Date: November 19. 2019

Title: A Prospective Randomized Controlled Trial Examining the Effectiveness of a Single Shot of Liposomal Bupivicaine for Reducing Post-operative Pain and Narcotic Use in Outpatient Rotator Cuff Surgery

NCT: 03822182

Principal investigator: Brian Badman, MD

Study site address: American Health Network

8607 E US Hwy 36, Avon, IN 46123

Phone: (317)208-3866

RESEARCH SUBJECT CONSENT FORM

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to evaluate the differences in pain scores and opioid medication use in patients undergoing rotator cuff repair with different methods of regional anesthesia. Interscalene regional anesthesia (nerve block in the shoulder area) has proven to relieve pain after this surgery. This technique involves introducing a needle under ultrasound guidance and placing medication around the nerves exiting your neck to numb them and provide pain relief after surgery. Historically, bupivacaine, a short acting numbing agent, has been the medication placed around the nerves during the block. This medication alone typically wears off in 4-6 hours. Dexamethasone, a steroid medication, has frequently been combined with the bupivacaine as it has been shown to lengthen the duration of the numbing effect. These two medications, therefore, are currently the medications routinely used for nerve blocks at our surgery center. Recently, liposomal bupivacaine (Exparel) was approved by the FDA for interscalene administration for the shoulder nerve block. This is a medication that is thought to provide a longer lasting numbing effect. We want to compare the standard medications (bupivacaine and dexamethasone) to bupivacaine and Exparel OR Bupivacaine with Exparel and dexamethasone to see if there is a difference in pain scores and narcotic use after surgery and to see if Exparel has a longer lasting effect (see table below). About 78 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last 120 hours (5 days).

What happens to me if I agree to take part in this research?

You will be put into a study group by chance (like picking an envelope).

You cannot choose your study group. Both you and your surgeon (Dr. Badman) will be blinded to the group you are randomized to. This means that both Dr. Badman and you will not know what group you are placed in and the process of picking a group will be by chance. You will select an envelope (beginning with a total of 78) that has been sealed which has your group noted on the inside. After selecting the envelope you will give this to the anesthesiologist who will administer the block and place the selected medications based on which group you randomly selected and noted from the card sealed in the envelope. Only the anesthesiologist will know what medications are given and your name will then be resealed back in the envelope to allow for data analysis at the completion of the study. This will be sealed and stored in a locked container at the surgery center until the study is finalized and all 78 patients are enrolled. After surgery, you will be prescribed a standard regimen of pain medications consisting of oxycodone IR 5mg tablets that will be taken as needed. These will be prescribed as 1-2 tablets every 4-6 hours as needed for moderate to severe pain. You will keep track of how many pain pills you take in an 8 hour period for 5 days after surgery.

	Group 1 (Control) Standard	Group 2	Group 3
	30 ml of 0.5% bupivacaine and 0.4ml (4 mg) of dexamethasone	15ml 0.5% bupivacaine and 10ml of Exparel (133mg) and 5.4ml Normal Saline	15ml 0.5% bupivacaine and 10ml Exparel and 0.4ml (4 mg) dexamethasone and 5ml Normal Saline
	26 subjects	26 subjects	26 subjects

During the research, you and the study doctor will not know which group you are in. (Your study doctor can find out in case of an emergency).

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

If you take part in this research, you will be responsible to:

Receive the text message and respond rating your pain on a scale of 0-10.

0 being no pain and 10 being severe pain in your shoulder. These texts messages will alert on your phone (or tablet) 3 times a day, at 8am, 2pm and 8pm.

You will also be responsible to respond to the number of pain pills taken via text. A total of 16 data points will be collected. The first alert will occur at 8pm the evening of your surgery.

Text alerts for both pain scores and numbers of pain pills taken in an 8 hour period will be sent via a secure text alert system for 5 days following your surgery. These responses are kept secure in a password protected and encrypted online database called CareSense which will only be accessible to Dr. Badman and research staff.

What are the risks of taking part in the study?

This research is collecting data on a combination of medicines which are routinely used for nerve blocks. They are all FDA approved. The following risks can be related to the procedure, study analysis, and medications given:

1. Risk of nerve block: Interscalene nerve block is a routine component of anesthesia for shoulder surgery. Like any medical procedure, there are risks associated with interscalene block. These risks include both occasional and unlikely risks. Occasional risks include block failure (pain immediately following the procedure), a spread of the numbing agent beyond its intended site causing unintended symptoms (including temporary eyelid droop, pupil dilation, hoarseness, and shortness of breath), and bruising at the injection site. Unlikely risks have been described with interscalene block. These include introduction of infection, damage to the lung requiring placement of a chest tube, injection of numbing agent into the bloodstream which can lead to heart failure and death, result in death and permanent nerve injury. Fortunately, these risks are extremely rare. Ultrasound guidance is utilized by the anesthesiologist to help accurately place the medications around the nerves and lessen these risks.

2. Risk of text alerts: A HIPPA compliant and password protected database called CareSense is the application that will help gather and collect the data. Texting is not a secure form of communication and there is a risk of loss of privacy by entering the information on your phone. One way to protect your privacy on your phone is to lock it with a password. Check with your phone carrier to find out what you can do to protect the information on your phone.

3. Risks of medications: Patients may have unknown allergies to one or more of the medications in the interscalene injection. Common side effects for each medication utilized are listed below.

    a. Bupivicaine: Common side effects can include nausea, vomiting, chills, shivering, headache, dizziness, anxiety, ringing in the ears and blurred vision.

b. Dexamethasone: Common side effects can include increased appetite, insomnia (difficulty sleeping), heartburn, increased blood sugar levels, irritability, nausea, bloating, headache and dizziness.

c. Exparel: Common side effects can include dizziness, nausea, constipation, vomiting, itching, headache, and constipation.

Will I be paid for participation?

You will not be paid for participating in this study.

Will it cost me money to take part in this research?

Your insurance company will be billed as usual for your surgery. You will be responsible for costs your insurance does not cover. There will be no added cost to you for inclusion in this research. There is no added cost for individual study groups or for the group being administered Exparel. Based on your cell phone data plan, there may be fees associated with the text alerts that you may incur.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research; however, possible benefits to you include improved pain relief after your shoulder repair because of the nerve block. Possible benefits to others include improved and longer pain relief, possibly making oral narcotics less necessary once we review the data from this study.

What other choices do I have besides taking part in this research?

Your alternative is to not take part in the research. Standard procedure is that you will still receive a regional block during your surgery and routine pain management after surgery.

How will my information be protected?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study.

Methods to protect your information will include storing the sealed envelopes in a locked container at the surgery center which will only be accessible by the chief of staff until entire enrollment of the study. Your information entered is also being stored in a password protected database called CareSense which is HIPPA compliant and only accessible by Dr. Badman and research staff. All identifiable information including your name will be removed at the end of the study to allow for data analysis by Dr. Badman and research staff. All information will be kept confidential.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA), etc. who may need to access your medical and/or research records.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Will my information be used for research in the future?

Information collected from you for this 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 is shared. Since identifying information will be removed, we will not ask for your additional consent.

Who will pay for my treatment if I am injured?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page. After business hours, please call [the on call physician at 317-208-3866.

In the event of an emergency, you may contact Dr. Badman at 317-208-3866.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a known allergy to the medication or a contraindication for regional anesthesia as deemed by the anesthesiologist
- You fail to reply to the required text alerts

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can: Please do so in writing or verbally to Dr. Badman.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____**Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____