to medication management and cryotherapy, the standard treatment for GI cancer patients receiving an oxaliplatin-containing regimen. You could use acupuncture without joining this study. The research treatment in this study might not be more effective than standard-of-care methods

You might get better if you receive acupuncture, but your condition could stay the same or even get worse. We hope the information from this study will help other people with GI cancers in the future.

You have other choices besides this study.

You do not have to join this study. You are free to say “yes” or “no”. Your regular medical care would not change if you decide to say “no”.

You have other choices for treatment. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about these choices.

Other choices include: Standard Treatment, Another Research Study, No Treatment.

Enrollment in this study may exclude you from other research studies.

Protecting Privacy as an Individual and the Confidentiality of Personal Information

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Research Center, University of Washington, and Seattle Cancer Care Alliance.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other regulatory agencies as required.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

Would we pay you if you join this study?

There is no payment for being in this study. If you complete this study, and are randomized to the acupuncture arm, you will receive all acupuncture treatments for free as a part of the protocol. If you are randomized to the standard of care (no acupuncture) study arm, you will receive coupons for six acupuncture sessions that you may schedule at your convenience following the conclusion of the study. If you are in the control arm and drop out of the study, you will not be eligible to receive the coupons for free acupuncture.

Would you have extra costs if you join this study?

There are no extra costs for being in this study.

What if you get sick or hurt after you join this study?

For a life threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact the study PI, listed on the first page of this consent. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information be used for?

Your information will be used for the purposes of this study.

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

In addition, be aware that by agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information. If you do not want your information to be used for future research studies without your consent, you should not participate in this study.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. Ifwe learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.
- If you decide to drop out, we would want you to tell the study doctor. The doctor could tell you about the effects of stopping acupuncture. You and the doctor could talk about the follow-up care and testing that would help the most.

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.

Your responsibilities

If you join this study, you would have some responsibilities.

- Follow the schedule of study visits and procedures.
- Take study medications as directed.
- Prevent pregnancy.
- Tell us about side effects.

For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	(206) 606-6725 (Dr. Stacey Cohen, PI)
If you get sick or hurt in this study	(206) 606-6725 (Dr. Cohen)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center) 206-543-0098 (Human Subjects Division, University of Washington)

Emergency number (24 hours): (206) 598-6190

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name	Signature	Date

If you served as an interpreter or impartial witness during the consent process, sign below to indicate you attest to the accuracy of the presentation and the participant's apparent understanding of and willingness to participate in the research.

Impartial Witness or Interpreter:

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date