Institutional Review Board
Informed Consent Document for Research

Principal Investigator Dr. Eric Shinohara
Study Title Prospective Observational Trial of Neoadjuvant Hypofractionated Radiotherapy Followed by Immediate Surgical Resection in the Treatment of Soft Tissue Sarcomas
Institution/Hospital Vanderbilt University Medical Center
Revision Date 3/21/2023 **NCT04506008**
Version Number 4

This informed consent applies to adults

Name of participant:_____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have a soft tissue sarcoma (STS) for which your doctors have recommended radiotherapy prior to surgical removal of your tumor. Radiation is typically given over 5-6 weeks prior to surgery over 25-28 treatments. A new form of radiation, called hypofractionation (HRT), decreases the number of radiation treatments. HRT has been used effectively in many other types of cancer, but its use in sarcomas is relatively new. Potential risks of this study are that HRT may be less effective than a 5-6 week course of radiation in preventing your tumor from coming back and that there may be slower healing with more surgical complications and joint stiffness. However, multiple small studies suggest that HRT is safe when used prior to surgery for sarcomas. In addition, two studies have performed surgery within seven days of HRT instead of waiting the traditional 4-5 weeks. In order to study this further, the experimental portion of this study would replace the 25-28 day course of radiation with five treatments (ultra-hypofractionation UH) or fifteen treatments (moderate hypofractionation MH) of HRT (as determined by your provider). Surgery may be performed immediately (<7 days after completion of radiation) or using a traditional interval of 3-6 weeks as determined by your surgeon.
The purpose of this study is to investigate the effectiveness, side effect profile, and quality of life in people who have HRT followed by immediate surgery for their sarcoma. The potential benefit for your involvement in this study is that your entire treatment would last 2-8 weeks compared to 2-3 months. Approximately 40 total patients will be enrolled in this trial.

2. What will happen and how long will you be in the study?

Initial Clinic Visit
You will be given the opportunity to enroll in this clinical trial during your initial radiation or surgery consultation. During this time a complete history and physical exam will be performed.

Should you choose to enroll on the study, additional information will be collected:

Your doctor will ask you questions about other health issues you may have.

Your skin in the area of the tumor will be examined as well as how well your joints work in the area of the tumor.

Planning scans for radiation will be scheduled during this visit.

The radiation oncologist will decide whether you are eligible for the UH, MH or both regimens.

Within 21 days of enrollment
You will start radiation treatments. You will have weekly visits with your doctor where they will ask you about your skin.

Completion of radiation
The doctor will see you and assess your skin.

Within 7 days of completion of radiation

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If you are in the immediate surgery arm, you will have surgery with appropriate pre-operative testing. Your skin and joint function may be evaluated prior to surgery.

Within 3-6 weeks of completion of radiation

If you are in the standard surgery arm, you will have surgery with appropriate pre-operative testing. Your skin and joint function may be evaluated prior to surgery.

Within 3 weeks of surgery

You will have follow up with radiation oncology or surgery. Your doctors will evaluate how your incision is healing. You will have your first set of scans to check for any residual tumor. Your skin and joint function may be checked.

Within 3 months of surgery

You will have follow up with radiation oncology and surgery. Your doctors will evaluate how your incision is healing. You will have your first set of scans to check for any residual tumor. Your skin and joint function will be checked.

Every 3-6 months after 3 month follow up

You will be seen by radiation oncology and surgery. At each visit your doctor will check to see how your incision is healing and a scan to check for tumor recurrence will be ordered. Your skin and joint function will also be checked.

Questionnaires

At several time points during the study, you will be asked to complete two questionnaires that will help us to understand your functional status. These questionnaires are the Toronto Extremity Salvage Score and the PROMIS-29. You will be asked to complete each of these questionnaires at your initial clinic visit; just before your surgery; 3 weeks postoperative; 3 months postoperative; and every 3-6 months post operatively. Your physician will also fill out an assessment of your status called the MSTS Extremity Functional Outcome Score at the time of your initial clinic visit, 3 weeks after your surgery, and at every 3-6 months post-operative.

3. Costs to you if you take part in this study

You are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance. HRT may or may not be covered by your insurance company. You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study

The investigational portion of this research study involves replacing the 25-28 day course of radiation with five or fifteen treatments of HRT followed by surgery. Risks include: The shorter course of radiation may be less effective at preventing your tumor from growing back or you may have more wound complications such as, radiation dermatitis, fibrosis, impaired wound healing, damage to the surrounding tissue, or joint stiffness. You will also be asked about your skin and joint function through surveys multiple times during the course of this study. There are also the risks of a potential breach of confidentiality. All precautions are taken to minimize this risk, as your questionnaire and skin assessment data are maintained as securely as your other medical records. However, there is the small risk for the potential breach of confidentiality.

5. Risks that are not known

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Because this treatment is investigational, there may be risks that we do not know about at this time.

6. Payment in case you are injured because of this research study

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

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There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

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7. Good effects that might result from this study

a) The benefits to science and humankind that might result from this study include demonstrating the efficacy of preoperative HRT and immediate surgical resection for the treatment of sarcoma, allowing patients with sarcomas to be treated in a much more rapid and convenient fashion.
b) The benefits you might get from being in this study include decreased travel time.

8. Other treatments you could get if you decide not to be in this study

The same standard of care therapies are available to you off-study if you choose not to participate.

9. Payments for your time spent taking part in this study or expenses

There are no payments to the participant for participating in this study.

10. Reasons why the study doctor may take you out of this study

If we are unable to perform HRT for any reason, you cannot participate in this study and you would receive a standard 5-6 week course of radiation. If early on in the study there appears to be more side effects associated with HRT, the study may be stopped early and you will be informed immediately. If you are removed from the study for any reason, we will inform you of the reason you have been taken out of the study.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

12. Who to call for any questions or in case you are injured

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Eric Shinohara [redacted]

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality

Records and data collected in this study will be maintained in your Vanderbilt University Medical Center patient chart accessible by the medical staff that performs direct medical care for you. Data analyzed in this clinical trial will be stored in a secure online database (REDCap) and accessed by secure computers on the Vanderbilt network.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Eric Shinohara and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

14. Authorization to Use/Disclose Protected Health Information

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All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Eric Shinohara and his study team may share the results of your study and/or non-study linked results (such as radiation planning records) as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and insurance companies for billing purposes. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Eric Shinohara in writing and let him know that you withdraw your consent. [redacted] At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____ Time _____

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Date of IRB Approval: 04/12/2023
Date of Expiration: 12/20/2023

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