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Informed Consent

Evaluation of Continuous Saphenous Nerve Block to Supplement a Continuous Sciatic Nerve Block After Ankle Surgery

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WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Department of Anesthesiology

Evaluation of the Addition of a Continuous Saphenous Nerve Block to Continuous Sciatic Nerve Block for Postoperative Analgesia Following Ankle Arthrodesis

Informed Consent Form to Participate in Research
Robert Weller M.D. Principal Investigator

Introduction

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are having an ankle fusion or fracture surgery, and you have already consented to a nerve block catheter for postoperative pain relief. A nerve block catheter is a small tube placed next to a nerve through a needle, and the needle is then removed. Numbing medicine is dripped through the tube to reduce pain sensation from the nerve. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

There are 2 nerves carrying pain sensations from the ankle, the large (sciatic) nerve and the smaller (saphenous) nerve. Patients undergoing ankle fusion or fracture surgery at Wake Forest University usually have a nerve block catheter placed next to the sciatic nerve to give local anesthetic (numbing medicine) for 24-72 hours. In addition, a single injection of local anesthetic is usually performed to block the saphenous nerve for 12-16 hours postoperatively. The purpose of this research study is to test whether the placement of a second nerve block catheter, rather than a single injection for the saphenous nerve block will improve pain relief and/or reduce pain medication needed after surgery enough to justify 2 nerve block catheters.

In this study, all patients will have a saphenous nerve block catheter, and all will receive the standard single injection of long-acting local anesthetic through this catheter for the initial saphenous nerve block. Half of the patients will then receive a local anesthetic drip and half will receive a saline, or placebo drip through the catheter. A placebo is a substance, like a sugar pill,

that is not thought to have any effect on your condition or pain. Placebos are used in research studies to see if the drug being studied really does have an effect.

How Many People Will Take Part in the Study?

74 people at 1 research site (Baptist Medical Center) will take part in this study.

What Is Involved in the Study?

On the day of your surgery you will be seen in the Regional Anesthesia area of the surgical center. After discussion with your Anesthesia team you will be given sedation through an I.V. and will have the two nerve block catheters placed. One of these will be on the back of your upper thigh (sciatic) and the other will be on the middle of the inside of your thigh (saphenous). Once we determine that your nerve block catheters are working well, you will have your ankle surgery either under general anesthesia or with a spinal numbing medicine, depending on your preference and discussion with the anesthesiologist. After the surgery is completed, your two nerve block catheters will be connected to two pumps that will administer numbing medications on the sciatic nerve, and numbing medication or a placebo on the saphenous nerve. During your hospitalization you will be seen on a daily basis by the Acute Pain Service, who will manage your pain medications and nerve block pumps. Most participants in the study will stay one night in the hospital, but your hospital stay will be up to your surgeon. When you do go home, the nerve block catheters and pumps will go home with you to provide pain control medications over approximately the next 2 days. The anesthesiologists on the Acute Pain Service will call you on a daily basis to assess how you are doing. You will also have phone numbers to call if you have any questions or concerns. The phone calls will take approximately 10 minutes each day. Sometime during the 3rd day after surgery, the nerve block pumps will run out and at that time the physician on the Acute Pain Service will direct you or a family member how to remove the nerve block catheters at home.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance, like flipping a coin. You will have an equal one in two chance of being placed in any group.

Neither you nor the investigator will know whether you will be receiving the numbing medicine or the placebo through the saphenous catheter, since the medicine is so dilute it may not make you feel numb, even if it is producing pain relief. This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency.
The saphenous nerve block catheter is the focus of this study, and it will be placed as mentioned above after IV sedative medicines and numbing medicine injected on the inside of your thigh. Ultrasound will be used to place this catheter close to the saphenous nerve and the branch of the femoral artery next to the nerve. Ultrasound is a medical device that uses sound waves from a hand-held probe to produce an image of structures in the body beneath the skin. It has been used by anesthesiologists for more than a decade to help place needles and catheters close to nerves with less chance of blood vessel puncture than other techniques. To be clear, our usual practice for surgeries such as yours is to use ultrasound to locate and numb the saphenous nerve with a needle and *single* shot of numbing medicine, but *without* placing a nerve block catheter. If you consent to participate in this study, a saphenous catheter will be placed, and all patients will

receive an initial dose of long acting local anesthetic before being randomized to one of the two groups. This initial injection is the same dose of local anesthetic you would receive through a needle if you were to decline to be in the study.

After surgery, the sciatic catheter will be connected to a pump as usual, with a constant drip of medicine and adjustment of the drip rate if needed. The saphenous catheter will be connected to a pump with numbing medicine or placebo (saline) drip. In addition, you will have pain medicine pills to take by mouth if you need them.

Since the saphenous block may cause weakness of the thigh, you will also have the muscle strength in your thigh tested on 2 or 3 occasions. To test your muscle strength, we will have you attempt to push your leg out (like kicking a soccer ball) against a small machine, called a dynometer, which one of the investigators will hold in their hands. This should cause no discomfort and will take approximately 30 seconds. Your muscle strength will be tested upon your arrival to the Regional Anesthesia holding area, after the nerve block catheters are placed, and again on the morning after surgery.

To summarize the research parts of this study: if you agree to participate, you are consenting to the placement of the saphenous catheter, the equal chance of either active or placebo anesthetic drip through this catheter for 2-3 days, and the muscle strength testing.

All study participants will be seen every morning by the Anesthesia Acute Pain Service while in the hospital. Your pain will be evaluated and you will answer several questions related to your pain, pain medications, satisfaction, and side effects. After you are discharged from the hospital, the Acute Pain Service physicians will call you at home each day to ask you these same questions. Once the pumps have run out of numbing medicine, you or your family member will be instructed on how to remove the dressings and the catheters and how to properly dispose of them. No follow up clinic or hospital visits will be needed.

As part of this research study, ultrasound images will be taken as the saphenous nerve block catheter is placed. This is being done to document the placement of the nerve block catheter. These images may be used for research publication or for medical education, but since they only show structures under the skin, you could not be identified by looking at the image. You may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the ultrasound image(s) before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, videotapes, audiotapes or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape 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 provide 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 until the numbing medicine in your saphenous pump runs out, which should be 48-72 hours after your surgery is completed.
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. If you decide to withdraw from the study early, the physician on the Acute Pain Service will direct you or a family member how to remove one or both of the nerve block catheters at home, and you would continue to take oral pain medications. You may experience increased surgery-related pain after the nerve catheters are removed and the numbing medicine wears off.

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. Nerve block catheters have been shown to provide good pain relief, but they also carry some risks and side effects, and as a part of the study you will receive two catheters rather than the usual one. The risks include soreness, bruising or swelling at the catheter site, and partial or absent pain relief (failure of block), and pain when the nerve block wears off. Infection may occur at the catheter site, but sterile technique is used to minimize this risk. Rarely, irritation or injury to nerves can occur causing continued numbness or weakness for days or weeks (1/500 patients). The local anesthetics (numbing medicines) can infrequently cause dizziness or light-headedness when absorbed into the bloodstream, but dosages will be low for postoperative nerve block. Nerve blocks may produce muscle weakness and numbness – you must not stand on the blocked leg, and must protect your leg and foot from injury while it is still numb. The saphenous nerve catheter is placed near an artery, and there is a risk of nicking this blood vessel and causing bleeding; the ultrasound machine is being used to minimize this risk.

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.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

You may receive improved pain relief from taking part in this research study, but you may also not have any personal benefit. We hope the information learned from this study will benefit other

people in the future.

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 may choose to proceed with the regional anesthesia (numbing shot) approach that is normally used for your surgery. This would include a nerve block catheter on the back side of your thigh and a shot of numbing medicine on the inside of your thigh, but no nerve block catheter at this second location.

Alternatively, you may choose to have no numbing shots and treat your pain with pain medications by mouth or in your I.V.

What about the Use, Disclosure and Confidentiality of Health Information?

By taking part in this research study, your personal health information, as well as information that directly identifies you, may be used and disclosed. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth. Your personal health information includes all information about you which is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, medical images, photographs/videotapes/audiotapes and information from study visits, phone calls, surveys, and physical examinations.

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.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If this research study involves the treatment or diagnosis of a medical condition, then information collected or created as part of the study may be placed in your medical record and discussed with individuals caring for you who are not part of the study. This will help in providing you with appropriate medical care. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Robert Weller
Department of Anesthesiology
Medical Center Blvd.
Winston Salem, NC 27157

If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

This authorization does not expire.

What Are the Costs?

There are no costs to you for taking part in this study. 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, however, which are not related to this study such as the cost for sciatic nerve block catheter will be your own responsibility or that of your insurance.

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 Hospital, and saphenous pumps are being provided by the I-Flow Corporation and Kimberly Clark Health Care 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 (336) 716-3467.

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 Robert Weller at (336) 718-4498 or after hours by paging (336) 806-9414.

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 it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, your nerve block catheter stops working, you failed to follow instructions, or because the entire study has been stopped.

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, Robert Weller at (336) 718-4498 or after hours by calling the hospital operator at (336) 716-2011.

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, you should contact the Chairman of the IRB at (336) 716-4542.

You will be given a signed copy of this 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

_____ _____

Person Obtaining Consent Date / Time