PROVIDENCE Cancer Center

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CONSENT FORM FOR A RESEARCH STUDY

Title: A Phase 2 study to assess the Safety and Efficacy of Scalp Cooling using Penguin Cold Caps for the Prevention of Chemotherapy-induced Alopecia in Stage I-III Breast Cancer (IRB # STUDY2017000277)

Principal Investigator: David Page, MD

Sponsor: Earle A. Chiles Research Institute

INTRODUCTION AND PURPOSE

You are being asked to take part in this research study because you have breast cancer and are going to begin chemotherapy treatment. This consent form will explain this study to you, and what you need to do if you take part. Make sure you understand what is written, and ask as many questions as needed before you decide whether to take part. After this study has been explained to you, and if you choose to take part, you will be asked to sign this consent form.

This is a study of an investigational (not approved by the Food and Drug Administration -FDA) device for the prevention of chemotherapy-induced alopecia (hair loss) in breast cancer patients. The device is called the Penguin™ cold cap system.

The Penguin™ cold cap is a portable scalp cooling system which uses gel-filled cold caps that are cooled on dry ice. It looks like a ski-hat into which the gel-filled caps can be inserted, and there is a buckle that goes under your chin to keep the cap in place.

To date, there is no currently accepted standard of care for the treatment of chemotherapy-induced hair loss. However, scalp cooling may be effective, which is why this study is being done.

Chemotherapy drugs are powerful medications that attack rapidly growing cancer cells. Unfortunately, chemotherapy can also cause hair loss. Cooling the scalp during chemotherapy may protect against hair loss by lowering the amount of chemotherapy that enters the hair roots, or by reducing the damaging effects of chemotherapy on the hair roots.

The purpose of this study is to see how effective the Penguin™ cold cap system may be in preventing or reducing hair loss in patients receiving chemotherapy for breast cancer. If you decide to join this study it will have no effect on the chemotherapy treatment you receive.

About 80 women will take part in this study. If you join this study, you will be in this study for the duration of your chemotherapy treatment and for 30 days afterwards.

PSJH IRB
IRB Number: STUDY2017000277
IRB Approval Date: 5/4/2020
IRB Parent Number: STUDY2017000277

STUDY PROCEDURES

If you decide to join this study, you will have the following screening procedures done to see if you are eligible for the study.

- Medical evaluations including history of present illness, chronic conditions, and history of allergies
- Baseline assessment of scalp to see if there is any hair loss prior to receiving chemotherapy
- Physical exam

If you are eligible and choose to take part, you and a caregiver will be trained on how to use the Penguin cold cap system.

STUDY TREATMENT

Participants will be provided cold-caps in a personal cooler (cooled by dry ice). Participants and their caretakers will undergo training to ensure appropriate handling and fitting of cold-caps.

Cold-cap therapy will start at least 50 minutes prior to each chemotherapy treatment, and will continue for at least 4 hours following completion of chemotherapy. The gel-filled cold-caps are exchanged every 30 minutes during this time. Participants may travel home with the cold-caps when they are done with chemotherapy, but must ensure to continue exchanging them every 30 minutes for at least 4 hours.

Before Day 1 of chemotherapy

Before starting chemotherapy, participants must identify a caretaker or caretakers to help exchange the cold caps during and after each chemotherapy session. You and your caretaker team will then participate in a training session, to learn how to use the Penguin cold cap system. Before initiating chemotherapy, you and your caretakers must demonstrate that you all have learned how to properly exchange the cold caps.

Day 1 of chemotherapy

On the first day of your chemotherapy treatment, your study doctor will assess your hair loss, and you will complete 2 questionnaires:

- Quality of Life scale
- Body Image scale

It will take you about 10 minutes to complete these questionnaires.

In addition, your hair and scalp will be photographed on Day 1.

During Chemotherapy

On each day that you receive chemotherapy, you will receive cold-cap therapy and your study doctor will assess your hair loss.

Follow-up
Thirty days after your last chemotherapy treatment, your study doctor will assess your hair loss, you will complete the same questionnaires as you did on Day 1, and your hair and scalp will be photographed. You will also complete the Was It Worth It (WIWI) Questionnaire that asks about your experience as a research study participant. It will take about 5 minutes to complete this questionnaire.

POSSIBLE RISKS

There are risks to you if you take part in this study. The treatment used in this study may cause all, some or none of the side effects listed below. In addition, unknown side effects may occur. Side effects should go away after the study treatment is stopped. If you have any side effects, report them to your study doctor or the research staff.

In previous research, the side effects listed below were observed during the first round (cycle) of chemotherapy:

Common (more than 10 patients out of 100)

- Headache

Less Common (fewer than 5 patient out of 100)

- Nausea
- Dizziness
- Chills
- Burning or prickling sensation (parathesia)
- Itching (pruritus)
- Dry skin or skin breakdown
- Scalp pain

In subsequent rounds of chemotherapy, there were fewer side effects reported, and with the exception of sinus pain, all of the side effects reported are in the list above.

It is possible that cold cap therapy reduces chemotherapy flow to the scalp and increases the likelihood that cancer spreads to the scalp. However, this has not been seen in previous research with cold cap therapy.

POSSIBLE BENEFITS

There are no guaranteed benefits to you for taking part in this study. This study treatment may even cause unwanted side effects. However, if effective, cold cap treatment may prevent or reduce hair loss.

The information learned from this study will help researchers learn more about the use of cold-cap therapy to prevent hair loss, and may help future patients receiving chemotherapy.

OTHER OPTIONS

You may choose not to take part in this study. Another option is to use scalp cooling machines such as DIGNICAP or PAXMAN, which are FDA approved and may prevent hair loss in some patients. However, these machines are not currently available at Providence Cancer Center or in any other cancer centers in Portland, but may be available in other clinics.

GENERAL INFORMATION

Your taking part in this study is voluntary. Your refusal to take part will not affect the health care benefits you have. If you decide to take part, you are free to stop at any time without any effect on your medical care, your relationship with your doctor(s) or Providence Health & Services.

While in this study, any important new information that may affect your wish to continue taking part will be given to you.

Your study doctor may remove you from this study at any time if he/she thinks it is medically necessary, you have a serious side effect, or you do not follow the study plan.

COSTS

You will not be paid to take part in this study.

You are responsible and must pay for the costs of your routine medical care and medications; however, these costs may be covered, at least in part, by most major insurance companies.

The study sponsor will provide the cold-cap to you at no cost while you are in this study.

Providence Portland Medical Center is not being paid by the sponsor to take part in this study.

LIABILITY

If you are injured as a result of taking part in this study, all of the necessary medical facilities are available for treatment, as is reasonably possible.

If you are injured during this study, you are responsible for the costs of treating a research-related injury and they may be billed to your insurance as appropriate.

Providence Health & Services is not able to offer you financial payment, nor to pay for the costs of medical treatment should you be injured as a result of taking part in this research.

You do not give up any of your legal rights by signing this consent form and taking part in this study.

PRIVACY

Your medical and study records are personal and private and only your study doctor, yourself and anyone you allow have the right to look at your records. It is important that the research staff, the FDA, the Center for Medicare and Medicaid Services (CMS), and the Providence Health & Services Institutional Review Board (IRB – a committee that reviewed this research to protect your rights), be able to look at your medical and study records. When you sign this consent form, you agree to allow this. If results of this study are reported in medical journals or at meetings, your identity will remain secret.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) gives you certain rights to protect the privacy of your medical information and records. Under HIPAA, you must give your permission before anyone uses or shares your medical information. This information is also called protected health information (PHI). Your rights, as well as the reasons for using your PHI, are described below.

The sponsor and your study doctor(s) will need to use your PHI for this study. Your study doctor will record PHI about you on study forms that are given to the sponsor. This includes your name,

address, telephone number, date of birth, past medical records and the results of tests and procedures done during this study.

By signing this consent form, you agree to allow your study doctor and the research staff to use and share your PHI for the following reasons:

- Make decisions about your medical care
- Evaluate the results of this study
- Make conclusions about the study results
- Provide study results to other study doctors
- Re-evaluate study results in the future, as needed
- Include your study information with results from other similar studies
- Send study information to government health agencies (for example, to the FDA to request approval of the treatment used in this study); this may also include government agencies in other countries
- Report side effects to the FDA and other government agencies
- Send study information to representatives of the study sponsor
- Any other purposes as described in this consent form.

If you are not willing to allow your PHI to be shared, you will not be able to take part in this study.

The IRB and any regulatory agencies may review your medical records and make copies. The reasons this might happen is to make sure this study is being done properly, study information is being collected correctly, and for other purposes allowed by law.

Once your PHI is shared with others, it is no longer protected by HIPAA law. However, it will be kept as confidential as possible.

Your permission to use and share your PHI will not end unless you change your mind. You may cancel your permission at any time by sending a written notice to your study doctor. Your PHI for this study will no longer be collected. In some circumstances, your study doctor will need to use or share your PHI that has already been collected to continue this research study.

If you cancel your permission, you will no longer be able to take part in this study. The sponsor will still use any PHI they received before you cancel your permission.

If you have questions about your privacy rights, please call the Providence Health & Services HIPAA Privacy Officer at (503) 574-9123.

QUESTIONS:

Any questions you have about this research study or a research-related injury can be answered by:

Study Doctor: _____ at _____

Research Coordinator: _____ at _____

Any questions you have about your rights as a research subject will be answered by the Providence Health & Services Institutional Review Board at (503) 215-2046.

You are free to ask questions about this study at any time.

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.

CONSENT:

I have read all of the above, asked questions and received satisfactory answers about what I did not understand. I agree to take part in this research study. I will be given a signed copy of this consent form for my records.

_____

Name of Patient (Please Print)

_____

Signature of Patient Date

_____

Name of Person Obtaining Consent (Please Print)

_____

Signature of Person Obtaining Consent Date