

Bassett Healthcare Network

Study Title: [Liposomal bupivacaine versus bupivacaine for interscalene nerve block for postoperative pain control in shoulder arthroscopy and arthroplasty: a prospective randomized controlled trial.](#)

Principal Investigator: Linda Demma, MD, PhD

Key Information: You are being asked to take part in this research project because you are having shoulder surgery that requires anesthesia. The study is comparing two types of nerve blocks that are given before surgery to provide pain relief both during and after the procedure. Information regarding your pain levels, what medicines you are taking for pain, and how you are doing in general will be collected by telephone for three days after your surgery. Both types of blocks are approved by the Food & Drug Administration (FDA) for this purpose and there are no additional risks expected above and beyond those risks already known to be associated with shoulder surgery and the administration of nerve blocks. Participation in this research study is voluntary and will include only people who choose to take part. You may choose not to participate and receive your anesthesia care according to the clinical judgment of your anesthesiologist and surgeon. Please read this consent form carefully and take your time making your decision. Please ask your research doctor or research staff to discuss this consent form with you and explain any words or information that you do not understand.

Purpose of the Study: The purpose of this study is to compare liposomal bupivacaine versus standard bupivacaine interscalene nerve blocks for postoperative pain control in patients having shoulder surgery. Approximately 90 patients will participate in the study.

Procedures to be Followed:

- Eligible patients who choose to participate in the study will be required to review and sign this consent form prior to surgery.
- Consented study participants will be randomized (like a flip of a coin) to receive either liposomal bupivacaine or standard bupivacaine prior to surgery. Participants will be randomized in a 1:1 ratio, which means you would have a 50 % chance of getting one type of block versus the other. Everyone in the study gets one drug or the other. There are no placebos given in this study. Participants will not know which study drug they have been given until the study is done. The anesthesiologist administering the block will know which study drug is given. This is called a single blinded study.
- You will receive a phone call from a study staff member each day for the first three days after your surgery to ask you about your pain levels, how much pain medication have you taken, have you had any side effects, and how you are doing in general.
- After you have completed your phone interview on the third day after your surgery, your participation in the study is complete.
- Research staff members will collect information from your medical chart such as: the type of surgery you received, how long the surgery took, what other medications were given in the hospital for pain control, etc.

Discomfort and Risks: Interscalene blocks are often offered as part of routine pre-operative care. There are no expected additional risks from participating in the study versus receiving a block as part of regular care.

Known complications from interscalene blocks are rare, but may include:

- allergic reaction
- Horner syndrome, causing droopy eyelid, watery eyes, and numbness in the back of the throat
- hematoma, or an abnormal collection of blood outside of the blood vessels
- recurrent laryngeal nerve block, a significant nerve in the airway, that may cause shortness of breath
- slow heartbeat,
- collapsed lung;
- low blood pressure,
- carotid artery puncture, or putting a hole in the artery that leads to the head

Known side effects of bupivacaine (both standard and liposomal) are also rare, but may include:

- nausea
- vomiting
- chills or shivering
- headache
- back pain
- dizziness
- problems with sexual function
- restlessness,
- anxiety,
- dizziness,
- ringing in the ears,
- blurred vision, or
- tremors.

Benefits

- a. Benefits to You: You may or may not get any additional benefits from participating in this study...It is expected that receiving a preoperative block will result in longer postoperative pain relief, but these results cannot be guaranteed.
- b. Potential Benefits to Society: The results of this study may help the study doctors learn how to provide better care to surgery patients in the future.

Alternatives to Participation in this Research Study: You can choose not to participate in this study. If you choose not to participate your surgeon and anesthesiologist will discuss your anesthesia and pain control options with you.

New Findings: If important new findings come up during your participation in this study that might change your decision to be in this study, you will be given information about those findings as soon as possible. A description of this study and a summary of the results will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you.

Confidentiality of Records and HIPAA Authorization: While every effort will be made to keep your information private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires your permission to use your health information created or used as part of the research. Health information may include information from your medical records, results of laboratory tests, and both clinical and research observations made during the research study, survey forms, questionnaires, etc.

If you agree to participate, your medical records containing protected health information (individually identifiable information about you) will be accessed for conducting this research, fulfilling regulatory duties, provision of treatment, to determine research results, to monitor your health status, to measure effects of the study drugs.

Representatives of the following groups may have access to your medical records and research related records for the purposes of conducting this research, reviewing the results and for regulatory duties:

- ✓ The investigators and staff coordinating this research;
- ✓ The Mary Imogene Bassett Hospital Institutional Review Board members and staff;
- ✓ The Department of Health and Human Services;
- ✓ The Food and Drug Administration (FDA)

If you decide to take part, your authorization for this study will not expire unless you cancel it. The information collected during your participation may be kept indefinitely. If you decide to withdraw your authorization, you must contact both parties listed below, in writing, and let them know that you are withdrawing authorization to use your protected health information:

Privacy Officer
Bassett Healthcare Network
Health Information Management
One Atwell Road
Cooperstown, NY 13326

Dr. Linda Demma
Bassett Healthcare Network
Anesthesiology
One Atwell Road
Cooperstown, NY 13326

If you cancel your authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others. For example, by Federal law, we must send study information to the FDA for drug and device studies it regulates. Information that may need to be reported to FDA cannot be removed from your research records.

The effective date for this authorization is the date that you sign the consent form.

Once information is disclosed under this authorization to someone who is not a health care provider, the information is no longer protected by the HIPAA federal privacy rule and could be disclosed to others by the recipient.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/authorization and not be part of the study. You can also decide that you want to leave the study at any time without canceling the authorization. By signing this consent form, you give permission to use and/or share your health information as stated above.

Right to Ask Questions: You have the right to ask to any questions you may have about this research. If you have questions later or concerns related to this study, or if you believe you may have developed an injury that is related to this research, you should contact Dr. Demma at 607-547-3153. If you have questions regarding your rights as a research subject, you may contact the Institutional Review Board Office at 607-547-3670.

Financial Responsibility: There should be no additional costs to you as a result of participating in this study.

In the event of physical injury resulting from research procedures, financial compensation is not available. Medical treatment is available through Bassett Healthcare Network at established charges. You would be responsible for any charges not covered by your own health care insurance. Further information may be obtained from the Office of Risk Management of Bassett Healthcare Network at (607) 547-6690.

Compensation: You will not be paid for participating in this study.

Research Funding: The institution and investigators are not receiving any funding to support this research study.

Voluntary Participation: Participation in this research study is voluntary. You are free to withdraw from this study at any time. Your withdrawal from this study or your refusal to participate will in no way affect your continuing medical care or access to medical services at Bassett Healthcare.

Subject's statement:

I willingly agree to participate in this research study. I have reviewed the content of this consent form. I have had a chance to ask questions and have them answered to my complete satisfaction. My signature below certifies that I consent to and give permission for my participation as a volunteer in this program of investigation. I have received a signed copy of this informed consent agreement.

Subject's Signature

Date

Time

Subject's Name (printed)

Witness (if necessary):

I, the undersigned, have witnessed the presentation of the material contained in this consent form and observed that _____ appeared to understand and willingly agreed to participate.

The subject was unable to sign because (i.e., physical disability, illiteracy):

Witness Signature (if applicable)

Date

Witness Name (printed)

[Witness signature is required for subjects who are unable to read the consent form but are competent to give consent]

Person Obtaining Consent:

I, the undersigned, have defined and explained the studies involved to the above volunteer.

Signature of Person Obtaining Consent

Date

Name of person obtaining consent (printed)

[Only those approved by the IRB to recruit and enroll subjects for this research may obtain informed consent].