Wake Forest®
School of Medicine

Department/Section of Anesthesiology

LUMBAR PLEXUS BLOCK VERSUS PERICAPSULAR NERVE GROUP BLOCK FOR PRIMARY ANTERIOR TOTAL HIP ARTHROPLASTY

Informed Consent Form to Participate in Research

Principal Investigator
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INTRODUCTION

You are invited to be in a research study. The purpose of this study is to compare two different types of nerve blocks that help with pain after hip replacement surgery. A nerve block is an injection that uses numbing medicine to take away some of the pain from surgery. We perform nerve blocks on nearly every person who comes in for a joint replacement surgery. You have been invited to be in this study because you have expressed interest in having a nerve block placed to help with pain management after your procedure, which is standard practice for the surgery you are having. Your participation in this research will involve two assessments and one brief questionnaire, and it should last for approximately 24 hours.

Participation in this study will involve randomly being assigned to receive one of two possible nerve blocks. Both involve using numbing medications that help to take away some of the pain from the surgery for several hours. All research studies involve some risks. One risk of this study that you should be aware of is that one of the nerve blocks may not work quite as well as the other. However, from what we have seen so far, they both seem to help equally with pain after hip surgery. We are using this study to confirm if the two blocks are equivalent.

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, such as choosing not to get a nerve block, or having the standard nerve block we would usually do but choosing not to participate in the study. You will not lose any services, benefits, or rights you would normally have if you chose 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 question(s) if you need help deciding whether to join the study. The person in charge of this study is Rawad Hamzi, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is:

Rawad Hamzi, MD, MS
Wake Forest Baptist Medical Center
Department of Anesthesiology
Medical Center Boulevard
Winston-Salem, NC 27157

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If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at 336-716-4542 or the Research Subject Advocate at Wake Forest at 336-716-8372.

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 Pericapsular Nerve Group Block (PENG). We believe that both nerve blocks help reduce pain following your type of surgery to the same extent, but we have never before compared them scientifically. The LPB is the type of nerve block we have used for years for patients getting their hip replaced, and we have demonstrated it is safe and effective for pain control. The PENG block is a newer block that has also been proven safe and effective, but we have not directly compared these two blocks for patients getting hip replacement surgery. The proposed benefit of the PENG block is that it may not make the hip muscles as weak for the duration of the numbness compared to the LPB, which does. The goal of this study is to find out of if the pain control from these two blocks is similar.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

One hundred and sixty patients will be enrolled in the study, all of whom will be having surgery at Davie Medical Center.

WHAT IS INVOLVED IN THE STUDY?

We are interested in improving pain relief following total hip replacement surgeries. One method for decreasing pain that we typically do is perform a nerve block (numbing shot) that will provide some numbness and pain relief in the area of your surgery. We also use a variety of oral medications to reduce pain and make it hurt less to move after surgery, which is an important part of recovery.

During your preoperative assessment clinic visit, the types of anesthesia and pain control options will be explained to you and you will be asked to sign a consent form, as is done with all patients presenting for joint replacement surgery. Should you elect to receive a nerve block, you will be approached by one of the research members involved in this study to discuss your potential participation. On the day of your surgery, you will be taken to a private bay in the preoperative holding area where you will meet the nursing staff and physicians responsible for caring for you. The types of anesthesia and the plan for a peripheral nerve block that can help provide pain relief after surgery will again be discussed with you in case you have further questions. Should you agree to participate, you will be asked to sign a consent form if you have not already. At that time, you will be randomized to receive either an LPB nerve block (Group 1) or a PENG nerve block (Group 2). Randomization means that you will be put into a group by chance, like flipping a coin. You will have an equal chance of being placed in either group, and your treatment team

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will not select the group. You will also be asked questions about your pain before surgery and have your leg strength briefly measured by having you lift the leg on which you are having surgery.

This study is comparing two methods for treating pain from 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 researchers you see you following surgery 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, however.

After your group has been determined, you will receive a typical regional anesthetic, which is described below.

WHAT WILL BE THE PROCESS FOR THE NERVE BLOCKS?

Once it has been determined that it is an appropriate time to proceed with your nerve block, monitors will be applied to watch 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, that all paperwork confirms these details, and that all of your pertinent history has been reviewed and does not contain any reason you should not have your surgical procedure. You will then receive sedation medications through your IV to relax and make you comfortable for the procedure. These medications will likely make you drift into a nap, or they may just make you very relaxed for the duration of the nerve block procedures. The next steps depend on which group you are assigned, but are very similar:

Group 1 (Lumbar Plexus Block group)
Once you are comfortable and sedated, we will use an ultrasound machine to look at the location where we would normally perform the PENG block on the front of your hip, and you will receive a small injection of numbing medicine at this site just under the skin. This small numbing injection for the skin is what we normally do before nerve blocks, to decrease the discomfort of the nerve block needle. This will be a “sham” block, meaning a numbing injection to make it unclear if you had a nerve block at this site. We will then turn you onto your side and place a small numbing injection just under the skin on the back where we would normally perform the LP block. You will then receive an LP block, which would involve us injecting numbing medicine near the nerves going to the hip joint and leg from the back.

Group 2 (Pericapsular Nerve Group Block group)
Once you are comfortable and sedated, we will use an ultrasound machine to look at the location where we would normally perform the PENG block on the front of your hip, and you will receive a small injection of numbing medicine at this site just under the skin. This small numbing injection for the skin is what we normally do before nerve blocks, to decrease the discomfort of the nerve block needle. You will then receive a PENG block, which would involve us injecting

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numbing medicine near the nerves going to the hip joint from the front. We will then turn you onto your side and place a small numbing injection just under the skin on the back where we would normally perform the LP block. This will be a "sham" block, meaning a numbing injection to make it unclear if you had a nerve block at this site.

The reason for both groups getting the small numbing injections to numb the skin at both block sites, even though you will only receive one of the actual nerve blocks, is to "blind" you and the researchers. In other words, we keep you "blinded" to make it unclear which group you were randomized to, so that the knowledge of which group you are in does not affect your perception of pain or strength and does not affect the measurement of these outcomes by the research staff. Our experience has been that either of these blocks will provide you with improved pain relief after surgery as compared to doing nothing.

After you receive the nerve block, if the plan was for you to receive a spinal block for the anesthesia, which is our typical plan for nearly all patients getting joint replacements, you will have a spinal placed by the anesthesiologist with you still sedated. Because of the sedation, you may not be fully aware of these procedures and will likely be napping during them. The goal is to keep you comfortable and safe throughout these procedures and the surgery.

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.

After the 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 awake enough and comfortable, you will be discharged from the PACU to your hospital room. You will have a nursing team that will take care of you in your room and get medications for you as needed. Research staff will follow up with you six hours after the placement of the nerve block to ask specific questions about your pain and measure your strength. We will also obtain phone numbers where we can call you in case you are sent home on the day of surgery, which is a decision that will be made by your surgery team and you. We will call you 24 hours after your surgery to ask you specific questions regarding your pain and recovery.

We will save images from the ultrasound to your electronic medical record. This is done to document our use of Ultrasound and the images obtained for safety and billing. The images will show a portion of your hip joint bone from the inside. You can choose to withdraw your consent to use and disclose the ultrasound pictures. You should also understand that you will not be able to inspect, review, or approve the images (including articles containing them) before they are used in this study.

At any point during this study, including before the surgery and afterwards, you may decide to withdraw your consent and not be included in the study, and any information we have collected about you will be destroyed. Your decision to not participate in the study or changing your mind to no longer participate will not affect your care or the treatment options available to you. With this informed consent, you agree that we may use the ultrasound images collected during the

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study to present results from this study, although they will not have any data that would identify you.

You may also decide to allow these ultrasound images to be used in future studies as long as they are kept secure, but you will not be able to inspect, review, or approve their future use, if they are used. These images will be de-identified and not be able to be traced to you. You may instead decide to request these ultrasound images be destroyed at the end of the study, although this consent form allows us to use them for presentation of data and results from 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 ultrasound images of me to be destroyed once their use in this study is finished.

_____ The ultrasound images 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?

Your involvement in the study will last about 24 hours. If you experience any side effects from the numbing 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.

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 PENG 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 without a nerve block

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

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, which includes medicines like Lidocaine and Novocain, 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 any of these signs of toxicity are rare and we take special measures to avoid them. 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.
An additional risk to the lumbar plexus block is the risk of the local anesthetic spreading inadvertently into the epidural space. When that occurs, you may potentially notice numbness from the waist down (as if having an epidural for your anesthesia) and a very low blood pressure. Should this occur you will be treated with the normal medications for your decreased blood pressure. The numbness below the waist will resolve to “normal” sensation within 1-2 hours as the numbing medicine wears off.

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. This would be a risk whether you are enrolled in the study or not. In any case of block performance, whether successful or considered a failure, all patients, regardless of which group they were randomized to, will have orders for as needed pain medications. You will not be left to be in more pain because you decide to participate in this study.

In addition, there is always a slight risk in research of a breach of confidentiality. We will do our absolute best to always protect your confidential information, and these breaches are extremely rare.

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. Specifically, there is a chance that the pain control will be better with the block you receive. We hope the information learned from this study will benefit other people in the future. The benefits of

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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 do not 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 specifically 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.

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

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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 (336) 716-3467.

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 Rawad Hamzi, M.D. at 336-716-4498 during normal business hours (7am until 4pm) or after hours call the hospital operator at 336-716-2011 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 6, 12, 18, and 24 hours. You will not be contacted between the hours of midnight and 0700 if the 12 and 18 hour assessments fall within that time frame.
3. Opioid pain medication use for the first 24 hours after placement of your block
4. Strength with raising your leg
5. Any reported opioid side effects (nausea, vomiting, itching)
6. Patient satisfaction questionnaire
7. Distance walked at first physical therapy session after surgery
8. Name
9. Weight
10. Height
11. Sex
12. Medical record number
13. Date of birth
14. 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,

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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 research personnel 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 (IRB); 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, and the 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.

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You can tell Rawad Hamzi, 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:

Rawad Hamzi, MD, MS
Wake Forest Baptist Medical Center
Department of Anesthesiology
Medical Center Boulevard
Winston-Salem, NC 27157

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.

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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, Rawad Hamzi, MD at 336-716-4498 during normal business hours (7am until 4pm) or after hours call hospital operator at 336-716-2011 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 (336) 716-4542 or the Research Subject Advocate at (336) 716-8372.

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

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