Lumbar Plexus Block versus Quadratus Lumborum Nerve Block for Primary Anterior Total Hip Arthroplasty

Informed Consent Form to Participate in Research

Principal Investigators
Christopher J. Edwards, MD, J. Douglas Jaffe, D.O., James D. Turner, MD

INTRODUCTION

You are invited to be in a research study. The purpose of this research is to compare two different types of nerve blocks that help with pain after anterior hip replacement. You have been invited to be in this study because you have expressed an interest in having a nerve block placed to help with pain management after your procedure. Your participation in this research will involve two assessments and one questionnaire and should last for approximately 24 hours.

Participation in this study will involve randomly being assigned to receive one of two possible different nerve blocks. All research studies involve some risks. A risk to this study that you should be aware of is that one of the nerve blocks may not work as well as the other.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include not receiving nerve blocks for post-operative pain relief, or having the blocks but choosing not to participate in the study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Christopher J. Edwards, M.D. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:

Christopher J. Edwards, M.D.
Wake Forest Baptist Medical Center
Department of Anesthesiology
Medical Center Boulevard
Winston-Salem, NC 27157

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject advocate at Wake Forest at [redacted].

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to compare two different nerve blocks, which are simply numbing shots that help reduce the amount of pain following surgery. These two different nerve blocks are called Lumbar Plexus Block (LPB) and Quadratus Lumborum Block (QLB). We think that both of these nerve blocks help reduce pain following your type of surgery to the same extent, but we have never before compared them scientifically.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Forty-four patients will take part in the study, all of which will be at this institution.

WHAT IS INVOLVED IN THE STUDY?

We are interested in improving pain relief following total hip replacement surgeries. One method for decreasing pain is to perform a nerve block (numbing shot) that will provide numbness and pain relief in the area of the incision associated with your surgery.

Prior to your surgery you will be taken to the regional anesthesia and acute pain medicine area where you will meet the nursing staff and physicians responsible for caring for you. Here you will be offered a peripheral nerve block that can help provide pain relief after surgery. Should you elect to receive a nerve block you will be approached by one of the physicians involved in this study to discuss your potential participation. Should you agree to participate, you will be randomized to receive either an LPB nerve block, or a QLB nerve block. Both of which have been used to provide pain relief after hip surgery. Randomization means that you will be put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. This study is comparing two methods for treating pain for your surgery. It is possible that one treatment group may have a better response than the other. Therefore, there is a risk that you may be assigned to a group that does not perform as well as its comparison. Neither you nor the investigator will know which treatment you are receiving. This is so a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency.

After your randomization group has been determined you will receive a typical regional anesthetic, which involves the following:

Once it has been determined that it is appropriate and timely to proceed with your nerve block, monitors will be applied to assess your vital signs throughout the procedure. A safety check will be performed to confirm that you are scheduled for the appropriate surgery, on the correct side, all paperwork confirms these details, and that all of your pertinent history has been reviewed and does not contraindicate you for your surgical procedure. You will then receive intravenous sedation to relax and make you comfortable for the procedure. Once comfortable and sedated we will use an ultrasound machine to look at the location for both of the nerve blocks and you will receive two very small injections of numbing medication just under the skin at the sites for both the LPB block and the QLB block. This should decrease your ability to feel the needle used to

reach the nerves that will be blocked for your procedure. One of these sites is located just above your "hip bone" on the back side of your hip and the other is located on the side of your back. Both sites will be visualized with Ultrasound so as to make it difficult for you to know which block you received. You will receive only one nerve block, either an LPB or QLB block as determined by your randomization. Our expectation is that either of these blocks will provide you with improved pain relief after surgery as compared to doing nothing. To determine if the numbing shot was successful we will assess you either prior to going to surgery or following surgery in the recovery room. The assessment consists of touching your skin in the surgical area with a sharp object without breaking your skin. We would expect you to be able to feel us touch, but should not be able to tell if the touch is sharp.

After completion of your numbing injections you will meet the members of the operating room (OR) team who will be responsible for caring for you during the surgical procedure itself. You will receive either a general anesthetic or a spinal anesthetic for the surgical procedure with the specifics of your anesthetic to be determined by you and the anesthesiologist who will be taking care of you in the operating room.

Upon completion of your surgery you will be taken to the post anesthesia care unit (PACU) for continued monitoring while you continue to recover from the effects of anesthesia. Once you are determined appropriate for discharge from the PACU you will be released as per your surgeon's orders. We may be calling you at 6hrs and 24hrs after your surgery to ask you specific questions regarding your pain and recovery. Additionally, at the 6 hour assessment we will check to see if you still have the ability to appreciate sharp touch on the first and fifth toe of your operative leg.

A picture of the Ultrasound screen will be taken. This is done to document our use of Ultrasound and the. . You can also withdraw your consent to use and disclose the photograph. You should also understand that you will not be able to inspect, review, or approve the photographs, (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the images/photograph used in this research study:

_____ I would like the images/photographs of me to be destroyed once their use in this study is finished.

_____ The images/photographs of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 24 hours. If you experience any side effects from the numbing shots such as prolonged tingling or pain, which are very rare, follow up will be provided to you.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

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WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to performing nerve blocks like the LPB or QLB blocks used in this study include the following.

As with any procedure that requires placing a needle through the skin, there is a risk of bleeding, bruising, and infection. When we perform nerve blocks we meticulously clean your skin with an antiseptic solution, wear sterile surgical gloves, utilize sterile ultrasound probe covers and diligently maintain sterility throughout the procedure. Infection would be considered a rare risk. Bleeding and bruising can occur, but usually are of no clinical significance unless you are currently taking a powerful blood thinning medication. You may note some tenderness at the injection site, but the discomfort should be minimal, especially when compared to the amount of pain you would have otherwise experienced at your surgical site.

There is also a very rare risk of nerve injury. Symptoms of this include numbness and tingling. When injuries occur the symptoms are generally short lived, and spontaneously resolve over the course of days to weeks, but longer durations measured in months to years have been reported, but rarely so.

Both nerve blocks will be performed using the same anesthetic medication at equal doses. This medication is called Ropivacaine, and when used appropriately is very safe. However, in all procedures involving this class of medication, toxicity can occur should the medicine be inadvertently administered within a vein or artery. To decrease this risk, we use several techniques to determine if this is happening. We add a medication called epinephrine, which if administered into your bloodstream will cause an almost immediate rise in heart and blood pressure, which we can see on our monitors. We also utilize ultrasonography to visualize the location of our needle and the spread of the numbing medications. These techniques help to minimize the risks of toxicity. When toxicity does occur it can lead to tingling in the lips or mouth, ringing in the ears, seizures and in severe cases death. However, the risks of toxicity are rare and have been reported to occur in 1 out of every 1700 nerve blocks performed with ultrasound.

With regards to performing nerve blocks, the risk that patients are most concerned about is failure. Despite optimal technique, it is possible that you could receive one of the study blocks

and receive little to no pain relief from it. In any case of block performance, whether successful or considered a failure, all patients regardless of which group they were randomized into will have orders for as needed pain medications.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the Information learned from this study will benefit other people in the future. The benefits of participating in this study may be: that future patients undergoing hip replacement will receive the best nerve block to ensure that their post-operative pain is optimally controlled.

It is possible that one type of nerve block is better than the other. However, currently we don't know that for sure. Because individuals respond differently to therapy, no one can know in advance if either nerve block will be more helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

1. You can elect to avoid a nerve block to help with pain after surgery
2. You can elect to have nerve blocks even if you do not take part in the study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by The Department of Anesthesiology at Wake Forest Baptist Health.

The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Christopher Edwards, MD or J. Douglas Jaffe, D.O., or James D. Turner, MD at [redacted] during normal business hours (7am until 4pm) or after hours call the hospital operator at [redacted] and ask for the acute pain management team.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we collect from you or from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

1. Block performed
2. Pain scores at rest and with activity at 8 and 24 hrs

3. Opioid pain medication use for the first 24 hrs after placement of your block
4. Ability to straight leg raise
5. Any reported opioid side effects (nausea, vomiting, itching)
6. Patient satisfaction questionnaire
7. Name
8. Weight
9. Height
10. Sex
11. Medical record number
12. Date of birth
13. Address

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

Additionally, the following people or organizations will be granted access to your Protected Health Information:

1. The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2. Other people or laboratories providing services for the research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3. The Regional Anesthesia and Acute Pain Management service team that helps to manage your pain should you stay in the hospital

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study will be maintained in the research records. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Christopher J. Edwards, MD, J. Douglas Jaffe, D.O., or James D. Turner, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Christopher J. Edwards, M.D.
[redacted]

Or

J. Douglas Jaffe, D.O.
[redacted]

Or

James D. Turner, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.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 Web site at any time.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because new information became available, the entire study has been stopped, or you have an unexpected reaction

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator Christopher Edwards, MD or J. Douglas Jaffe, D.O., or James D. Turner, MD at [redacted] during normal business hours (7am until 4pm) or after hours call the hospital operator at [redacted] and ask for the acute pain management team.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain

additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

WFU School of Medicine
Institutional Review Board
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