Pectoralis (II) Block with Liposomal Bupivacaine vs Bupivacaine plus Dexamethasone for Mastectomy with Immediate Reconstruction

NCT Number: NCT03383198

Date: 11Jan2019

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Pectoralis (II) Block with Liposomal Bupivacaine vs Bupivacaine with Dexamethasone for Mastectomy with Immediate Reconstruction

Study to be conducted at: Greenville Health System
Greenville Memorial Hospital
701 Grove Road
Greenville, SC. 29605

Greenville Health System
Patewood Memorial Hospital
175 Patewood Drive
Greenville, SC. 29615

Sponsor Name: Greenville Health System

Principal Investigator: William R Hand, MD (864-455-8300)

INTRODUCTION

You are being asked to participate in a research study. The Institutional Review Board of the Greenville Health System has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations. However, before you choose to be a research participant, it is important that you read the following information and ask as many questions as necessary to be sure that you understand what your participation will involve. Your signature on this consent form will acknowledge that you received all of the following information and explanations verbally and have been given an opportunity to discuss your questions and concerns with the principal investigator or a co-investigator.

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.

PURPOSE

You are being asked to participate in this study because you are having breast surgery for a medical reason. This surgery will require anesthesia, and one component of this anesthesia is the use of local anesthesia (numbing medicine) to help with pain during and after surgery. This study is trying to better understand how long different local anesthetics (numbing medicines) last for this surgery.

Approximately 10 participants will be enrolled in this study at either Patewood Memorial Hospital or Greenville Memorial Hospital. Your participation in this study is expected to last no longer than 72 hours. Participation will include questions about your medical history and what medications you are taking, having the medicine injected after you are asleep for surgery, and verbal pain scale ratings on a scale of 0-10 at several intervals after surgery. Participation will also include us calling you after your hospital discharge to follow up on your pain or lack of pain. This study is considered a pilot study.

PROCEDURES

If you decide to participate in the study, you will be asked to sign this informed consent form prior to beginning any study activities. The study procedures are as follows:

- The participants enrolled in this study will receive liposomal bupivacaine and aqueous bupivacaine injected near their armpit (PEC II block). Enrollment in this study is not considered standard of care.
- The side of your body that the liposomal bupivacaine will be placed on will be randomly determined. Randomization means the study team has no say in what side the medicine goes on. Your information is put into a computer and the computer picks what side to place the medicines. The study team will open an envelope, which will state which side the liposomal bupivacaine (right or left side) will be injected into. There is an equal chance for the liposomal bupivacaine to be placed on the right or left side. The use of liposomal bupivacaine is not considered standard of care, but the aqueous bupivacaine used on the other side is standard of care.
- You will be asked to verbally rate your pain using a numerical rating scale (0 – 10) in relation to both sides of your wound after surgery. You will also be asked if you feel pain any differently on either side of your body, and if so, what feels different between the sides. You will be asked about your pain score at 2 hours, 4 hours, 6 hours, 8 hours, 12 hours, 18 hours, 24 hours, 30 hours, 36 hours, and 48 hours after surgery. Your pain score will be taken throughout your hospitalization and by phone after you leave the hospital. Some of these time points will be considered standard of care and others will not.
- Information from your medical records will be collected throughout this study. You will also be asked questions about your medical and surgical history as well as what medications you are currently taking. This is considered standard of care.
- Your demographic information will be collected, including your age, date of birth, race, sex, height, weight, and ethnicity. This is considered standard of care.

POSSIBLE RISKS

Any treatment has possible side effects. The treatments and procedures used in this study may cause all, some, or none of the side effects listed. There is always the risk of very uncommon or previously unknown side effects happening.

The possible risks associated with liposomal bupivacaine are reported to occur less commonly than with aqueous local anesthetics, and they include:

- Ringing in ears
- Numbness around the mouth
- Seizure
- Low blood pressure
- Death (very rare)

Other possible risks and discomforts may include:

- An allergic reaction to the medicine(s). Allergic reactions may range from minor itching or rash to major reactions, which can lead to death.
- The possible release of your personal health information. Your study records are considered confidential, but absolute confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

POSSIBLE BENEFITS

It is not possible to know whether or not you may benefit from participating in this study. The treatment or procedures you receive may even be harmful. The information gained from this study may be used scientifically and may be helpful to others.

It is questionable that there will be any immediate benefit to you or the other participants in this study; however, future care may be enhanced. By evaluating whether the liposomal bupivacaine works longer, patient care could be impacted by reducing pain during and after surgery.

ALTERNATIVE (OTHER) TREATMENTS

You can still receive evaluation and treatment for your condition if you do not participate in this study. Discuss any alternative treatments with your regular doctor and/or the study doctor before you decide to participate in the study. The decision to participate is entirely up to you. If you decide not to participate in the study, you will not be penalized or lose any benefits, and your decision will not affect your relationship with your doctor or hospital.

COST TO YOU FOR PARTICIPATING IN THIS STUDY

Although study funds will pay for certain study-related items and services, we may bill your health insurer for routine items and services that you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If you are confused about what is or is not paid for in this study, please discuss this with your study doctor or study staff.

Procedures performed as part of standard of care (routine) and procedures performed specifically for this study (not as part of standard of care) have been outlined in the procedure section of this informed consent form. The procedures that are performed as part of standard of care will be billed to your insurance company. You will be responsible for any co-payments, deductibles, or costs that your health insurer does not cover. The cost of the liposomal bupivacaine and pharmacy charges related to liposomal bupivacaine will be paid for by the study.

PAYMENT FOR PARTICIPATION

To You:

You will not be paid to participate in this study.

To Investigators:

The investigators will not be paid above their regular salaries for conducting this study.

COMPENSATION FOR INJURY AS A RESULT OF STUDY PARTICIPATION

The Greenville Health System will provide you the care needed to treat any injury or illness that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties for the care you get for the injury. You may be responsible for these costs. For example, if the care is billed to your insurer, you will be responsible for the payment of any deductibles and co-payments required by your insurer, or even possibly the entire cost of the service.

Injuries sometimes happen in research even when no one is at fault. The Greenville Health System or the investigators as part of this study have no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the 'Contact for Questions' section of this consent.

VOLUNTARY PARTICIPATION

Participation in this study is completely voluntary (your choice). You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits. Your decision will not affect your relationship with your doctor or hospital.

In addition, your study doctor may stop your participation in this study at any time if he/she believes it is in your best interest, if your medical condition changes or for any other reason. Greenville Health System may also end the study at any time.

If your participation in this study is stopped, your study doctor will discuss any tests or procedures that may be needed for your health and safety. You may refuse any or all of these recommended tests.

NEW INFORMATION

During this study, you will be told of any important new information that may affect your willingness to participate in this study.

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical records that is related to the research study.

Your study doctor and his/her research team will collect the following health information during the study: your gender, age, recent medical history, previous surgeries, recent hospitalizations, and current medications. Additionally the location of each medication injection will be documented and patient pain scale scores (0-10) will be collected throughout the study.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. To evaluate the results of the study and for compliance with federal and state law, your health information may be examined and copied by the Institutional Review Board of the Greenville Health System. This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

To help protect your confidentiality and to enhance the protection of your medical records the study physician will assign a coded patient ID number at the time of consent. The coded patient ID number will be tracked for study purposes and for data processing. The coded patient ID numbers will be placed on all study related items (standard numerical pain scale (0-10) scores and data collection sheets) for each participant. All data collected for this study will be stored in a GHS password-protected computer. The

digital data will be maintained on a password-protected GHS computer for 3 years after the study has ended.

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

If you have any questions about the privacy of your health information please ask your study doctor.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, William R Hand, M.D. at (864)-455-8300.

You may also contact a representative of the Institutional Review Board of the Greenville Health System for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

CONSENT TO PARTICIPATE

My study doctor, _____, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given a copy of my study doctor's Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I understand I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant Date Time

_____ _____ _____
Signature of Witness Date Time

INVESTIGATOR STATEMENT

I have carefully explained to the participant the nature and purpose of the above study. The participant signing this consent form has (1) been given the time and place to read and review this consent form; (2) been given an opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and (3) appears to understand the nature and purpose of the study and the demands required of participation. The participant has signed this consent form prior to having any study-related procedures performed.

_____ _____ _____
Signature of Investigator Date Time

Principal Investigator	**Phone**
William R Hand, MD	(864) 455-3264

Co-Investigators	**Phone**
Andrea Nisonson, MD	(864) 455-3264
Elizabeth Faucher, MD	(864) 455-3264
Wendy Cornett, MD	(864) 455-7886
Lily Fatula, MD	(864) 455-3264

_____
Participant's Initials