H-33692- SCALP COOLING FOR ALOPECIA PREVENTION (SCALP)

Background

You are invited to take part in a research trial using a new device that we are studying to see if it helps prevent hair loss during chemotherapy. You are being invited to take part in this research because you have been diagnosed with breast cancer and your doctors are planning to treat you with chemotherapy. Please read this information and feel free to ask any questions before you agree to take part in the study.

When patients take chemotherapy there are usually side effects that often happen. One of the side effects is the loss of hair (alopecia). Hair loss during chemotherapy is called "chemotherapy-induced alopecia". The most common and effective chemotherapy treatments can cause complete hair loss. Since chemotherapy works by slowing down the growth of cancer cells, it also slows down the growth of hair because it cannot tell the difference between the cells that are cancer and the cells that cause hair growth (hair follicles). For many patients, this hair loss is found to be troublesome or distressing.

A number of doctors and researchers have noticed that cooling the scalp during chemotherapy treatment may help prevent the loss of hair. The idea is that the cold shrinks or constricts the blood flow to the skin of the scalp when the chemotherapy is being introduced into your body. It is believed this would make the hair follicles less likely to the damage of chemotherapy treatment. In past years, ice packs were used to try to prevent hair loss. The sponsor of this research trial has developed a device that allows for constant cooling of the scalp. The device applies cold to the scalp in the hope that it could help prevent the loss of hair due to chemotherapy. The device is called the Orbis Scalp Cooler.

The Orbis Scalp Cooler is a "cap" connected to a "pump". The "pump" part of the device moves cool fluid into the "cap" that is placed snuggly on your head. Because the pump is always moving and circulating the fluid, the cold temperature remains steady during the treatment.

Voluntary Participation

Your participation in this study is entirely voluntary. Should you decide not to participate in the study, you will continue to receive the best possible treatment from your doctor. Being in the study or not being in the study will have no effect on the treatment of your breast cancer. You may withdraw from the study at any time. Your decision will not affect your future medical care and treatment. If you do agree to take part in the study, you are free to withdraw from the study at any time, without having to give a reason, and this will in no way affect your future healthcare. Your doctor may also stop your participation in the study should he or she determines that this study is not in your best medical interest.

Please read this document carefully before you make a decision about participating in this clinical trial, and ask your doctor or a member of the study team to explain anything that is unclear to you. Your doctor and the Sponsor of the study (Paxman) want to make sure you fully understand the study and its requirements.

If you decide to participate in this study, you will be asked to sign this consent form. By signing, you are indicating that you have read and understand the information. It also shows us that you will join in this study, and will follow the study requirements, including the follow-up visits.

Purpose
We would like to learn whether or not the Orbis Scalp Cooler is helpful in reducing the amount of hair loss that is often seen when patients are on chemotherapy.

Procedures
The research will be conducted at the following location(s):
Baylor College of Medicine, HCHD: Harris County Hospital District, and Harris Health System- Smith Clinic.

We are hoping to enroll 235 patients onto this study. We plan to offer this study at up to 10 sites. Baylor College of Medicine is one of the 10 sites. There are two clinics at Baylor College of Medicine that will enroll subjects for this study. One of the clinics is at the Baylor Clinic and the other is at the Smith Clinic which is part of the Harris Health Services.

If you are interested in being in this study, you will need to discuss this document (consent) with your doctor and the study team. You may want to take this consent home and talk about it with your family or friends before deciding to join the study.

If you decide that you want to participate in the study you will have a study visit with the research doctor and team. This visit will be called your "baseline" visit. At this time the study team will collect information about you like your age, height, race, etc. You will have a brief exam by the doctor and you will have an ECOG performance status test. The ECOG performance status test is a test that many doctors use to see how well their patients are handling day-to-day activities while they are being treated for cancer. You will be asked about any current medications that you are taking, including over the counter treatments and vitamins.

You will have your blood drawn, (about one to two teaspoons) to make sure that you can join this study. If your blood was already drawn within the past 4 weeks, the study doctor will make sure that the tests needed to join this study have been done. If they have been done, you may not need to have another blood draw. If your blood was tested for TSH (a test that can determine if you are likely to lose your hair) in the past year, this test will not need to be repeated.

The study team will ask you about your medical history. You will be given a "baseline alopecia score." This first score is important because it will be used throughout the study to see how much hair-loss you have experienced during chemotherapy.

Once you are enrolled onto the trial, you will be randomized into one of two groups. Randomized means that neither you nor your doctor can choose the group. This procedure is done by chance just like when you flip a coin. Some patients will be randomized into the group that will have the scalp cooling device during chemotherapy treatment. This group is called the "study group". The other group will not have scalp cooling. This group is called a "control". The "control" group is the group that receives "standard of care" or what is known as routine or "regular" care. Having two groups will help us see if using the Orbis Scalp Cooler device is helpful or not in preventing hair loss.

If you are randomized into the scalp cooling group, you will be given a brochure with instructions on proper hair care. You will also need to have a cooling cap fitting. This procedure is very important because the cap must fit snugly onto your head to be effective. You will be asked to wear the scalp cooling cap at every visit for chemotherapy. If you are in the control group, you will not need to wear the scalp cooling cap.

Both groups will be asked to complete some questionnaires. Before you have chemotherapy we will give you 3 questionnaires to complete. They will only take about 10 minutes to complete. These questionnaires will be completed again after 4 cycles of chemotherapy and again after you have completed all of your chemotherapy treatments (if you were scheduled for more than 4 cycles). The questionnaires will help us understand your feelings about yourself and in particular if your hair loss changes your feelings in any way.

The participants randomized to the scalp cooling group will wear the Orbis Scalp Cooler (cap) for at least 30 minutes prior to chemotherapy, during the chemotherapy infusion and for at least 90 minutes after the end of your infusion. The study nurse will record the start and stop times when you are wearing the cap. You will have the cap loosened for 5 minutes before it is removed and you will have another 5 minutes to allow your scalp to warm up. Right after the cap is removed, we will ask you to rate your comfort level. This information can help us understand if the cap is uncomfortable or bothersome during or after the treatments. If you are wearing the cooling cap and you still lose most of your hair, we will stop treating you with the cooling cap, but would still like you to complete the questionnaires at the required time point(s). If you should stop the treatment with the cap because it bothers you too much, we also would like you to complete the questionnaires at the required time point(s).

You will be seen by a medical oncologist and one other health care provider 2 to 3 weeks after each cycle of chemotherapy treatment to see if there are any changes in hair loss. The second health care provider will be "blinded" to the group you are in. This means, they are not supposed to know whether you received scalp cooling or whether you received routine care. If you enroll on this study, we ask that you agree not to tell the blinded observer what arm (treatment group) you are in. The loss of hair, if any, will be documented by using a picture scale. You will be asked to judge your own hair loss and we will ask you if you used a head cover (hat) or wore a wig between treatments.

If you are one of the first 25 patients enrolled, we will ask your permission to take photographs at your baseline visit and 2 to 3 weeks after each chemotherapy treatment of your right side, left side, front and back of the head as well as the top of the head. Your personal information will not be written on these photographs and your name will not be associated with them if they are ever published. If you are not one of the first 25 patients enrolled, photos will only be taken at your baseline visit, 2 to 4 weeks after 4 cycles of chemotherapy and 2-4 weeks after your last chemotherapy treatment (if you're getting more than 4 cycles). The photos may be published or presented as educational tools for training during and after the study is completed. You will not be identified in any of the pictures because they will not include your face and will be taken in such a way as to prevent you from being recognized.

Everyone in the study will be seen by the study team within 2 to 4 weeks after finishing chemotherapy. At the last visit, a final review of hair loss will be done and you will complete your last set of questionnaires.

We would like to continue to contact you once a year for the next five years after you finish the treatment. This would be done during your routine clinic visits to the doctor or by calling you on the phone once a year to see how you are doing and to learn if your cancer has returned.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, HCHD: Harris County Hospital District, and Harris Health System- Smith Clinic to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Billing or financial records
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, HCHD: Harris County Hospital District, Harris Health System- Smith Clinic, and PAXMAN COOLERS LIMITED and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

The data coordinating center will have access to the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, HCHD: Harris County Hospital District, and Harris Health System- Smith Clinic are required by law to protect your health information. By signing this document, you authorize

Baylor College of Medicine, HCHD: Harris County Hospital District, and Harris Health System- Smith Clinic to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, HCHD: Harris County Hospital District, and Harris Health System- Smith Clinic maintain 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 Baylor College of Medicine, HCHD: Harris County Hospital District, and Harris Health System- Smith Clinic to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, HCHD: Harris County Hospital District, and Harris Health System- Smith Clinic.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, PAXMAN COOLERS LIMITED and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, data coordinating center, Data and Safety Monitoring Board, HCHD: Harris County Hospital District, and Harris Health System- Smith Clinic may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Julie Nangia, MD - One Baylor Plaza, BCM 660 Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

There are side effects or risks that could occur during this study. Because this is a "randomized" study, there is always the risk that you will not be in the group that receives the scalp cooling treatment. In that case, the list of side effects would not apply to you.

If you are in the group that receives the scalp cooling treatment there could be risks or side effects that you may experience.

The most common side-effect reported with scalp cooling in general are:
* headache
* the feeling of coldness
* uncomfortable sensations
* a heavy feeling on the head
* lightheadedness (that goes away after the cap is removed)
* neck pain

Patients in other studies using the Orbis Scalp Cooling Cap have experienced the following side effects:
* complaints of coldness -cold-related discomfort (during scalp cooling)
* headache, ranging from mild to severe (during and following scalp cooling)
* forehead pain (during scalp cooling) resulting from pressure and tightness from the cooling cap
* light-headedness or dizziness (during scalp cooling and/ or following removal of the cooling cap at the end of scalp cooling)
* complaints of uncomfortable sensations
* heavy feeling of the head
* lightheadedness that comes and goes
* neck pain that comes and goes
* cold injuries (like frost-bite or cold urticaria (itchy hives or rash at the site of the cold cap)
* nausea

Although it is highly unlikely, there is a very slight risk that your breast cancer could metastasize to the scalp. We will continue to check on you throughout this study period (for five years after the study has ended).

Some of the questions on the questionnaires may be upsetting to you or you may feel uncomfortable answering them.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits
The benefits of participating in this study may be: that if you are in the group that will be using the scalp cooling device, you may not lose as much hair during chemotherapy. If you are in the "control" group, this would not apply to you, but we will still learn from your participating whether or not scalp cooling is helpful and safe. However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not want to use the scalp cooling cap, or if you have a serious reaction to the device) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

Research Related Injury

The study team and the clinical staff will watch over you closely during your treatments and will assist you by removing the cap or helping to make you more comfortable while you are using the cap.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, JULIE RANI NANGIA, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: JULIE RANI NANGIA at 713-798-1999 during the day and after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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.

The National Institutes of Health (NIH) and the National Cancer Institute (NCI) may have access to your records for research purposes. Coded information may be provided to the NIH/NCI such as your Patient ID, your Zip code, your country and your birth date (month and year). However, in the event of an audit, the NIH/NCI might have access to more information that is part of your research record."

What will happen at the end of the study? The study results will be submitted for product approval to the United States Food and Drug Administration and to the governing agency of other countries. You can visit the Sponsor's website to request a copy of the final report after it has been published. After you complete the study, you will be followed by your doctor per standard of care.

In the event of injury resulting from this research, the Harris County Hospital District is not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date