Consent Form

Ultrasound-guided Pec infiltration with liposomal bupivacaine for breast surgery: A prospective randomized study.

Researcher Team Contact Information: Jason Habeck MD

For questions about the research study, research results, or other concerns, call the study team at:

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Supported By: This research is supported by the Department of Anesthesiology at the University of Minnesota.

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

What is research?

Doctors and researchers are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Researchers learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of treatment is to help you get better or to improve your quality of life. Doctors can make changes to your treatment plan as needed.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you will be undergoing elective lumpectomy or partial mastectomy +/- axillary node dissection.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to evaluate a pain control method for patients undergoing elective breast lumpectomy/partial mastectomy procedures to see if one method works as well or better than the other. This method has been used in clinical care, but it is not known exactly how effective it is. We want to find out if pectoralis liposomal bupivacaine infiltration ("Pec block") with Exparel will provide as or more effective and safe pain control compared to incisional bupivacaine infiltration.

How long will the research last?

We expect that you will be in this research study for 72 hours following your procedure with additional

follow-up phone calls from the research team at 3, 6, and 12 months.

How many people will be studied?

We expect about 112 people will be enrolled in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you agree to participate in this study, we would ask you to consent to have a member of the anesthesia team talk to you about your pain each day for the first 3 days after surgery. In addition, we ask consent to access your medical chart to obtain information regarding narcotics use and presence or absence of complications. We also ask that you are willing to complete a questionnaire related to your quality of recovery on post-operative day 3.

In addition, we ask that you consent to be put in one of two groups: (1) Patients receiving pectoralis liposomal bupivacaine infiltration ("Pec block") or (2) Patients receiving a bupivacaine infiltration directly into the incision space. Both medications are the standard treatment. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given either treatment.

If you are randomly assigned to group 1:
A Pec block will be placed prior to surgery using ultrasound guidance. A numbing medication (liposomal bupivacaine) will be injected into the pectoralis minor muscle layer and in the space beneath pec minor above the serratus anterior muscle. Upon completion you will be monitored in the preoperative area until you are brought into the operating room for your procedure.

If you are randomly assigned to group 2:
You will have a bupivacaine injection into the dermis and subcutaneous space while you are in the operating room after undergoing anesthesia just prior to incision. Throughout the procedure additional incisional bupivacaine infiltration into the surrounding tissues will be performed as needed for local anesthesia.

Patients in both groups will have pain assessed by the study team after the procedure at 1, 2, 6, 24, 48, and 72 hours. If you are discharged home, you will be contacted to assess your pain over the phone or via text message if you prefer. During these intervals we will collect information on opioid use and any related complications. Following discharge from the hospital you will be instructed to take acetaminophen 1000mg every 8 hours for 3 days. You will be given a prescription for opioid pain medication of either oxycodone or hydromorphone and will be instructed to take as needed for pain. Additional follow-up contacts from the research team will occur at 3, 6, and 12 months.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to discuss your pain scores and pain medication use with a member of the anesthesia team.

What happens if I do not want to be in this research?

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current of future relations with the University of Minnesota. The alternative to this study is to receive the standard of care without data being collected.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time. Leaving will not be held against you. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Meaning, your choice not to be in this study will not negatively affect your right to any present or future medical treatment. You have the right to ask questions about the study at any time.

During the study, your study doctor or a member of his staff will answer questions you may have about the study. During the study, the study doctor or a member of his staff will tell you about any important new facts about the study drug that may reasonably change your decision to continue in the study.

What are the risks of being in this study? Is there any way being in this study could be bad for me?

The following risks of participating in this study include:

- Failure of the block
- Wound infections
- Complications related to placement of the Pec block including: lung perforation, nerve injury or intravascular injection.
- Local anesthetic toxicity

These complications all fall within the standard risks of surgery. Any intervention being provided as a part of this study falls within the standard of care of Pec infiltration and surgeon infiltration and are within the standard treatments for post-operative pain and are currently used as analgesic options at UMMC. There may also be unforeseen risks that will be treated as necessary by the operating physician. Any complications will be noted and treated as needed by the operating physician and reported to the Institutional Review Board (IRB) and research staff. No provision has been made for financial payments or other forms of compensation (such as lost wages, medical cost reimbursement, lost time or discomfort) with respect to such injuries**.** No arrangement has been made for further compensation from UMMC. However, patients do not waive any legal rights by signing a consent form.

Effects of the Study Drugs:

EXPAREL contains bupivacaine. Serious side effects related to bupivacaine are not common, but may occur if too much is given or if it is accidentally injected into a blood vessel. Given incorrectly, side effects may involve the brain and spinal cord or the heart. The effects on the brain and central nervous system may include:

• Restlessness
• Anxiety
• Dizziness
• Tinnitus (ringing in the ears)
• Blurred vision
• Tremors (shaking) possibly proceeding to convulsions.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

Will it cost me anything to participate in this research study?

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to others from your taking part in this research.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research

study and medical records, to people who have a need to review this information. Confidentiality cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at 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.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting (or a recording of your consent meeting). Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not record any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting (or a recording of your consent meeting) without your permission ahead of time.

Who do I contact if I have question, concerns or feedback about my experience?

You may ask any questions you have now, or if you have any questions later you are encouraged to discuss this study with your family, care team, or anyone else.

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

After the study, you might be asked to complete a survey about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information

What else do I need to know?

In the event that this research activity results in an injury, treatment will be available, including first aid,

emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

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Signature of Participant Date

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Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent