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CONSENT FORM

A Double-Blind Randomized Comparison Trial of Tolerable Postoperative Pain in Patients Undergoing Total Shoulder Arthroplasty Who Receive Interscalene Blocks With or Without Liposomal Bupivacaine

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Sponsor: Endeavor Health

The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The purpose of this research is to understand the quality of your recovery and pain control from an interscalene brachial plexus block (ISB) of short acting local anesthetic (plain bupivacaine) or the addition of long acting local anesthetic (liposomal bupivacaine) for total shoulder or reverse total shoulder replacement. An ISB block is an injection of local anesthetic in the neck that targets the brachial plexus nerve. Plain bupivacaine and liposomal bupivacaine are local anesthetics used in ISB blocks which is intended to prevent pain by blocking nerve endings of the brachial plexus, nerves that send signals to the shoulder. It is expected that investigators will observe and compare the following outcomes in both the long acting local anesthetic and short acting local anesthetic groups after surgery. Interscalene blocks are performed routinely for patients undergoing total shoulder or reverse total shoulder replacements at Endeavor Health to relieve the pain of surgery both during and after your procedure.
- **Duration.** It is expected that your participation will last from the time of your initial clinic appointment with your surgeon to 30 days after your surgery.
- **Procedures and Activities.** Your total shoulder or reverse total shoulder replacement will be performed the same whether you participate in this study or not. If you join the study, you will be randomly selected like a flip of a coin to receive an interscalene brachial plexus nerve block of either long acting local anesthetic mixed with short acting local anesthetic or short acting local anesthetic alone. You will be asked to participate in six surveys after

your surgery that will ask you questions about your pain level, how many pain pills you have needed to take, and how you are recovering. You will be asked to fill out a survey at 1, 2, 3, 4, 5, and 30 days after your surgery.

- **Risks.** Interscalene blocks are an invasive procedure that does carry a minimal amount of risk. There are no additional risks to the patients enrolling in this study other than the general risks of surgery and anesthesia. All drugs used for the interscalene blocks are FDA approved and are in regular use in our clinical practice as the standard of care for patients without contraindications.
- **Benefits.** There are no absolute benefits outside of being part of the study to investigate the potential benefits of long acting local anesthetic in terms of reducing pain after surgery and improving the quality of recovery for patients when compared to short acting local anesthetic.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate. You can get either of these ISB block treatments outside of this research study if you choose to do so.

Detailed Information about this Study:

Introduction: You are being asked to volunteer for this clinical research study because you are a patient that is planning to undergo a total shoulder or reverse total shoulder replacement. This Consent Form gives information about the study so that you can talk about it with your doctor and/or family. You are being given this information to help you make your decision. If you have any questions, you can ask the study doctor or staff.

Why is this Study Being Done?

At Endeavor Health, the anesthesia team routinely performs Interscalene Brachial Plexus blocks (ISB) on patients undergoing total shoulder or reverse total shoulder replacement to help with pain control during and after surgery. An ISB block is an injection of local anesthetic in the neck that targets the brachial plexus nerve located there.

If you choose to be in the study, on the day of surgery, you will be randomized into one of two groups to receive either an injection of short acting local anesthetic (plain bupivacaine) lasting between 18-24 hours on average, or short acting local anesthetic plus long acting local anesthetic (plain bupivacaine with liposomal bupivacaine) possibly lasting up to 72 hours on average. Randomization is a procedure used to assign research subjects, by chance, to a study group in a clinical trial (similar to a toss of a coin, roll of dice, etc.). It is used to make sure study results are not influenced by the selection of subjects in one group as compared to another.

Studies examining the addition of long acting local anesthetic have shown that it may help with pain control for up to 3 days, and improve the quality of recovery for patients up to 1 day after surgery. We want to understand quality of recovery and pain control differences between block groups in patients undergoing total shoulder or reverse total shoulder replacements.

This study will include a total of 130 subjects. Of those subjects, all will be from Endeavor Health.

What Will Happen During the Study?

If you agree to participate in this study, you will be asked to sign this consent form before any research-related activities are done.

1. You will be asked to complete a baseline survey after you sign this consent.
2. On the day of surgery, you will be randomized into one of two groups. In this study, you have a 50% chance of being assigned to the ISB of short acting local anesthetic or short acting local anesthetic with the addition of long acting local anesthetic group. You and/or the study doctor cannot decide in which group you will be placed. Once you are assigned to a group, you cannot be switched to another group.
3. Following surgery, you will complete six surveys which will be sent to you electronically. If you do not complete the electronic survey, you will be contacted by one of our research staff via a phone call. These surveys should be completed on Post-Operative Days 1-5 and 30. In addition to these six surveys, the nurse who takes care of you in the post-operative area immediately after your surgery will record how much pain you are in on a scale from 0-10 (10 signifying the worst pain you have ever felt and 0 being no pain at all) as well as how much pain medication you are given.
4. Depending on your surgeon and your medical history you may or may not spend one night in the hospital following your surgery.
5. We will also look at your electronic health record to collect demographic information on your age, sex, past medical history, etc. as well as information pertaining to your surgery such as which type of shoulder surgery you are planning to have (if applicable). We will also record how much pain medication you needed after surgery and how you rated your pain level in the recovery area.

During this study, the research team will collect information about you for the purposes of this research. Your responses to our surveys about your recovery and pain levels

- How much pain medication you use or are given from the time you are admitted to the hospital for your surgery to 5 days after surgery. We will collect this to understand what medications are helping with your pain control.
- Your age, sex, race, Body Mass Index (BMI), medical history, surgical history, prior and current medications, tobacco and alcohol use, and American Society of Anesthesiologists (ASA) physical status score (ASA score). This will be collected so we can understand whether certain people are more or less likely to recover well after surgery.
- Surgical information including the type of surgery you are having and the length of your surgery. This information may influence the amount of pain you may experience after surgery.
- Data obtained before, during, and after your surgery including the pain medications given during your surgery, whether you require admission to the hospital, if you return to the operating room after your initial surgery, how long you stay in the hospital, and if you experience any complications from your surgery or from the ISB block (if applicable). These factors could also impact the amount of pain you experience after surgery.

How Long Will I Be in the Study?

We expect your participation to last 30 days after your surgery.

What Other Choices Do I Have?

You do not have to take part in this study for pain management surrounding your total shoulder or reverse total shoulder replacement. Other treatments are ISB with long acting local anesthetic, ISB with short acting local anesthetic, or no block. You can get either of these ISB block treatments outside of this research study if you choose to do so. You are free to talk about these options and your health with your doctor.

Are There Benefits to Taking Part in the Study?

This study may allow doctors to learn more about how liposomal bupivacaine works to manage pain in total shoulder and reverse total shoulder replacement patients. Taking part in this study may or may not make your health better. Doctors hope that this procedure will be more useful in treating your disease than the usual treatment. However, current evidence varies on this. There is the possibility that your health may become worse while you are in this study.

What Side Effects or Risks Can I Expect?

The interscalene brachial plexus block used in this study might have undesired effects. Undesired side effects may be mild or very serious. Sometimes they can be life-threatening. The effects can be serious, long lasting, or may never go away. The study doctor will watch you carefully and will provide treatment for any effects. This may include taking you off the study or giving you other medications.

Risks of Bupivacaine include:

Uncommon (less than 1 in 100 incidence)

- **Excessive plasma levels from over-dosage, unintentional intravascular injection, or slow metabolic degradation**
- **Unintentional subarachnoid injection**
- **Neurologic Reactions**
 - a. **Anxiety**
 - b. **Dizziness**
 - c. **Tinnitus**
 - d. **Blurred Vision**
 - e. **Tremors**
 - f. **Nausea/Vomiting**
 - g. **Seizures**
- **Cardiovascular System Reactions**
 - a. **Hypotension (low blood pressure)**
 - b. **Arrhythmia (irregular heartbeat)**
 - c. **Cardiac arrest**
 - d. **Tachycardia (high heart rate)**
 - e. **Bradycardia (slow heart rate)**
- **Allergic**
 - a. **Itchiness**
 - b. **Swelling**
 - c. **Anaphylaxis (a severe allergic reaction)**

- **Insomnia (lack of sleep)**
- **Muscle spasms**
- **Back pain**
- **Procedural pain**
- **Fever**
- **Dizziness**
- **Seizures**

Risks of Liposomal Bupivacaine include:

Common (2-10 in 100 incidence)

- **Anemia (low blood counts)**
- **Hypotension (low blood pressure)**
- **Tachycardia (high heart rate)**
- **Insomnia (lack of sleep)**
- **Muscle spasms**
- **Back pain**
- **Procedural pain**
- **Fever**
- **Dizziness**

Less Common (less than 2 in 100 incidence)

- **Chills**
- **Redness**
- **Bradycardia (low heart rate)**
- **Anxiety**
- **Urinary Retention (inability to go to bathroom)**
- **Pain**
- **Edema (swelling)**
- **Tremors (involuntary shaking or movement)**
- **Syncope (passing out)**
- **Apnea (inability to breathe)**
- **Blurred vision**
- **Hypersensitivity (allergic reaction)**

Risks of Interscalene Brachial Plexus Nerve Block (less than 1 in 1000 incidence) include:

- **Bleeding**
- **Infection**
- **Nerve Injury**
- **Local Anesthetic Systemic Toxicity (symptoms may include: confusion, dizziness, drowsiness, auditory changes, mouth numbness, metallic taste in the mouth, difficulty speaking)**

Common Side effects of Placing the Nerve Block include (4 to 38 in 100):

- **Horner's Syndrome (drooping eye)**
- **Phrenic Nerve Block (shortness of breath)**

- Recurrent Laryngeal Nerve Block (Hoarse voice)

Other side effects may happen that are not listed here or have not been seen before. Please talk to your study doctor for more details on side effects.

Risks Associated with Completion of Questionnaires

You may feel uncomfortable answering some of the questions. You can stop the questionnaires at any time. You may also skip some of the questions or not answer questions.

You may stay in the study even if you skip some of the questions.

Reproductive Risks: If you are of childbearing age and undergoing surgery, you will be screened with a pregnancy test. You will be excluded from the surgery and the study if you are pregnant as pregnancy is a contraindication to liposomal bupivacaine.

Will My Medical Information Be Kept Private?

Information from this study could be published in journals or presented at meetings. If either of these happens, your name and other personal information will not be used. The researchers running this study will try to keep your personal information private. Your study related information may be looked at by other doctors in this study. Your research file can also be looked at by the Endeavor Health Institutional Review Board, other medical personnel at Endeavor Health who are involved in your care, or by the Food and Drug Administration (FDA).

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.

Will my information be used for research in the future?

Information collected from you for this research study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information are shared. Since identifying information will be removed, you will not be asked for additional consent.

Protected Health Information (PHI)

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “protected health information (PHI).” In general, under federal law, PHI is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your PHI for research and why they may need to do so.

Your PHI will only be used for the purposes described in this Consent Form. Your authorization for activities described in this section does not have an expiration date.

What protected health information (PHI) will be used?

- Past, present, and future medical records, including information housed in the Electronic Medical Record called “Epic,” which is maintained by Endeavor Health
- Information about research procedures, including research office visits, medical tests, procedures, interviews, and questionnaires

Who may see, use, and share my PHI and why may they need to do so?

- Endeavor Health research staff involved in this study
- Non-research staff within Endeavor Health who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Endeavor Health IRB board that oversees the research and the Endeavor Health research quality improvement program
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US government bodies that oversee or review research)
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

Some people or groups who get your PHI might not have to follow the same privacy rules that we follow. We share your PHI only when we must and we ask anyone who receives it from us to protect your privacy. However, if your information is shared outside Endeavor Health, we cannot promise that it will remain private.

Do I have the right to withdraw permission for the use of my PHI?

You have the right to withdraw your permission for us to use or share your PHI for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. Once permission is withdrawn, you cannot continue to take part in this study. However, you will not be penalized or lose any benefits to which you are entitled.

Do I have access to my health information?

You have the right to see and get a copy of your PHI that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. However, to protect the study, you will not be able to see some of the study information until after the study is completed. The researchers are not required to release to you research information that is not part of your medical record.

You have the right *not* to sign this form that allows us to use and share your PHI for research; however, if you do not sign it, you cannot take part in this research study.

Will I Be Paid for Participating?

You will not be paid for being in this study.

Will There Be Additional Costs?

There is expected to be no additional cost to you from being in this research study. You will still be responsible for all costs that you would normally incur as part of routine care.

There is a difference in cost of the two drugs used in this study. You should check with your insurance company to make sure that research study treatment is covered under your policy. There may be extra costs to you.

You will still be responsible for any co-pays or deductibles as specified by your insurance plan.

What If I Am Injured During the Study?

If you become hurt or sick because of being in this research study, you can get medical treatment at Endeavor Health. You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. You can ask for more information from the Research Institute of Endeavor Health.

Health insurance plans (including Medicare) may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Can I Withdraw from the Study?

Your participation in this research study is voluntary. If you decide not to be in this study, you can still get medical care as usual. If you decide to participate now, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

Your doctor may stop this study or take you out of the study without your permission. If this happens, it might be the result of a bad reaction you have. There could also be new information that your doctor learns about the safety or helpfulness of this treatment.

What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at 224/364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

formation from this research that may affect your medical care (
Who Can I Call with Questions?

The study doctor and staff will answer any questions you have. If you have additional questions at any time during the study, you may contact the Principal Investigator, Dr. Johnny K. Lee, at telephone: 847-570-1197.

INDIVIDUAL PROVIDING EXPLANATION:

The procedures and/or investigations described in the above paragraphs have been explained to you by:

Name of Person Explaining Study (Please PRINT)	
Signature of Person Explaining Study	
Date Study Was Explained	

CONSENT TO PARTICIPATE:

I understand that the Principal Investigator and study staff will supervise the study. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I have been told about all of my treatment options. I give permission for the research study procedures described in this consent form.

I have reviewed this information with the study doctor and/or staff. I have had enough time to talk about all of my questions and concerns. I willingly consent to be a part of this study. I will receive a signed and dated copy of this Consent Form.

Subject's Name (Please PRINT)	
Subject's Signature	
Date Subject Signed	