

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Pilot Randomized Feasibility Trial Comparing an Investigational Hand Therapy Intervention to a Traditional Occupational Therapy Intervention to Prevent Chemotherapy-Induced Peripheral Neuropathy of the Hands in Patients Receiving Albumin Bound Paclitaxel plus Gemcitabine-Containing Combination Chemotherapy

PROTOCOL NO.: AX-CL-PANC-PI003347
WIRB® Protocol# 20161094

SPONSOR: HonorHealth

INVESTIGATOR: Gayle S. Jameson, MSN, ACNP-BC, AOCN
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**STUDY-RELATED
PHONE NUMBER(S):** Gayle S. Jameson, MSN, ACNP-BC, AOCN
480-323-1350 (24 hours/day)

You are being asked to take part in a research study. Your participation is entirely voluntary. To allow you to make an informed decision as to whether you want to take part in this research study, this document describes the purpose of the study, your rights and obligations, the procedures needed by the study, and the possible benefits and risks of participating. You should read all of this information carefully and discuss your questions and concerns with your study doctor or healthcare team. You may take home an unsigned copy of this consent form to think about or discuss your decision with your family, friends and anyone you choose. You should not join this research study until all of your questions are answered. A person who takes part in a research study is called a research or study subject. In this consent form, “you” always refers to the research subject.

Research studies include only people who choose to take part. Please take your time to make your decision. If you have any questions, you can ask your study doctor for more explanation about the study, this form, or your disease. This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not understand.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

PURPOSE OF THE STUDY

We will be exploring the possible benefits of an investigational hand therapy intervention to prevent chemotherapy-induced peripheral neuropathy (CIPN) of the hands in patients receiving albumin bound paclitaxel plus gemcitabine-containing chemotherapy.

Many people who have been treated with chemotherapy complain of upper extremity numbness, tingling or pain, known as “neuropathy”, which interferes with their activities of daily living including work, and negatively impacts their overall quality of life. Fine motor skills may be affected, impairing activities such as buttoning, donning earrings, doing clasps, handling or manipulating small objects. Certain chemotherapy agents are known to cause this problem but are necessary for best medical management. It has been reported that up to 71% of patients receiving chemotherapy with albumin bound paclitaxel plus gemcitabine experience some degree of CIPN.

To date, there are no proven interventions for the prevention of CIPN. This protocol will be the first to study a hand therapy intervention in the prevention of CIPN among patients with pancreatic cancer being treated with a taxane, specifically albumin bound paclitaxel. The hand therapy may include light exercises and stretches of the upper extremities and activities using your hands.

How Many Research Subjects Will Take Part in This Study?

Approximately 60 patients with pancreatic cancer will take part in this study. People in the study are referred to as "subjects". All subjects will be enrolled at HonorHealth in Scottsdale, AZ.

How is the study being conducted?

As part of this study, you will participate in a hand therapy program that provides education and exercises to possibly prevent peripheral neuropathy of the hands, a common side effect of chemotherapy.

There will be two treatment groups with different exercises or activities to be done at home. It is not known if either of these programs will prevent peripheral neuropathy.

This is a randomized study, which means you will have a 1 in 2 chance, like flipping a coin, to be assigned to one group or the other group prior to start of hand therapy intervention. Participants will be evenly divided between each group.

You, your physician and medical care team will be unaware of which treatment group you have been assigned.

Occupational Therapists

Occupational Therapists are clinical experts in promoting upper extremity motion and function. Occupational Therapists often treat patients with neuropathy that is caused by something other than chemotherapy.

Length of the Study for Each Participant

You may participate in this study through 12 weeks (84 days) of chemotherapy. If CIPN of the hands occurs before the end of the study, participation will end at the time of onset of CIPN.

Who Can Participate?

This study is designed for adult patients with pancreatic cancer who meet the study's eligibility criteria. Your suitability for this study will be determined by the research team.

Who Cannot Participate?

This study is not designed for patients with pancreatic advanced cancer who have had prior chemotherapy with albumin bound paclitaxel plus gemcitabine or who currently have an existing peripheral neuropathy.

PROCEDURES

If you decide that you would like to participate in this study, the following will occur.

1. You will be asked to read and understand, each page of this consent form and sign one page on the form once you have had all your study-related questions answered.
2. During the Screening Period of the Study (within 14 days of the start of the study) the following will happen:
 - a. A brief medical history will be done.
 - b. A limited physical examination including a measurement of your vital signs (temperature, blood pressure, pulse rate, and respiratory rate), height and weight and a brief neurological exam will be performed. Your current medications including prescription and over-the-counter medications will be reviewed.
 - c. You will meet with the Occupational Therapist to receive instructions for the home program you have been assigned, up to 5 visits:
 - i. Within 14 days before the start of chemotherapy
 - ii. Within 2 weeks, 4 weeks and 7 weeks after starting chemotherapy treatments
 - iii. At end of study participation.
3. You will be expected to do the home program and complete a daily diary while participating in the study.

If you are unable for any reason to complete the expected home program participation as described in #3, then your participation in the study will end.

At the end of your study participation:

1. The physician or nurse practitioner will:
 - a. repeat a brief medical history
 - b. conduct a limited physical examination and medication assessment
 - c. have your vital signs (temperature, blood pressure, pulse rate, and respiratory rate) and height and weight recorded
2. The Occupational Therapist will repeat the assessments for sensation and upper extremity function

RISKS AND DISCOMFORTS

Other than the time it will take you to complete the daily home program (estimated to take about 15 minutes), there are no known risks for you taking part in this study.

We will take reasonable safeguards to minimize any potential risks but unknown and/or unanticipated side effects might occur.

Other Risks

Your condition may not get better or may get worse during this study.

NEW INFORMATION

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the treatments under research in this study, and any information that may affect your interest in remaining in the study. You will be told about anything new that might change your decision to be in this study. If there is new information, you may be asked to sign a new consent form.

BENEFITS

You may or may not develop CIPN while receiving chemotherapy. We cannot guarantee that you will experience any medical benefits from participating in this study. Others may benefit in the future from the information we obtain while you are in this study.

COSTS

Other than your time, there are no costs to you to participate in this study. You will not be charged for the hand therapy. You or your insurance company will be billed for your routine care in the usual way.

SOURCE OF FUNDING FOR THE STUDY

The Principal Investigator for this trial, Gayle S. Jameson, is receiving salary support for the portion of her time spent completing study-related duties. The Institution/hospital is receiving a grant from Celgene Corporation to help cover the costs of the research nurse and the study-related tests and procedures.

Consent Visit	Hand Therapy Visit 1	Chemo Day 1	Chemo Day 8	Hand Therapy Visit 2	Chemo Day 15	Chemo Day 22	Hand Therapy Visit 3	Chemo Day 43	Hand Therapy Visit 4	Chemo Day 64	End of Study
\$35	\$35	\$35	\$35	No	\$35	\$35	No	\$35	No	\$35	\$35

PAYMENT FOR PARTICIPATION

As a participant in this study, you will receive payments of \$35 at designated study visit to compensate you for your time and effort for completing the required study diaries. If you complete the study diaries, you will receive payment at the visits indicated in the table below. You will be compensated for what you complete, even if you do not complete the overall study.

Greenphire is a company working together with HonorHealth Research Institute to manage the reimbursement process. You will be issued a Greenphire ClinCard, which is a specially designed debit card for clinical research onto which your funds will be loaded. After a visit is completed, funds will be approved and loaded onto your ClinCard. The funds will be available following the completed visit and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen a replacement card will be provided, at an additional charge.

Additionally, you will have the option to receive updates related to appointment reminders and payment alerts via text message (standard text messaging rates will apply) or email message. You will have the opportunity to opt-in to receive these messages. You are not required to provide your cell phone or email address to be enrolled in the study or to use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out.

In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire will need to collect information about you, including:

- Your name
- Your address
- Your date of birth

This information will be collected from you by the staff at your study doctor's office.

All information is stored in a secure fashion and conforms to regulations relating to personal data Protection. Your information will not be shared with any third parties or the Sponsor of this trial and will be kept completely confidential..

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program. Please be aware that some fees may apply for inactivity (over a period of 3 months), and specific transactions. Please be sure to read the instructions that come with the ClinCard so that you are aware of potential fees that may apply.

ALTERNATIVE TREATMENT

Since there are no approved or generally used preventative treatments for CIPN, your alternative is to not participate in the study.

COMPENSATION FOR INJURY

We will make every effort to prevent study-related injuries and illness. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you may go to any emergency room or urgent care facility to seek medical treatment. If it is determined that the injury or illness is not related to the research, the costs of this care may be charged to you or to your health insurer. No funds are offered from HonorHealth to compensate you for a study-related injury or illness. This does not mean that you are giving up any of your legal rights.

The study doctor will provide you medical care if you need it, and will also treat you for any complications that may occur during your participation in the study. If you become ill or are injured as a direct result of your participation in this study, you will be provided the reasonable and necessary treatment for that injury or illness. The bills for the injury or illness not caused by study participation may be billed to your medical insurance or to your third party or governmental programs in which you participate.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to take part or you may leave the study at any time. Your decision will not cause any penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- It is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- Or, for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information will be collected by the study doctor and his research staff for this study?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and her research staff conducting the research.

Who will receive your personal and medical information collected?

Information from this study will be given to the study sponsor. “Sponsor” is the person or entity that initiates, provides oversight of activities within the study, and includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study. Medical records which identify you and the consent form signed by you will be looked at and collected for research purposes by:

- People working for or with the sponsor
- HonorHealth Research Institute, the sponsor and study site
- Celgene Corporation, the funder

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Western Institutional Review Board® (WIRB®)
- Celgene Corporation

The HonorHealth HSRPP and the HonorHealth Research Institute have the authority to review and monitor all records related to this research.

Why will this information be used and/or given to others?

- for research purposes as described in this consent form,
- to make sure the study was conducted as approved by the IRB.
- to be used for future research purposes

What will happen if you decide not to give permission to use and give out your private health information?

You cannot be in this research study.

Will you have access to the information collected during the study?

To maintain the integrity of this research study, you will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you may request access to your health information that HonorHealth maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at HonorHealth. If it is necessary for your care, your health information will be provided to you or your physician.

Does this authorization expire?

This authorization does not expire unless it is canceled by you in writing.

Can this authorization be withdrawn or canceled?

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

QUESTIONS

Contact Gayle Jameson, MSN, ACNP-BC, AOCN at 480-323-1350 for any of the following reasons:

- if you have any questions about your participation in this study,
- if at any time you feel you have had a research-related injury or a reaction to the study drug, or
- if you have questions, concerns, or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, input or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue, S.E., Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form and understand what has been discussed. All my questions about the study and my part in it have been answered. I voluntarily consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Subject Name

Signature of Subject

Date

Signature of Person Conducting Informed
Consent Discussion

Date

----- **Use this witness section only if applicable** -----

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

Signature of Impartial Witness

Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.