Comparison of Quadratus Lumborum Blocks with Medical Management for Pain Control after Lumbar Spine Fusion Surgery

NCT04588389

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UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: H00016236: Comparison of Quadratus Lumborum Blocks with Medical Management for Pain Control after Lumbar Spine Fusion Surgery

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Consent Version: Version 3.0 dated 12.30.2020

Subject's Name: _____ **Date:** _____

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

In this form, "you" generally refers to the person who takes part in the research. If you are being asked as the legally authorized representative, parent, or guardian to allow someone else to take part, "you" in the rest of this form generally means that person.

KEY INFORMATION

You are being invited to participate in a research study because you are having elective spinal fusion surgery.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main purpose of this study is to try and answer the question whether or not injections of a local anesthetic to block nerve pain (also known as a nerve block) following spinal fusion surgery in addition to usual pain management treatments are more effective in managing pain than just the usual intravenous pain medications alone. Severe pain immediately following spinal fusion surgery delays patients from getting up and moving after surgeryas well as delays rehabilitation and decreases overall patient satisfaction with their experience immediately

following surgery. The excessive use of opioids for pain management following surgery is one

of the causes of the current opioid epidemic. Finding alternates ways to manage pain can potentially decrease opioid consumption and would be a valuable step in curbing this problem.

The goal of this research study is to assess whether getting a nerve block in addition to the standard pain management therapy will result in a reduced use of opioids and provide better pain control following surgery than standard pain management treatment alone.

The Quadratum Lumborum Block (QL) is an injection of a local anesthesia into an area directly next to the Quadratum Lumborum muscle in the lower back. It is successfully used for treating pain following abdominal surgery by blocking nerve pain. The injection would not interfere with the spinal fusion surgery site.

If you join this research, you will be randomly assigned (like pulling a name out of a hat) to receive either:

- Standard of Care Therapy: You will receive IV pain medication in the form of opioids, and Ketorolac immediately following surgery while you recover from anesthesia. After spending sometime in the recovery room, you will be moved to a regular hospital floor. Your pain management there will include opioids, Tylenol with or without Ketorolac as a pill that you would swallow or by injection.
- QL 2 block: You will receive Standard of Care therapy described above AND a QL 2 Block (Quadratum Lumborum Nerve Block injection to the area behind the muscle)
- QL 3 block: Standard of Care therapy described above AND QL 3 Block (Quadratum Lumborum Nerve Block injection to the area in front of the muscle)

You may not want to be in this study if you are uncomfortable with:

- The fact that neither you nor your doctor will get to pick which group you are in
- Sharing your private information with researchers

Risks:

If you are randomized to the nerve block groups, you may feel discomfort when the needle is placed to start the nerve block. On rare occasions patients may develop temporary mild leg weakness. This weakness improves in few hours when the local anesthetic effect wears off. In that case you should not get out of bed without assistance, until the weakness resolves. Other possible extremely rare risks include: infection, swelling and/or bruising caused by a small amount of bleeding into surrounding tissue at injection siteand persistent neuropathy (tingling, numbness, or temporary weakness in your legs or feet). This is a risk for anyone undergoing a nerve block. This risk is extremely rare occurring in only 0.04% of patients, meaning four in one thousand. If any complications happen it will be dealt with immediately as needed. We will take steps to protect your personal information. However, there is a risk of breach of confidentiality. There may also be risks that we do not know yet.

Benefits:

We cannot promise any benefits if you take part in this research. Your participation will help us to gain knowledge that may help other patients with pain relief after surgery.

Alternatives: Your other choice is to receive the standard of care postoperative treatment.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

How many people will take part in this research?

About 30 people will take part here at UMass Memorial Campus

How long will I be in this research?

You are expected to participate in the study until you are discharged from the hospital.

What happens if I say yes, I want to be in this research?

After obtaining consent from you, you will be randomized to 1 of 3 groups by chance (like pulling names out of a hat). 10 people will be in each group. You or your doctor cannot choose your study group. The 3 study groups are:

- Standard of Care Therapy: You will receive IV pain medication in the form of opioids, and Ketorolac immediately following surgery while you recover from anesthesia and once you are awake and moved to a regular hospital floor you will receive the opioids, and Tylenol with or without Ketorolac as a pill that you would swallow.
- QL 2 block: Standard of Care therapy described above AND QL 2 Block (Quadratum Lumborum Nerve Block injection to the area behind the muscle)
- QL 3 block: Standard of Care therapy described above AND QL 3 Block (Quadratum Lumborum Nerve Block injection to the area in front of the muscle)

You will be evaluated before surgery to make sure that you still meet the criteria for the study. Standard of care anesthesia medications will be given to you in the operating room by your anesthesiologist. If you are in the group that will receive an injection you will receive it after the surgery is completed. This can happen either before or after you wake up in the recovery room.

If you are randomized to receive either the QL 2 block or the QL 3 block, your hip will be raised up on the side of the intended injection. That side will be scrubbed using a disinfectant solution. Then using a sterile ultrasound probe, the intended point of injection will be defined, then that point will be numbed with a very small needle, after that another needle will be used to inject the local anesthetic medications in the target point in front of or behind the muscle as decided by the randomization envelope. The procedure will then be repeated on the other side of your body. Your vital signs will be recorded every 5 minutes for 30 minutes after the procedure. Your pain score will be recorded using the VAS (Visual Analog Scale) where you will rate your pain from zero to 10. The sensations in your legs will be examined by testing you reaction to cold sensations and the strength of your leg movement will be evaluated by asking you to move your legs in certain directions.

We will track and collect the data of your pain scores and the medications you used following surgery while you stay in the hospital as well as any side effects or adverse experiences that you had experienced while you were involved in the study.

During the research, you, your surgeon and your postoperative care team will not know which group you are in. However, your study doctor can find out in case of an emergency.

Will you be collecting any specimens from me?

No, we will not be collecting any samples for purposes of this study.

Could being in this research hurt me?

The standard medication management has been used for years and it's safety is known. Side effects like nausea, vomiting, drowsiness are not common. While severe side effects like stopping breathing and kidney injury are possible they are rare.

- For the injection, you might feel some pressure, pain or discomfort at the introduction site of the needle to place the nerve block. You could develop a harmless black and blue mark or experience mild soreness at the injection site.
- A possible yet rare side effect is temporary mild leg weakness. If this happens it should be mild and reversible within a few hours after the local anesthetics wears off. However, we use low concentration of the local anesthetic so the effect will be mild. It will be detected within an hour of placing the block. If this side effect happens you and your nurse will be informed to avoid moving out of your bed without assistance until a physicianclears you.
- Other extremely rare risks include infection, swelling and/or bruising caused by a small amount of bleeding into surrounding tissue at injection siteand persistent neuropathy (tingling, numbness, or weakness most likely in your leg or foot), these should be dealt with immediately depending on the situation.
- There is a risk that data we have stored about you could be lost or exposed. If those data suggest something serious about your health, it could be misused. For example, it could make it harder for you to get or to keep a job or insurance. We believe the chance these things will happen is very small, but we cannot make guarantees. All study staff is trained to protect your data and we will do everything we can to make sure that your information remains protected.

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

Regardless of which group you are randomized to you or your insurance will NOT have to pay for any medications administered or procedures that are done for research purposes only. However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

Will I be given any money or other compensation for being in this study?

You will not be paid for taking part in this research.

What happens if I am injured because I took part in this research?

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

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

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

- Follow the directions of the study doctor and research staff.
- Tell your study doctor and staff about all prescriptions, over the counter medications, and vitamins or herbal supplements you are taking, and about all of your health issues.
- Tell your other health care providers that you are in a research study.

What happens if I say yes, but I change my mind later?

Participating in this study is voluntary. You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Information that we have already collected will stay in the study database and cannot be removed in order to maintain the integrity of the research. However, you can ask us to destroy any information that identifies you so that no one can tell the data belonged to you. Our contact information is below.

Can I be removed from the research without my approval?

The person in charge of this research study can remove you even if you want to continue. This may happen if it is in your best interest or we don't see good spread of the local anesthetics under the ultrasound.

How will my information be stored and when will it be destroyed?

We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data.

We will keep paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data. We will destroy the master list of identifiers when the data analysis is completed.

It is possible that we might use the research data in other future research. We may also share data with researchers and companies that are not part of UMMS. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

In the event you die while enrolled in the study, all medical records related to your treatment and death at any healthcare facility will be released to Eman Nada, MD, and their research staff.

Your health information and research records will be shared with the study team and with individuals that conduct or watch over this research, in order to conduct the study to make sure it is conducted as described in this form. Information and records may be sharted with:

- Federal and state government agencies
- The University of Massachusetts Medical School and UMass Memorial Medical Center, including the Institutional Review Board (IRB) and research, billing, and compliance offices

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, current and past medications or therapies
- Information from physical examinations, such as blood pressure reading, heart rate, temperature, height/weight, and lab results
- All tests and procedures that will be done in the study

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

Your medical record will contain a copy of this form. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

We are legally required to disclose information about child abuse, abuse of the elderly or disabled, you potentially harming yourself or others, and certain reportable diseases.

Monitors, auditors, the Institutional Review Boards, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedures and data. These individuals have been trained to protect confidentiality.

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. In such a case, you will not be allowed to continue to participate in the study. We will not collect any new information and may only use the information already collected for this research study. Your information may still be used and disclosed if you have an adverse event.

You do not have to sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Will you share any results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

We can share your individual results with you if you ask. However, because these are research tests, they are for your interest only. They cannot tell you about your health or diagnose any condition. They will be available when the study data is completely analyzed.

Who can I talk to?

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 on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Signature Block for Capable Adults

Your signature documents your consent to take part in this research.

_____	_____
Signature of adult research participant	Date
_____	
Printed name of adult research participant	
_____	_____
Signature of person obtaining consent	Date
_____	
Printed name of person obtaining consent	