Informed Consent Form

RAD4737-19: Feasibility of Vertebral Body Sparing Intensity Modulated Proton Therapy Craniospinal Irradiation with in Vivo Range Verification in Growing Children

NCT Number: NCT04276194

Document IRB Approval Date: 11/1/2019

You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 10 people who are being studied at Emory.

Why is this study being done?
This study is being done to answer the question: Can the entire brain and spine be treated with proton therapy while avoiding the vertebral bodies in order to reduce the side effects of treatment? You are being asked to be in this research study because you require radiation to the brain and spine for a brain tumor.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for the duration of radiation therapy which will be 6 weeks, plus 1 year of follow-up procedures. The researchers will ask you to do the following: Have an MRI of the spine (without contrast) 3-4 times during the course of your radiation treatment and have additional blood drawn at the same time as regular blood draws, as well as toxicity assessments & follow-up procedures. These will be performed at the Emory Proton Therapy Center at the same time as a scheduled treatment. All of these procedures are part of the standard care and should be covered by medical insurance, or will be at no additional cost to you. You may require sedation during radiation treatment, and if so, you will be asked to sign a separate clinical consent form with the anesthesiologist that will provide more details of the risks of that procedure. You will also be asked to sign a separate clinical consent form addressing the risks of craniospinal irradiation as part of your standard of care treatment.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. You may also benefit because you will receive less radiation exposure to your spinal column and body.

What are the risks or discomforts I should know about before making a decision?
The study will take time. The procedure that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include losing time due to the MRI scans, having irregular growth of the spine, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study

You may receive standard of care radiation therapy out side of the study.

Costs

You MAY have to pay for some of the study procedures. All of the treatments you will receive are part of the standard care and should be covered by medical insurance. We will work closely with your insurance to get this therapy covered. If it is not covered, you will be responsible for the cost. The study team can help you work out how much you might have to pay. There is more information in the cost section below.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University and Children's Healthcare of Atlanta
Consent to be a Research Subject / HIPAA Authorization

Title: Feasibility of Vertebral Body Sparing Intensity Modulated Proton Therapy Craniospinal Irradiation with MRI in Vivo Range Verification in Growing Children

Principal Investigator: Bree Eaton, MD

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** 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.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to test whether the entire brain and spine can be safely and effectively treated with proton therapy while minimizing the radiation exposure to the vertebral bodies. Proton therapy is an advanced form of radiation treatment that has reduced radiation exposure to normal tissues than photon (x-ray) radiation. Because proton therapy stops in the body with minimal to no exit dose, it may allow for us to treat the spinal canal while simultaneously reducing or even eliminating the radiation dose delivered to the vertebral bodies, which is not possible with photon (x-ray) radiation. The study is also designed to test whether MRI imaging of the spine during treatment can confirm that the treatments have been delivered appropriately.

What will I be asked to do?

You will receive standard of care proton therapy craniospinal irradiation treatment and you will asked to sign a standard clinical consent explaining the risks of this treatment. You will be asked to complete up to 4 MRIs of the spine, without contrast, at the Emory Proton Therapy Center during the course of your treatment. Once a week during your treatment CT scans will be done while you are being treated to make sure treatments are delivered appropriately. An additional tube(s) of blood will be drawn for study blood tests up to 5 times during the course of this study. This will be done during your routine blood draws so that no additional sticks or pokes are required.

Who owns my study information?

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

- The extra time it will take to have the additional MRI. If you require sedation or anesthesia for treatment or MRIs, this may extend the amount of time you are asleep.

The less common risks and discomforts expected in this study are:

- Anxiety or worry about the clinical trial or the MRI.
- Decreased blood counts from having your blood drawn

Rare but possible risks include:

- Injury during the MRI
- Inaccurate delivery of the radiation therapy
- Abnormal growth of the spine

If you are a woman: to protect against possible side effects of the study, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you are a man: you should not get a sexual partner pregnant while receiving radiation for 6 months after completing treatment. You and the study doctor should agree on a method of birth control to use throughout the study.

MRI Risks: MRI exams use powerful magnets to create images of the body. In addition to the possible reactions to contrast materials, you may feel claustrophobic while in the magnet, and will hear loud beeping or hammering noises. If you have tattoos or any metal items in your body such as implants, pacemakers, clips or shrapnel, we will do special screening to make sure your MRI scan is done safely.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study may or may not benefit you directly. This study is designed to learn more about new delivery techniques for proton therapy. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will get $25 for each completed MRI, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $100 total, if you complete all study visits.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. You can receive standard of care proton craniospinal radiation treatment. The study doctor will discuss these with you. You do not have to be in this study to be treated for your brain or spine tumor.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

No results returned to participants

In general, we will not give you any individual results from the study of the information you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory and Children's Healthcare of Atlanta patient before, then you already have an Emory and Children's Healthcare of Atlanta medical record. If you have never been an Emory and Children's Healthcare of Atlanta patient, you do not have one. An Emory and Children's Healthcare of Atlanta medical record will be made for you if an Emory and Children's Healthcare of Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Children's Healthcare of Atlanta medical record you have now or any time during the study.

Emory and Children's Healthcare of Atlanta may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Children's Healthcare of Atlanta medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Emory and Children's Healthcare of Atlanta places may not become part of your Emory and Children's Healthcare of Atlanta medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Bree Eaton at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Children's Healthcare of Atlanta will help you to get medical treatment. Neither Emory, nor Children's Healthcare of Atlanta will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and Children's Healthcare of Atlanta have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory and Children's Healthcare of Atlanta, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or Children's Healthcare of Atlanta employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

The study will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study does not pay. The study will not pay for your regular medical care. If you have insurance, Emory and Children's Healthcare of Atlanta will submit claims to your insurance for items and services that the study does not cover. Emory and Children's Healthcare of Atlanta will send in only those claims for items and services that it reasonably believes your insurance will pay and that the study has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and Children's Healthcare of Atlanta will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Children's Healthcare of Atlanta will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation: if it was felt there was no ability to reduce the radiation exposure to your vertebral bodies.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Study

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.

- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study. [

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Children's Healthcare of Atlanta may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The research team and may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Children's Healthcare of Atlanta offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration;

  - Public health agencies.
  - Research monitors and reviewer.
  - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Bree Eaton, MD at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____ _____ **am / pm**

Signature of Subject (18 or older and able to consent) or Parent/Legal Guardian **Date** **Time (please circle)**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____ _____ **am / pm**

Signature of Person Conducting Informed **Date** **Time (please circle)**