**Official Study Title:** Prevention of Oral Mucositis in Children and Adolescents Undergoing Hematopoietic Cell Transplant Using Photobiomodulation Therapy

**CTG Number:** NCT04227340

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**PREVENTION OF ORAL MUCOSITIS IN CHILDREN AND ADOLESCENTS UNDERGOING HEMATOPOIETIC CELL TRANSPLANT USING PHOTOBIOMODULATION THERAPY**

**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 being admitted for a bone marrow transplant and at risk for severe oral mucositis, sores in your mouth and throat from chemotherapy and/or radiation given to prepare your bone marrow for the transplant.

**B. What is the usual approach to treat mucositis?**
When admitted for the transplant all patients are prescribed mouth washes to be used daily. Pain medication is used to treat the pain if mucositis occurs. Currently, there is no standard of care for preventing mucositis.

**C. Why is this study being done?**
Low level light therapy (Photobiomodulation Therapy) intra oral (device directly light in the mouth only) treatment has been included in the standards of care for adults receiving radiation to the head/neck or bone marrow transplant for the prevention or treatment of oral mucositis. It may be hard to treat some children with a device in the mouth, this study would support the use of extra oral (treating through the skin) and intra-oral (if tolerated) treatment in children, adolescents and young adults.

**D. What will happen if you decide to take part in this study?**
If you take part in the study, a nurse from the study staff will apply the light to your right and left cheek, under your chin and each side of your neck, and lastly will shine the light in your mouth. If the child or adolescent can tolerate, an intra oral light lollipop may be used instead of the light being directed into the mouth. If mouth sores are found on exam, we will treat the sore with an intra-oral light probe directly on the sore. The total treatment will take 6-7 minutes. Treatment will begin the first day of chemotherapy and continue until Day 20 or when your counts have recovered. (ANC 500 for 2 days in a row). For patients undergoing an autologous transplant, the light therapy will continue until blood counts recover and mucositis is gone for two days in a row.

**E. What are the research risks and benefits of taking part in this study?**
There is no major risk associated with the light therapy. There is a small risk of irritation caused by the light. You will be given glasses to wear during the treatment to assure the light does not bother your eyes. The benefit is possible prevention or less days with mouth sores.

**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.

**F. How many people will take part in this study?**

St. Jude would like to enroll 66 participants.

**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 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 the research study **PrOM**, more detail will be provided in the following pages.

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St. Jude Children's Research Hospital
IRB NUMBER: 19-0225
IRB APPROVAL DATE: 01/28/2021

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

You are being asked to take part in this clinical trial, a type of research study, because you are at risk for severe oral mucositis (mouth sores) from the chemotherapy and radiation. Chemotherapy and radiation are given to prepare you for a bone marrow transplant. 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 form. You will be given a copy to keep. The use of low-level light therapy has not been approved by the FDA but is now included in adult treatment guidelines for oral mucositis that develops during bone marrow transplant.

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

This study is being sponsored by St. Jude Children's Research Hospital and the Association of Pediatric Hematology Oncology Nurses Association.

The principal investigator (researcher) in charge of this study is Dr. Belinda Mandrell, who can be reached by phone at 901-595-3300, if you have any questions or concerns about this research.

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

The purpose of this study is to test the effects of low-level light in preventing or reducing the severity and number of days that patients may have oral mucositis (mouth sores) and compare the rate of mucositis to patients that previously only received the standard of care mouth washes.

This study will help the study research doctors find out if this treatment is better than the mouth washes alone. To decide if it is better, the study nurses will be looking to see if the light prevents or reduces the severity (grade) of your mouth sores during the transplant.

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

- Informed consent will be conducted during your bone marrow work-up, prior to admission. The education will include looking at and touching the light device including a demonstration of the light application using a non-functional device.
- A study nurse will begin the treatment the first full day of chemotherapy.
- Six areas will receive the light therapy: left/right cheek, under the chin, left/right neck and you will be asked to open your mouth. Each area will receive light for 1 minute, for a total of 6 minutes of treatment daily.

- If you can tolerate, an intra-oral probe resembling a lollipop will replace opening of the mouth for light therapy
- If a mouth sore is noted, an intra-oral dental light will treat the lesion for 1 minute
- While your mouth is open, we will assess for mouth sores
- We will assess your level of pain before and after the light treatment
- We will ask you and your parent six questions after each treatment, specific to pain, swallowing, eating and drinking and use of pain medications
- The light therapy will continue until Day + 20 in transplant or until your counts have recovered and your absolute neutrophil cell (ANC) count is equal to or more than 500 for two days in a row (whichever comes first).
- For autologous transplant the treatment will continue until mouth sores are gone for 2 days in a row
- You will be off study at transplant discharge, unless you are to receive a second autologous transplant. You will be removed from study at discharge of the second transplant.
- This procedure is research to determine light application in the prevention of mouth sores.

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

**Risks**

There is no major risk associated with low level light therapy. There is a small risk from eye irritation from the light. The light should not be directly aimed into the eye and the use of safety glasses is required for protection. Participants, staff and observers will wear the glasses during treatment because there is risk.

**Benefits**

You may or may not benefit from taking part in this study. However, this study treatment may help prevent or reduce your grand or oral mucositis and improve your quality of life. By taking part in this study, you may help researchers learn more about the treatment of oral mucositis which may help children and adolescents in the future.

What we learn in this study may help us develop better treatments for children and adolescents at risk for oral mucositis.

**6. What are the risks to pregnancy, to an unborn child and to the ability to have children when taking part in this study?**

There are no risks to pregnancy, an unborn child, or the ability to have children.

**7. Can you stop taking part in this study?**

Yes, you may refuse to be in this research study or stop at any time. The decision will not affect your care or your relationship with your doctor or St. Jude. If available, you may receive routine medical care at St. Jude Children's Research Hospital.

**8. Can you be taken out of this study without your consent?**

If you become acutely ill during therapy and miss 4 days in a row of light therapy, you will be taken off study. If your condition worsens, or researcher decides that continuing the study would be harmful, you will be taken off the study.

**9. What are your other options?**

Your other options include not participating in this research study. You can receive standard of care therapy which includes daily mouth washes.

**10. How much will it cost you?**

If you have healthcare coverage, we will bill your health care insurer for all standard of care services, tests, and procedures. Billing your healthcare 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. The research-only tests and procedures, such as the light therapy, will not be billed to you or your health care insurer.

**11. Will you be paid for your time or expenses?**

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

**12. 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. Belinda Mandrell , 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.

**13. 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.

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

The researcher will give you information about the overall results of this study. Whether you will know your personal test results will be discussed in another part of this document. 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.

**15. What about privacy and confidentiality?**

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) may be used or given to someone outside 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.

Federal agencies such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), the National Institutes of Health (NIH), and St. Jude Children's Research Institutional Review Board (IRB), your insurance company and

other health benefits plan (if charges are billed to these plans), as well as other regulatory agencies, committees, or persons involved in overseeing research studies may review your research and medical record.

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at St. Jude. Your name will not be passed to anyone else outside the research team or the Sponsor, who is not involved in the trial. You will be given a trial number, which will be used as a code to identify you on all trial forms. Any research-related information about you which leaves the hospital will have your name and address removed so that you cannot be recognized.

Your records will be available to people authorized to work on the trial.

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.

**16. Permission (Authorization) to Use Your Data/Information: HIPAA**

If you sign this document, you give permission to the study 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 disclose (release) for this research includes your age, sex, primary diagnosis, transplant type, conditioning regimen, radiation dose time to engraftment, days of nutritional support utilization of pain medication and results of positive oral, nasal or blood cultures during transplant.

The health information listed above may be used by and/or disclosed (released) to all researchers and their staff at St. Jude Children's Research Hospital.

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

The following entities will disclose information:

- St. Jude Institutional Review Boards or Data Safety and Monitoring Boards
- Clinical research monitors/auditors
- Institutional Biosafety Committee
- Internal Monitoring Committee Members
- St. Jude Scientific Review Board
- Association of Pediatric Hematology Oncology Nurses Association

If the research study is conducted by an entity other than the covered entity, the authorization need only list the name or other identification of the outside researcher (or class of researchers) and any other entity to whom the covered entity is expected to make the disclosure.

- You do not have to sign this Authorization, 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 Authorization at any time. Even if you revoke this Authorization, 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 Authorization, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105

This Authorization does not have an expiration date.

## 17. 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 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 EXPERIENCE ANY DISCOMFORT OR UNUSUAL SYMPTOMS, OR SIDE EFFECTS, PLEASE CONTACT ANY OF THE DOCTORS LISTED BELOW.**

**Principal Investigator, Researcher:**

Belinda Mandrell, PhD, RN

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 at 901-595-4357 or the 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 are outside of the Memphis area, please call toll-free 1-866-583-3472 (1-866-JUDE-IRB).

If you decide you would like to take part then 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 filed in your patient notes, one will be filed 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 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 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 my questions were answered. I agree to take part in this 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

Research/Designee Signature Date Time (circle one)

_____

Print Name

_____ _____ _____AM/PM

Interpreter (if needed) Date Time (circle one)

PLEASE FAX CONSENT FORM TO CLINICAL TRIALS OPERATIONS
SCAN and EMAIL to: protocoleligibilityoffice@stjude.org or FAX to: (901) 595-6265