Quadratus Lumborum Block for Analgesia Following Hip Arthroscopy

NCT03557125

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Utilization of quadratus lumborum block for postoperative analgesia following hip arthroscopy: A prospective, randomized clinical trial.

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to find out if a nerve block named quadratus lumborum (QL) block can provide better pain relief than having no nerve block for hip arthroscopies. This block is being used is currently after some hip arthroscopy surgeries but it is not routinely used in hip arthroscopy surgery. The QL block is done by injecting numbing medicine between the muscles by looking with an ultrasound approximately 10 inches to the side of the belly button. There will be two groups in this study: one group will have the QL block placed and one group will not. If you participate in the study you have a 50/50 chance of being in either group and neither you nor your study doctor will decide to what group you are assigned. In the holding room before surgery, your anesthesiologist will place you in position to receive the block after some sedation has been provided for your comfort. You will not know if you received the block or not as all participants will have the skinned cleaned with special soap, a small spot on the skin numbed, and an ultrasound placed on the abdomen. Before surgery and after you are awake from surgery, a study team member will ask you about your level of pain. If you receive the QL block you may have better pain relief although that isn't guaranteed. There is a risk of loss of confidentiality when participating in research studies. There is less than 1% chance of other complications with any nerve block including nerve damage, infection, bleeding or having the medication go into the blood stream.

The amount of pain medication you receive will also be documented after your surgery. Once you meet criteria to leave the recovery room, you will be asked again about your pain and your overall satisfaction. Your participation in the study will end when you are discharged from the hospital.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you are scheduled to have a hip arthroscopy surgery. The study is sponsored by The Medical University of South Carolina. The investigator in charge of this study at MUSC is Sylvia Wilson, MD. The

study is being done at The Medical University of South Carolina. Approximately 46 people will take part in the study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. The researchers will check your medical records to gather information about you.
2. If the medical record review shows that you are eligible for the study, you will be randomly assigned to one of two groups. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A (will receive a QL nerve block) and Group B (will not receive a nerve block).
3. All participants regardless of your group assignment will be positioned, sedated, have an area on the side of the stomach cleaned, have an ultrasound placed on the belly, and numbing medication placed just below the skin as though you are having a block placed. Vital signs (blood pressure and oxygen levels in the blood) will be monitored during this time. This will be done so that you and the team collecting result will not know what group you have been assigned to.
4. Care in the perioperative period will otherwise be routine care. All patients will receive general anesthesia and standard of care medications.
5. You will be asked about your pain prior to surgery, after you wake up from surgery and before you leave the recovery room. Your overall satisfaction and any side effects to pain medications such as nausea, vomiting, and itching will also be noted.

C. DURATION

Participation in the study will end when you are discharged from the recovery room.

D. RISKS AND DISCOMFORTS

Less than 1%:
Bleeding

Infection

Although unlikely there is a very small chance (less than 0.01%) of nerve damage. Any nerve injury is temporary and resolve within 6 months or less. Injuries to a nerve would

involve a tingling feeling over the belly.

Injecting numbing medication into the blood stream by mistake – This is risk is minimized by injecting the numbing medication slowly, watching the injection on the ultrasound and by looking in the syringe for any sign of blood.

There is a risk of loss of confidentiality as a result of participation in the study. You will be assigned a study ID number that will be used to identify you as a study patient.

E. MEDICAL RECORDS

Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

F. BENEFITS

The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed.

G. COSTS

You or your insurance provider will be responsible for all costs related to your medical care, including the drugs used in this study. You may wish to contact your insurance representative to discuss this further before making your decision about participating in the study. It is possible that your insurance company will refuse to pay for the costs associated with study participation in which case you will be held financially responsible.

H. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

There is no plan to share results of the study with participants.

L. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

M. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

N. CLINICAL TRIALS.GOV

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.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company

denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled. The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Sylvia Wilson at (843) 792-2322. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, please sign below.

_____	_____	_____	_____
Signature of Person Obtaining Consent	Date	Signature of Participant	Date