Hartford HealthCare

Informed Consent for Research

6816

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You have been asked to participate in the research study, ***LIBERATE**: **LI**pososmal **B**upivacaine v**ER**sus **A**djuncts in **T**otal should**E**rs.* You are being asked to take part in this study because you are undergoing a shoulder joint replacement.

The Hartford HealthCare Institutional Review Board (IRB) has reviewed the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

The purpose of this study is to compare two different numbing medicines for use in shoulder nerve block for patients undergoing shoulder surgery. We plan to compare them by tracking the amount of opioid pain medications taken after surgery and asking questions about your pain control.

Pain control after shoulder surgery often requires multiple types of pain treatment, referred to as a "multimodal" pain control. Injecting numbing medication near the site of the nerves that affect the shoulder helps with pain control both during and after surgery. We will be comparing our usual numbing medications (called bupivacaine) to a similar numbing medication that may be longer-acting (called liposomal bupivacaine). The goal is to determine if the liposomal bupivacaine causes a longer-lasting numbing block- and less pain after surgery.

A.2. What procedures are involved with participation in this research study?

All patients who have shoulder replacement surgery will be considered for a shoulder nerve block. If the anesthesia doctors think that the shoulder nerve block would be safe for you after speaking with you about your medical problems and medications, you will be offered the block with one of the two numbing medications will be chosen by chance. You will be assigned to one of the two groups by chance (like the flip of a coin): neither you nor the doctor that interviews you about your pain will be able to decide to which group you are part of. This is called "randomization."

We plan to follow your progress during the surgery and in the recovery room.

On the day of your surgery, after you are checked into the POHA (preoperative holding area), you will undergo an assessment of motor and sensory function prior to placement of the block. At least 15 minutes after placement of the block, prior to the start of your general anesthesia, you will undergo another assessment of motor and sensory function.
After surgery you will have two in-person evaluations where you will be asked questions regarding the quality of the block and pain scores. The first one will occur at time of discharge from the PACU (post-anesthesia care unit) and the second will occur the morning of POD#1 (postoperative day number one). The morning of POD#1 you will also undergo an assessment of motor and sensory function.
Prior to discharge you will be given a medication diary and instructions on completing it, along with hospital discharge instructions from your surgeon. Your discharge summary will include instructions on how to take your prescribed medications, including your opioid pain medications.
When you are ready to go home from the hospital, your surgeon will provide you with prescriptions for pain medication, along with instructions on how to take your prescribed medications, including your opioid pain medications. The discharge instructions and any medications provided are part of your surgeon's standard practice. Our research team will provide you with a small diary to record your pain levels and the pain medicine you take at home for three days. We would then contact you by telephone and ask a series of questions three additional times: two days after surgery, four days after surgery, and sixty days after surgery. We expect each call will take approximately 5-10 minutes. . After your call on postoperative day 4, you will be reminded to send back your medication dairy in the self-addressed stamped envelope previously provided to you.

A.3. Which of these procedures is experimental?

Both numbing medications that will be used are approved by the US Food and Drug Administration (FDA) for use in shoulder nerve blocks. However, the collection of clinical data and comparing them is considered experimental.

A.4. Where will participation take place?

This procedure will take place at the Bone and Joint Institute located at 32 Seymour Street, Hartford, CT 06106.

A.5. How long will participation last?

The study will last for approximately 1 year, but your participation will last 60 days.

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

If you choose to participate in this study you are at risk for the following side effects that may be due to the procedure:

Reversible and less serious side effects (occurring 1-10% of the time):

- Block Failure (it does not work to help with postoperative pain control)
- Drooping of the eyelid
- Constriction of the pupil

- Vocal cord paralysis (hoarseness)
- Discomfort/pain at injection site

Rare (occurring less than 1% of the time):

- Hematoma (bruising and swelling at the site of injection)
- Intra-arterial or intravenous injection (Injection into an artery or vein)
- Seizure
- Allergic reaction to any medication used
- Difficulty Swallowing
- Neuralgia (Nerve Pain)
- Nerve Damage
- Epidural spread of the local anesthetic
- Intrathecal (spinal) spread of the local anesthetic
- Pneumothorax (collapsed lung)
- Infection over the site of the needle

You should discuss these with the researcher and/or your regular doctor. There may be other side effects that we cannot predict at this time. Other medicines will be given to make the side effects less serious and less uncomfortable. Many of the side effects go away shortly, after the shoulder nerve block is stopped, but in some cases side effects can be serious or long lasting or permanent.

C. There are possible benefits to you or others to be expected from your participation in this research.

With both types of numbing medicines injected around the nerve roots you should experience less pain after surgery and usually require fewer pain pills during the first several hours after surgery. If you receive the liposomal bupivacaine, the numbing medicine may last longer to help control your pain and decrease the amount of pain pills you need. There may or may not be a direct benefit to you as a result of taking part in this study. However, what is learned in this study may help in controlling pain after total shoulder arthroplasty and may advance scientific knowledge.

D. There are alternatives to participation in this study that you should consider.

You do not have to be in this study to receive treatment for your condition. Instead of being in this research study, you can choose not to participate. Of note, the standard practice at our institution is for every patient having shoulder surgery to receive a shoulder nerve block with numbing medicine.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #
the research, research-related treatments, or a research related injury	Kevin Finkel, MD	(860)972-5978
your rights as a research participant	An IRB Representative	(860) 972-2893
the research in general	Director of Research	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

F. Your participation in the research is voluntary.

You may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Harford HealthCare. Participating in this study is voluntary. Your regular care and your relationship with your study doctor and the study staff will not be affected. You may leave the study simply by notifying your study doctor.

G. You will not receive financial compensation for your participation in this research.

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford HealthCare will protect all the information about you and your part in this study, just as is done for all patients at Hartford HealthCare. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form.

Records of your participation in this study will be held confidential to the extent permitted by the applicable laws and regulations, and consistent with the Health Insurance Portability and Accountability Act ("HIPAA") Authorization that you will be asked to sign. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA), as well as governmental agencies in other countries where the study drug may be considered for approval and the Ethics Committee/Institutional Review Board (IRB) will be able to inspect and copy confidential study specific records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified

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 Website will include a summary of the results. You can search this Web site at any time. The NCT identifier for this study is NCT03887650.

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, you will receive help in the following way:

If you have medical insurance, Hartford HealthCare will collect fees for medical treatment at Hartford HealthCare from your insurance company. If you are not fully covered by insurance or uninsured, Hartford HealthCare will cover these expenses.

There is no plan for Hartford HealthCare to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

J. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, ***LIBERATE***: ***LI****pososmal* ***B****upivacaine v****ER****sus* ***A****djuncts in* ***T****otal should****E****rs*
, and that you consent to the performance of the procedures listed above.

Participant's Signature	Printed Name	Date

Person Obtaining Participant's Signature	Printed Name	Date

Witness signature	Printed Name	*Date*

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)