Official Study Title: PILOT STUDY OF COLD CAP THERAPY FOR PREVENTION OF HAIRLOSS IN PEDIATRIC PATIENTS RECEIVING CHEMOTHERAPY FOR NON-MALIGNANT INDICATIONS AND SOLID TUMORS

CTG Number: NCT04764357

Document Date: 12/10/2024

PILOT STUDY OF COLD CAP THERAPY FOR PREVENTION OF HAIRLOSS IN PEDIATRIC PATIENTS RECEIVING CHEMOTHERAPY FOR NON-MALIGNANT INDICATIONS AND SOLID TUMORS

Note: When we say "you" in this consent, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study, or research protocol.

Key Information

To start, we want to highlight the risks and study requirements that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more detail.

A. Why are you being asked to volunteer in this study?
You are being asked to take part in this clinical trial, a type of research study, because you are receiving chemotherapy as part of your treatment. Researchers want to understand if cooling the scalp can prevent the hair loss that often happens with chemotherapy.

B. What is the usual approach to this condition/cancer?
There is no known way to prevent hair loss from chemotherapy.

C. Why is this study being done?
This study is being done because researchers want to see if the Paxman scalp cooling device can safely prevent or reduce hair loss in pediatric patients receiving chemotherapy for non-cancerous conditions and solid tumors.

D. What will happen if you decide to take part in this study?
If you decide to take part in this study you will be asked to wear the cooling device on your head at least 30-45 minutes before treatment, during treatment, and at least 120-180 minutes after treatment. If you are being treated for a non-cancerous condition you will have five photographs taken of your hair before and after treatment (chemotherapy), and you will be asked to complete brief surveys at several time points. If you are being treated for a solid tumor you will have additional photographs taken of your hair 2-5 weeks after every 2 cycles of chemotherapy and you will be asked to complete brief surveys at several timepoints.

E. What are the research risks and benefits of taking part in this study?
The risks of the cooling cap include side effects of coldness, headache, scalp pain, and head heaviness. The surveys also may make you feel distressed or uncomfortable. There may not be a direct benefit to you for participating in this study; however, we hope that the device will minimize your hair loss and help researchers know how to help pediatric patients in the future.
There is a theoretical potential risk that scalp cooling could lead to increased incidence of scalp metastasis/relapse in solid tumor patients. Based on planned patient inclusion, and large studies in other populations, this risk is thought to be extremely low. Patients with cancers that have higher potential to metastasize (spread) to the scalp will not be enrolled in this study to minimize this risk. These cancers include neuroblastoma, melanoma, other skin malignancies, any head/neck malignancies, or those with known metastasis to scalp or top part of the skull, and those who have had or plan to undergo cranial irradiation. Large scale studies in patients with breast cancer, as well as smaller studies of adults with other solid tumors, have not shown increased risk of metastasis or impact on cure rates or long-term outcomes in patients who have received scalp cooling

and we believe that the pediatric solid tumor patients enrolled on this study will have similar low risk of scalp cooling impacting cancer outcomes.

F. How many people will take part in this study?
A total of 40 people will take part in this study at St. Jude.

G. What are your options?
   a. Taking part in this research study is completely your choice.
   b. If you decide to take part in this study, you can change your mind and stop at any time.
   c. If you decide not to take part in this study, you may still be able to receive care at St. Jude.
   d. You may choose no treatment or to seek treatment somewhere else.

If you are still interested in taking part in this research study, Pilot Study of Cold Cap Therapy for Prevention of Hair loss in Pediatric Patients Receiving Chemotherapy for Non-Malignant Indications and Solid Tumors, or COOLCAP, more detail will be provided in the following pages.

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1. **Why are you being asked to volunteer for this research study?**

   You are being asked to take part in this clinical trial because you are receiving chemotherapy as part of your treatment for a non-cancer condition or solid tumor. The medicine or chemotherapy that you will be given is known to cause people's hair to fall out. This study is to see if using a device to cool your scalp will prevent or lessen hair loss. The PAXMAN cooling device is approved by the FDA for use in adults but has not been tested yet on children. Please take your time in deciding and feel free to discuss it with your family, friends, and St. Jude staff. Before agreeing, it is important that you read this consent form that describes the study. After you understand the study and if you agree to take part, you will be asked to sign this consent document. You will be given a copy to keep.

2. **Who is sponsoring this study?**

   This study is sponsored by St. Jude Children's Research Hospital and the scalp cooling device is provided by Paxman. The Principal Investigator (PI) of this study is Dr. Deena Levine who can be reached at 901-595-3300.

3. **What is the purpose of this study?**

   This study is being done to see if the Paxman scalp cooling device can prevent hair loss in pediatric patients receiving chemotherapy for non-cancerous conditions and solid tumors. Researchers want to know how much and how often hair loss happens in pediatric and young adult patients receiving chemotherapy for non-cancerous conditions and solid tumors who have used a scalp cooling device.

   Researchers also want to compare the amount of hair loss between patients receiving chemotherapy for non-cancerous conditions and solid tumors who wear the scalp cooling device during chemotherapy and those who do not wear the device during their chemotherapy treatment.

4. **What will be done in this study?**

   If you agree to be in the study, you will have the following, either in the clinic or hospital, assisted by one of the study team members:

   - Informed Consent discussion
   - Pre-study evaluation including a physical exam
   - Photographs of your hair will be taken prior to the use of the scalp cooling system and once at the end of the study. Patients with solid tumors will have additional photographs taken after every 2 cycles of chemotherapy.
   - Patient Reported Outcomes questionnaires (or surveys) including:
     - Selected questions from NCI PRO-CTCAE, CADS, and PediQUEST Memorial Symptom Assessment Scale, at the following time points: baseline, after every 2 cycles of chemotherapy, end of chemotherapy administration, and 4 week follow up.
   - Those receiving CoolCap therapy will have the following:
     - A visit the week before the start of your chemotherapy to fit the cool cap properly on your head.

  - Scalp hypothermia (coldness) delivered to your head by the scalp cooling system
  - Starts at least 30-45 minutes before your chemotherapy treatment,
  - Stays on through your treatment,
  - And it stays on at least 120-180 minutes after stopping the medication.
  - Each time the cooling cap is used and at the end of study you will complete the Tolerability Questionnaire.
- Data collected from your medical record for details regarding the treatment. Patients with solid tumors will have their medical records reviewed for 5 years post-study.
- An off study physical exam will be completed at the end of the study.

5. **What are the risks and benefits of taking part in this study?**

a. Risks

For those receiving cooling cap therapy short-term side effects that might happen during or following scalp cooling with the Orbis Paxman Hair Loss Prevention System are as follows:

- Complaints of coldness or chills
- Headache
- Forehead pain due to pressure and tightness of the cooling cap
- Light-headedness or dizziness
- Uncomfortable feelings like tingling, tickling, pricking, numbness, or burning of the skin: “pins and needles”
- Scalp itching
- Heavy feeling of the head
- Neck Pain
- Nausea
- Sinus pain

These adverse effects are known to last a short time and have no long-term effects.

Rarely, cold injuries could happen, like:

  - Skin tissue disorders
  - Skin ulceration

It is possible that this research study involves risks that we currently do not know about.

Patients with sickle cell disease can be at risk for pain crisis after cold exposure however the risk of this occurring from cooling cap therapy is extremely low due to the nature of the therapy and the cooling cap itself as well as the preparation for transplant which includes medication and exchange transfusion to achieve low sickle cell percentage in the blood.

In patients with solid tumor malignancies there is a theoretical risk of relapse or scalp metastasis. However research in adults has shown scalp cooling is very unlikely to increase relapse risk for patients with solid tumors. Studies in adult patients have been

largely in women with breast cancer though other tumor types have demonstrated similar low risk of negative outcomes from scalp cooling. It is possible that pediatric solid tumor patients may not be completely similar to the patients in the available published studies. As a result, the enrollment in this study will be limited to only patients with solid tumors deemed to be low risk for scalp metastasis to further minimize the potential for this risk.

b. Benefits

We hope that the scalp cooling system will decrease your chances of hair loss, but this is not guaranteed. This study may also give information to help with chemotherapy hair loss in future patients.

6. **What are the risks to pregnancy, to an unborn child and to the ability to have children when taking part in this study?**
   a. **Female Risks:** Not applicable as pregnancy is an exclusion criterion for front line chemotherapy studies.
   b. **Male Risks:** Not applicable.
7. **Can you stop taking part in this study?**
   a. **Can you change your mind about participating in this research study?**
   You may change your mind about taking part in this research study and stop at any time. This decision will not affect your care or your relationship with your doctor at St. Jude. If available, you may continue to receive routine medical care at St. Jude Children's Research Hospital.

   If you change your mind about participating in this study, samples or related information that have already been given to or used by researchers will not be returned or removed.

   b. **Can you be taken out of this study without your consent?**
   Yes, you can be taken out of this study without your consent. Participants will be taken out of the study if:
      - The Study Doctor decides that continuing in the study would be harmful to you
      - Your condition gets worse, or your study evaluations are complete.
      - The Study Doctor determines you have lost more than half of your hair compared to before receiving chemotherapy.
8. **What are your other options?**

   You do not have to participate in this study at all. You have two choices. If you decide that you do not want to use the cool cap, you will still receive the chemotherapy treatment (chemo) that is planned for you.

   a. You can participate fully in this study by using the cool cap along with your chemo.
   b. You can decide to not be in the study at all and still receive your chemo.
9. **How much will it cost you?**

If you have health care coverage, we will bill your health care insurer for all standard of care services, tests, and procedures. Billing your health care insurer impacts your annual deductible and life-time maximum, if any. This may affect your health care coverage to some extent if you go to another health care provider or institution in the future.

At St. Jude, you will not be responsible for or receive bills for co-pays, co-insurance, deductibles, or similar patient-liability amounts, or for the cost of medical care not covered by your health insurer. This includes research-only costs. Research-only tests and procedures (such as optional biopsy or blood samples for biomarker testing) will not be billed to you or your health care insurer.

10. Will you be paid for your time or expenses?

You will not be paid for your time or expenses. Also, your samples and/or information may be sold or used to develop a new product or medical test, which may be sold for profit. If this happens, you will not receive any payments.

11. What if there is a problem?

If you have any questions about this study or if you are injured because of this study, contact Dr. Deena Levine M.D., at 901-595-3300 immediately. If you are injured from being in this research study, St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate. It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

12. How will new findings related to your participation in this study be shared with you?

The researcher will tell you of any new information learned during your study participation which might cause you to change your mind about continuing the study.

13. How will you find out the results of this study?

St. Jude researchers share information with people in studies in many ways including:

- Articles on www.stjude.org
- In newsletters
- In medical or scientific journals
- In the media
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by the U.S. Law. This website will not include information that can identify you. At most the website will include a summary of the results. You can search this website at any time.

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports.

14. Will any genetic tests be done and what are the risks of genetic testing?

Not Applicable: there will be no genetic testing with this study.

15. What about privacy and confidentiality?

Privacy

Information from research testing, imaging, and other procedures or studies, and other sensitive information, is relevant to your health and is placed in your medical record unless it is from a research-only laboratory. When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI (protected health information), including research information placed in your medical record, may be used or given to someone outside of the hospital. You have the right to read the Notice of Privacy Practices before you sign this form. It may have changed since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude internet website: www.stjude.org.

A decision to take part in this research means that you agree to let the research team use and share your PHI with other researchers for purposes of the study explained above. This information will be kept indefinitely. You have the right to see, copy, and ask for changes to your protected health information that will be used or given out. However, research information may not be seen until the end of the study.

These groups, agencies or people may view your information from your research and medical records:

- Food and Drug Administration (FDA)
- Office of Human Research Protections (OHRP)
- National Institutes of Health (NIH)
- Other government agencies
- Your insurance company and other health benefits plan
- St. Jude Children's Research Hospital Institutional Review Board (IRB)
- Other committees or people involved in overseeing research studies

Confidentiality

All data collected for research purposes will be de-identified. Identifying information (names, addresses, and phone numbers) will be used initially only to identify potential patients to approach. The only link between the participant identifiers and their study identifier will be kept on a password protected database. There are no patient identifiers collected and retained for research purposes.

St. Jude will be responsible for keeping the photographs, surveys, and case report forms until study completion. They will be kept in a locked file cabinet with access only by the study staff.

Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

The study is covered by a Certificate of Confidentiality from the federal government. With this Certificate, the researchers cannot be forced to give out your personal information, document, or specimen, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other process. The Certificate of Confidentiality does not protect release of information in certain circumstances. These include clinical or

research data that are placed in the medical record for the purposes of clinical research and clinical care. The researchers will use the Certificate to block any demands for information or specimens that would identify you, except in the cases listed below:

- United States Government for audit or to check federally funded projects
- To meet the needs of the FDA

This Certificate will not keep researchers or hospital staff from making reports required of them. These include the following:

- Suspected child abuse
- Disease that spread from person to person
- Threat of harm to self or others

16. What about identifiable private information and identifiable biospecimens?

No specimens will be collected for this study. Your private and health information obtained from cool cap procedures, your medical record and surveys will be kept in a secure database. The database is protected by password and an audit trail.

17. Permission to Use Your Data/Information- Permission/HIPAA

If you sign this document, you give permission to all researchers and their staff at St. Jude Children's Research Hospital 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 release for this research includes all information in the medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to your condition.

St. Jude Children's Research Hospital is required by law to protect your health information. By signing this document, you give St. Jude Children's Research Hospital permission 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.

If you sign this document, you give St. Jude permission to share your information for future research studies and for the placement of information on databases as described in #15 of this consent form. By signing, you will also give St. Jude permission to put your research information, including testing, imaging, genomic and genetic information, other information and studies, and other sensitive information in your medical record (unless the research information is from a research-only laboratory). Any information placed in the medical record becomes a permanent part of your medical record and is not protected by the Certificate of Confidentiality discussed in #15 of this consent form, but is protected like any other part of your medical record as described in the Notice of Privacy Practices.

- Trial Master Data coordinating centers that will receive and process PHI
- St. Jude Children's Research Hospital
- St. Jude Institutional Review Board

You do not have to sign this document and give your permission, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and revoke (take back) this permission at any time. Even if you revoke this permission, St. Jude Children's Research Hospital 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. To revoke this permission, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105
This permission does not have an expiration date.

18. Further Information and Contact Details for Questions about this Research Study

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with the up to date information about the drug(s)/procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor.

If there is anything you do not understand, or have any other questions, please contact the researcher listed below.

IF AT ANY TIME DURING THE STUDY YOU HAVE ANY DISCOMFORT OR UNUSUAL SYMPTOMS, OR SIDE EFFECTS, PLEASE CONTACT ANY OF THE DOCTORS LISTED BELOW.

Principal Investigator, Researcher:

Dr. Deena Levine

St. Jude Children's Research Hospital

262 Danny Thomas Place

Memphis, TN 38105

Tel: (901) 595-3300

If you require any medical or surgical treatments outside of St. Jude such as with your local doctor or another hospital during this study, your researcher and their team would need to be informed.

You can get more details about your rights as a research participant by calling the St. Jude Institutional Review Board (IRB)/ Research Participant Advocate at 901-595-4644 or 901-595-1139. The Research Participant Advocate is an individual who is not part of the research study team and is available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team.

If you decide you would like to take part in this research study, please read and sign the consent form. You will be given a copy of this information and the consent form to keep. A copy of the consent form will be put in your patient notes, one will be put with the study records, and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider taking part in this study.

PARENT/GUARDIAN STATEMENT (Required for participants younger than 18 years):

I have read this document, or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give my permission for my child to be in this research study.

_____ _____ _____AM/PM
Parent/Legal Guardian Signature Date Time (circle one)

ASSENT DISCUSSION (Required for participants 7-13 years old)

□ The research was explained to the minor participant in age-appropriate terms and the minor verbally agreed to take part in the study.

□ Minor declined to take part in the study. The minor declined for the following reason(s):_____
_____

□ An assent discussion was not initiated with the minor for the following reason(s):

□ Minor is under 7 years of age.

□ Minor is incapacitated.

□ Minor refused to take part in the discussion.

□ Other_____

RESEARCH PARTICIPANT STATEMENT (14-17 years old and Adult Participants 18 years and older):

I have read this document, or it was read to me. I have been encouraged to ask questions and all of my questions were answered. I agree to take part in this research study.

_____ _____ _____AM/PM
Research Participant Signature Date Time (circle one)

RESEARCHER/DESIGNEE STATEMENT:

I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this form has been given to the participant or his/her representative.

_____ _____ _____AM/PM
Researcher/Designee Signature Date Time (circle one)

_____
Name Printed

_____ _____ _____AM/PM
Interpreter (if needed) Signature Date Time (circle one)

For non-English speaking participants, an interpreter is required. The interpreter may serve as the impartial witness. (Need to address serving as an Advocate)

- For all therapeutic studies greater than minimal risk, add the Research Participant Advocate section
- The IRB can determine that a Research Participant Advocate is required for each consent conference as specified in the IRB determination letter. If an advocate is not required, this section can be removed.

Research Participants Advocate Statement

I observed the informed consent process. The research study, intervention/observation, risks, benefits, and alternatives were presented to the research participant and/or legal guardian(s). They were encouraged to ask questions, and research team members answered all their questions. The participant/parent(s) indicated that they: 1) understood the information presented; and 2) voluntarily consented/agreed to take part in the research.

_____ _____ _____AM/PM
Research Participant Advocate Signature Date Time (circle one)