STUDY TITLE: Volume versus concentration: A prospective, double blind, parallel study to compare the clinical effectiveness of single shot quadratus lumborum block using either a high volume / low concentration or low volume / high concentration injectate for total hip arthroplasty

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INFORMED CONSENT FORM

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University of Pittsburgh

Department of Anesthesiology

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Volume versus concentration: A prospective, double blind, parallel study to compare the clinical effectiveness of single shot quadratus lumborum block using either a high volume/low concentration or low volumen/high concentration injectate for total hip arthroplasty

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SOURCE OF SUPPORT: None

NOTE: A copy of this consent will be archived in the chart of the patient.

Why is this research being done?
Pain management after hip joint surgery is essential: not only does it guarantee your comfort but also allows you to walk earlier after surgery. One of the procedures that is standard of care for pain management for this surgery is called the “quadratus lumborum block.” The quadratus lumborum block is actually placed by using a needle attached to a syringe of numbing medicine inserted into your back (called ‘injection") that is guided by ultrasound imaging. The numbing medicine works to blocks your nerves so you don't feel pain, or any sensations during the surgery in that area. The anesthesiologist who will place the injection will also use ultrasound to guide where the needle is placed. Ultrasound is when a wand device is used to apply sound waves through a gel to produce an image of the area. You may have heard the term "sonogram" which is the image the ultrasound produces. The ultrasound allows us to have an inside view of soft tissues (muscles, fat, tendons) in your back as we do the injections. It is essential for you to know that these injections are not going to be located in your spine. The injections will be located at your right and left back muscles and will help you to reduce your pain after surgery.

This type of block or injection is standard of care for hip joint surgery. However, there is no agreement yet about what is the best concentration and volume (quantity of liquid to inject) for these injections. Concentration means how much medicine is dissolved in the volume of liquid that is injected. If the volume is changed, it changes the concentration. And we would like to know if the difference between concentrations and volume affects pain control after surgery. The purpose of this study is to evaluate two different sets of concentrations and volumes (quantity of liquid to inject), with the same amount of numbing medicine that has been shown to produce pain relief after surgery.

Who is being asked to take part in this research study?
You are being invited to participate in this research study because you will undergo hip joint surgery. People being invited to participate must be over 18 years of age. We will enroll 60 subjects.

What procedures will be performed for research purposes?

Screening Procedures:

There are no specific screening tests or procedures for this research study.

Research Procedures:

If you qualify to take part in this research study, you will undergo the procedures listed below:

You will be randomized, or assigned by chance, via a computer-generated number system, into one of the two intervention groups. Randomized is like flipping a coin where you have a 50:50 chance of being assigned to either group. One group will have their pain relief medication in a solution of about 4 teaspoons of liquid and the other group will have theirs in a volume of 8 teaspoons. The concentration of the medication will be lower in the group that has the 8 tsp. volume. Sterile salt water is used to dilute the medication and is safe for this use.

After the randomization, you will receive the hospital's standard of care intervention for pain control. This consists of a multi-modal pain management regimen, meaning using different types of drugs to control your pain, including a nerve block, the Quadratus Lumborum Block.

For this study, the only differences will be the concentration and volume of liquid that is injected during the nerve block. You will receive the same amount of numbing medicine as if you were not included in the study, but this amount of numbing medicine could be more or less diluted. This study is double-blind, so neither you nor your surgeon or nurses will know which volume you receive. The only person aware of what volume you receive will be the anesthesiologist performing the injection.

Monitoring/Follow-up Procedures
Your participation in the study will be for 24 hours after your surgery. We will follow up with you to do the following tests:

- *Pain Level:* We will ask you to rate your pain with movement and at rest on a scale of 1-10. We will ask you at 3, 6, 12 and 24 hours after surgery.

- We will collect this information from your medical record:

    - *Pain Medications Consumption*: We will record when your 1st request for pain medication occurs; also, we will you're the total pain medications (narcotics and non-narcotic analgesics) given to you in 24 hours or until discharge.

    - *Mobility*: we will record from the physical therapist note when you are were able to walk 100 feet.

- *Pain Management Survey*: At 24 hours after surgery, the investigator will ask you a few questions regarding your satisfaction with your pain management.

What are the possible risks, side effects, and discomforts of this research study?
There are risks associated with your surgery, anesthesia, and hospitalization. These risks will be discussed with you by your surgeon and anesthesiologist and are independent of your participation in this research study.

Risks associated with participation in the study are:

1. Changing the concentration and volume of liquid in the Quadratus Lumborum block may result in less or more effective pain management. It may require you take more of other pain medications.

   Your medical record will be accessed by study team. Some of the information reviewed and recorded from your medical record includes medical history, surgical and anesthesia record, medication record and pain scores. All of your medical record and study-related information will be considered protected health information and will be kept confidential per HIPAA privacy act. There is, however, a risk of breach of confidentiality. That is, in very rare cases, people not associated with this research study may inadvertently see your identifiable research results. We will do everything in our power to prevent this from happening by keeping all research records in locked files and identify medical information by a research record number, rather than by your name or social security number. The codebook containing your name and number will be kept secure by the study team.

What are possible benefits from taking part in this study?
There is a potential benefit to you if one of the groups is shown to have better pain relief and/or requires less opioids.

What treatments or procedures are available if I decide not to take part in this research study?
If you decide not to take part in this research study, you will receive the standard of care anesthesia and post-operative pain management.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required

by US 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 insurance provider or I be charged for the costs of any procedures performed as part of this research study?
Some of the services you will receive during this study are considered to be "routine clinical services" that you would have even if you were not in the study. These services will be billed to your health insurance company or you, if you do not have health insurance.
You will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan.

You may talk to a member of the study staff and/or a University of Pittsburgh Medical Center (UPMC) financial counselor to get more information on your routine clinical services costs. These costs are not connected to any study activity.

Alternative treatments
If you do not participate in this study, you will likely still participate in the ERAS protocol as it is the standard of post-operative care at UPMC facilities and will receive nerve block according to anesthesiologist's preference.

Will I be paid if I take part in this research study?
You will not receive any payment for participating in this research study.

Who will pay if I am injured as a result of taking part in this study?
University of Pittsburgh researchers and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet, which will include information collected from your electronic medical record. Your identity on these records will be indicated by your name, medical record number, specific study case number. The purpose of these identifiers is strictly for study procedures in order to confirm your eligibility for the study, as well as follow up procedures. Only authorized research staff will have access to these research records. All confidential subject folders will be kept in a locked file cabinet for 7 years after the conclusion of the study and will then be sent to records management. You will not be identified by name in any publication of the research results. We will attempt to

preserve your medical record and participation in this study as confidentially as possible, but breach of confidentiality is a risk of participation.

In the future, the investigators may decide to share data with other investigators both within and outside of this institution. If that were to occur, we would de-identify all of the information prior to sharing any data in this way.

Will this research study involve the use or disclosure of my identifiable medical information?
This research study will involve the recording of past, current and/or future identifiable (pertaining to only you) medical information from your hospital and/or other health care provider (e.g. physician office) records. This information that will be recorded will be limited to diagnostic information, lab results, medications, and medical history. The information will be used to determine your eligibility for this study and to follow your care once you are enrolled in the study.

If you participate in this study, identifiable information will be placed into your medical records held at UPMC, including a copy of this consent form. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes:
-which volume is administered and that you are a participant in this study
-response to study treatment including adverse events (side effects).

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of the study team, who are also part of the Department of Anesthesiology and the Acute Interventional Perioperative Pain Service, will review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the

investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information, this include but not limited to: your name, diagnoses, treatments, age, sex, weight) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for an indefinite period of time.

May I have access to my medical information that results from my participation in this research study?
In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

Is my participation in this research study voluntary?
Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your anesthesiologist is involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your anesthesiologist.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study. Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for use of your medical records and/or participation in this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no

effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you decide to withdraw from study participation after you have received the study drug, no study assessments will be done after your withdrawal.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers if, for example, you have an unexpected change, complication in your anesthesia or surgery or serious adverse reaction. If you are withdrawn from participation in this research study, you will still be treated for your post-surgical pain. Please consult your surgeon or anesthesiologist if you have any further concerns.

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the principal investigator listed on the first page of this consent document at the telephone number given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and to authorize Dr. Uskova and the members of her research team to access my medical records and extract research data from them, as described in this document. Dr. Uskova will sign this consent and a copy of this consent form will be given to me. Also, I further certify that no research component of this protocol was begun until after the consent form was signed.

_____

Participant's Signature

_____ _____

Printed Name of Participant Date/Time

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date /Time