RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A hair loss prevention study for patients with advanced pancreatic cancer utilizing scalp cooling

PROTOCOL NO.: HonorHealth IRBNet # 1418537-1

SPONSOR: HonorHealth Research Institute

INVESTIGATOR: Amy Mirabella PhD, RN
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Scottsdale, AZ 85258
United States of America

STUDY-RELATED PHONE NUMBER(S): Amy Mirabella PhD, RN
480-323-1350 (24 hours)

INTRODUCTION

You are being asked to take part in a clinical trial, a type of 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 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 the study staff for more explanation about the research study, this form, or your disease. This consent form may contain words that you do not understand. Please ask study staff to explain any words or information that you do not understand.

You are being asked to participate in a research study to determine the effectiveness of scalp cooling, using the FDA (U.S. Food and Drug Administration) cleared Paxman scalp cooling device, in preventing hair loss in patients with pancreatic cancer who are receiving treatment

containing nab-paclitaxel, gemcitabine and cisplatin.

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

The purpose of the study is to determine the effectiveness of scalp cooling, using the FDA cleared Paxman scalp cooling device, in preventing hair loss in patients with pancreatic cancer undergoing treatment with nab-paclitaxel, gemcitabine and cisplatin.

Who can participate in this study?

Individuals with pancreatic cancer undergoing treatment containing nab-paclitaxel, gemcitabine and cisplatin.

PROCEDURES

After signing this consent form, the screening period will begin. During the screening period you will have your fitting for the cooling cap.

Photographs of the top of your head, back of head and right and left side of the head will be taken at various time points during the study. You will be asked to use a blank sheet of white paper (8.5x11”) to cover your face. The study Sponsor may use the photos at medical meetings and in medical magazines, so that others can find out about the study. You will not be identified by name or other identifying information from the photo in any such publications. If you leave the study, information already collected about you will still be used. You will be asked to sign a separate form consenting to the photographs as the photographs are a mandatory part of the study.

The table on the next page shows the assessments for each study visit. The “X” means that an event will occur at that time point.

Cooling will consist of precooling (30 minutes prior to the start of chemotherapy); infusion

cooling (length of time it takes to infuse the chemotherapy) and post-infusion (90 minutes following the chemotherapy infusion). The use of the cooling cap should not lengthen your treatment day in the clinic as many times you will be receiving hydration during the 90 minute post-infusion cooling time.

Research Study Plan:

Assessments	Screening ≤ 10 days prior to C1D1	Cycle 1, Day 1	Cycle 1, Day 8	Cycle 2, Day 1	Cycle 2, Day 8	Cycle 3, Day 1	Cycle 3, Day 8	End of Study (2-3 weeks after last chemotherapy treatment in Cycle 3)
Signed Informed Consent	X							
Review medical history including pre-existing/current conditions	X	X						
Adverse Events		X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	
Fit for Cooling Cap	X							
Photographs	X	X[1]		X[1]		X[1]		X
Premedication with Tylenol or Ibuprofen		X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	
Scalp Cooling		X	X	X	X	X	X	
Subject Questionnaire-CADS		X[1]		X[1]		X[1]		X
Subject Questionnaire-Comfort Scale		X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	

[1] Prior to scalp cooling

[2] Following scalp cooling

[3] If clinically safe as determined by the provider

RISKS AND DISCOMFORTS
There may be risks to you if you are in this study.

"Adverse event" is the name given to an undesirable experience occurring to a participant of a research study, whether or not it is considered to be related to the treatment.

Some of the adverse events may be the following: chills, dizziness, headache, nausea, paresthesia (tingling), pruritus (itchy skin), sinus pain, skin and subcutaneous tissue disorders, skin ulceration.
There have been rare cases of scalp metastases but the rate is low and comparable to patients who did not use scalp cooling.

Other Risks
There may be side effects that are not known at this time.

NEW INFORMATION
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
It cannot be promised that you will receive any medical benefits from being in this study.

There may be no direct medical benefit to you from participating in this study, except you may gain information about your health from the different tests that are done as part of the study. Information obtained from this study might lead to treatments that help others in the future.

Hair preservation is the intended benefit.

COSTS
The cooling cap and the scalp cooling treatments will be provided at no cost to you, meaning you will not be charged. Once you have completed the study assessments, you will have the option to continue scalp cooling at no cost to you. You will also be able to keep the cooling cap.

PAYMENT FOR PARTICIPATION
You will not be paid to participate in the study.

ALTERNATIVE TREATMENT
This is not a treatment study. Your alternative is not to be in this study.

CONFIDENTIALITY OF YOUR INFORMATION COLLECTED DURING THE STUDY
As required by the Federal Health Insurance Portability and Accountability Act (HIPAA), every effort will be made to safeguard the confidentiality of information that identifies you and relates

to your past, present and future physical and mental health. We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

Unless required by law, you will not be identified on any electronic form by name, social security number, address and telephone number or any other information that can directly identify you. The information shared with the Sponsor is protected by the use of a code, which is a number specifically assigned to you. The researcher is in control of the code needed to connect your data to you, but the researcher will not send the list with the code to the Sponsor. However, the study forms may contain other information about you, such as your age, sex and medical history. It is possible that this other information could be used to identify you even though your name does not appear.

The results of this study may be published by the Sponsor, including in a medical journal and shown at medical meetings. You will not be identified (by name or any other means) in any of these publications.

Because this research is regulated by the Food and Drug Administration (FDA), the FDA may inspect records related to this research, which may include your protected health information or other information about you derived or maintained as part of this study.

Information derived from this study may be used for research purposes that may include publication and teaching. However, information used for publication and teaching will not disclose your identity.

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 available 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 healthcare team 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.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The name and phone number are listed in this consent form.

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 entitled.

Your participation in this study may be stopped at any time by the study staff 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 staff to have some tests or procedures done so that you leave the study safely.

SOURCE OF FUNDING FOR THE STUDY

Dr. Jill Gives Hope Foundation has provided HonorHealth and the researcher with a grant to conduct this research study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information will be collected by the healthcare team for this study?

The healthcare team will collect your personal and medical information. This may include:

- 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 healthcare team and 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:

- The sponsor
- HonorHealth Research Institute, the study site

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported,

- HonorHealth Institutional Review Board (HIRB)

The HonorHealth IRB 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,
- for consideration by the FDA or any governmental agencies in other countries for drug approval,
- to make sure the study was conducted as approved by the FDA and IRB,
- to be used for future research purposes.

What will happened 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 principal investigator. 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 Amy Mirabella 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:

HonorHealth Institutional Review Board (HIRB)
10290 N. 92nd Street, Suite 305
Scottsdale, AZ 85258
Telephone: 480-323-3071 or 1-833-354-6667 (toll free)
E-mail: HSRPP@honorhealth.com

HIRB will not be able to answer any study-specific questions, such as questions about appointment times. You will need to contact the researcher at the number above. However, you may contact HIRB 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 (printed)

_____ _____
Signature of Subject Date

_____
Name of Person Conducting Informed Consent Discussion (printed)

_____ _____
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.