Department/Section of Department of Radiation Oncology

THE ROLE OF HISTAMINE IN BREAST CANCER BONE PAIN.

Informed Consent Form to Participate in Research
Doris Brown, M.D., Ph.D., Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have cancer that has spread to the bone. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

We are investigating the association between cancer bone pain and the levels of a chemical in the blood called histamine. A better understanding of this association may advance our efforts to reduce cancer bone pain and perhaps prevent further bone metastasis.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 32 people will take part in this study. This study is only being done at the Comprehensive Cancer Center of Wake Forest University (CCCWFU).

WHAT IS INVOLVED IN THE STUDY?

As part of this study, you'll undergo the best treatment for the cancer that has spread to the bone. This may include medications given to you by your medical oncologist (chemotherapy, hormone therapy, bone strengthening medications, etc.) and/or radiation therapy that is standard treatment for palliation of cancer that has spread to the bone causing pain. You will be assigned to one of the following two groups:

Group 1 – patients who are not undergoing radiation for bone pain
Group 2 – patients who are undergoing radiation for moderate to severe bone pain

Before Study (All Groups)

Before you begin the study you will need to have the following to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study.

Physical examination including: Neurologic exam (testing the brain and nervous system), radiologic imaging (X-ray, CT, or MRI) to check your bones, for fractures or measure bone structural properties. If you are female, you will have a blood (serum) pregnancy test done.

Evaluation of your ability to carry out your daily activities.

You will have approximately 1.5 tablespoons of blood taken from a vein in your arm for research purposes. You will be asked to complete surveys that evaluate your quality of life and other outcomes.

You will be asked to identify how much pain you are having by choosing a number from 0 (no pain) to 10 (the worst pain imaginable) as well as by completing a short survey about your pain. This could also be done over the phone or by mail. You will be asked what other medicines including pain medicines, if any, you are taking and what dose and how often you take the medicine.

Radiation Treatment and Study Follow-up (Group 2 only)

If your pain is severe enough to warrant radiation treatment (as standard care, not for research purposes), we will monitor your pain as well as any changes seen in the blood and on X-ray or CT imaging after radiation. This information will be compared to the information we obtained before your radiation treatment in order to better understand how the radiation affects these factors.

At one month after you finish treatment, we will call you on the phone and ask you to identify how much pain you are having by choosing a number from 0 (no pain) to 10 (the worst pain imaginable). We will also ask you to tell us about changes to your medications and any unusual or adverse symptoms you may be experiencing.

In the follow-up visits (1, 3, and 6 months after treatment) you will receive the following tests/questions/procedures to see how you and your cancer were affected by the treatment you received. Some of these tests and procedures are part of regular cancer care.

- Completion of a short survey about your pain.
- Pertinent physical examinations by your doctor.
- You will have approximately 1.5 tablespoons of blood taken from a vein in your arm for research purposes.

Evaluation of any side effects you may be experiencing.

You also will be asked about any unusual symptoms you may be experiencing. You will be asked to identify how much pain you are having by choosing a number from 0 (no pain) to 10 (the worst pain imaginable) as well as completing a short survey regarding your pain.

You will be asked what other medicines including pain medicines, if any, you are taking and what dose and how often you take the medicine. You will be asked to complete surveys that evaluate your quality of life and other outcomes.

If you are undergoing any other cancer treatments during your time on this study, this 3-6 month follow-up visits can be done by your treating physician. The study coordinator or nurse may call you on the phone to ask you about your pain level, adverse symptoms, and the quality-of-life questionnaires within 5 days of this visit.

Storage of Biological Tissue

If you agree to participate in this study, we will have approximately 1.5 tablespoons of blood withdrawn from a vein before treatment and again 1, 3, and 6 months later to use for future research. This sample will be kept and may be used in future research to learn more about other diseases. Your sample will be obtained in the CCCWFU. The sample will be stored in the CCCWFU by Dr. Yusuke Shiozawa and it will be given only to researchers approved by Dr. Shiozawa. An Institutional Review Board (IRB) must also approve any future research study using your tissue sample.

Your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

In the future, people who do research may need to know more about your health. While the study investigator may give reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to be contacted in the future.

____YES you many contact for future research studies

____NO I do not want to be contacted regarding future research studies.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 6 months, or until the study has completed recruiting patients. You can stop participating at any time.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.
You will be asked questions about your pain, how you feel about your pain, the type of pain medication you are taking, and how well it is working. While many of these questions are part of regular cancer care, you may feel the emotions that are being asked about more intensely while fulfilling the questionnaires.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure

and allowing only authorized people to have access to research records, will be made to keep your information safe.

At the time of blood draw, you may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. We will follow all standard procedures for blood collection to keep you as safe as comfortable as possible during each blood draw. Frequent donation of blood can result in low iron in your blood (iron deficient anemia); the risk of this occurring after such a small amount of blood draw is very low.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive direct benefit from participating in this study. We do know that the information from this study will help researchers learn more about breast cancer bone pain and the effects of radiation therapy for the treatment of cancer that has spread to the bone. This information could help future cancer patients by allowing us to better detect, characterize, and potentially prevent further spread to bones.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you may simply choose not to participate. The treatments will be up to you and your doctor and will be according to accepted standards of care.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: disease status, medical conditions, demographics, pain, medications, radiation history, chemotherapy history, quality of life, social support, performance status, and other information.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You can tell Doris Brown, M.D. that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Doris Brown, M.D.
Wake Forest University
Medical Center Blvd
Winston Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by 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 Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

Parking validation will be provided for all study-related visits.

You will receive no payment or other compensation aside from parking validation for taking part in this study.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Science.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Doris Brown, M.D. at 336-713-3600 (or 336-716-2011 after hours).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm