Official Title: Continuous Vs Single Shot Adductor Canal Block After ACL Reconstruction – A Randomized Study

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Northwell Health

Campus: Plainview/Valley Stream/Huntington/Long Island Jewish/North Shore University Hospital

Consent for Participation in a Research Study

Title: Randomized adductor canal single shot versus continuous peripheral nerve block after ACL reconstruction and effects on opioid use, pain, sleep quality.

Principal Investigator: Randy Cohn, MD

About this research
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	In this study we look to compare these two methods of pain control after ACL reconstruction examining the effects on pain control, opioid use, and patient satisfaction.
What will happen to me during the study?	In this study you will be randomized. This means that you will be assigned to a group by chance. You will have an equal chance of being in either group. One treatment group will leave the hospital with a pump that delivers numbing medication slowly over time. The other treatment group will get a single shot of numbing medication in the operating room before waking up. Both options are approved and used frequently for patients having the same surgery as you are having. You will also be assessed in person, after the procedure. Following that, you will be sent surveys via email each evening for a total of 7 nights.

	You will get these surveys on post operative days 0, 1, 2, 3, 4, 7 and 14. These short surveys will assess your pain, opioid use and sleep quality. You will need to complete all of these surveys to be enrolled in the study You will also be contacted via telephone on day 1, 2, 3, 4 and 7 after surgery to assess for any side effects. Lastly you will be asked to attend a follow-up appointment to see the orthopedic surgeon where you again will rate your opioid use, pain, sleep quality and overall satisfaction. The follow up appointment will be anywhere between 10-14 days after your procedure.
How long will I participate?	If you choose to take part in this study, you will be followed for a total of 10-14 days. By agreeing to participate in this study, you agree to complete electronic emailed surveys on post-operative days 0, 1, 2, 3, 4, 7 and 14. These short surveys will assess your pain, opioid use and sleep quality. You will need to complete all of these surveys to be enrolled in the study. You also need to be available to receive telephone calls on post-operative day 1, 2, 3, 4 and 7 to assess for any side effects
Will taking part expose me to risks?	Risks associated with single shot adductor canal block ● Peripheral Nerve Injury ● Local Anesthetic System Toxicity ● Local Infection Risks associated with a pump that delivers medicine slowly over time: 1. Block Failure 2. Accidental Catheter Migration/Removal 3. Localized Infection 4. Local Anesthetic System Toxicity Randomization: Your group may receive less effective treatment or have more side effects than the other group. Loss of confidentiality: We will be collecting information that can identify you. Therefore, there is a risk of breach in confidentiality.
Are there any benefits to participation?	You may or may not benefit from participation. Your group might receive more effective treatment and/or have fewer side effects than the other treatment group(s). Your participation in this research project will help us measure and determine if one of these options has superior effects than the other treatment group.
What are my alternatives to participation?	Each treatment option can still be offered to you for post-operative pain control. You also have the option of declining to use any regional anesthesia (nerve block). Regional anesthesia has been shown to be an effective option for decreasing pain after ACL reconstruction.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction

You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

This consent form is written from the point of view of a research participant. If the parent or legal guardian of a minor or a legally authorized representative will be providing consent, the words "you" and "your" should be read as ("your child" or "the research participant").

This study is being conducted by your surgeon in conjunction with the orthopedic surgery residents of Northwell Health.

Why is this research study being done?

The goals of the study are to see if one treatment intervention is superior to another in reducing opioid use, improving pain, sleep and patient satisfaction. The intervention may or may not help you but the results can be used and applied to future patients to help provide better care. This will help us develop a stronger postoperative plan for patients undergoing ACL reconstruction.

Why is this research?

This is a research study because we are trying to determine whether one approach to post-ACL surgery pain relief is superior to another. Both treatment options are currently used by orthopedic surgeons and have been shown effective and helping control pain after surgery. We are hoping to see if they both work equally or if one is better than the other.

How many people will take part in this study?

This research study hopes to enroll 85 patients total among five different hospitals.

How long will you be in this study?

If you choose to take part in this study, you will be followed for a total of 10-14 days. By agreeing to participate in this study, you agree to complete electronic emailed surveys on post operative days 0, 1, 2, 3, 4, 7 and 14. These short surveys will assess your pain, opioid use and sleep quality. You will need to complete all of these surveys to be enrolled in the study. You will also be contacted via telephone on post-operative day 1, 2, 3, 4 and 7 to assess for any side effects.

What will happen in this research study?

In this study you will be randomized. This means that you will be assigned to a group by chance. You will have an equal chance of being in either group. One treatment group will go home with a pump that delivers numbing medication slowly over time. The other treatment group will get a single shot of numbing medication in the operating room before waking up. There is a 1 in 2 chance you will be assigned to either group.

Both options are approved and used frequently for patients having the same surgery as you are having.

For participants in the continuous pump group:

Administered by an anesthesiologist, a catheter is then placed overlying the covering of the nerves. This catheter is then connected to a device with a reservoir that administers pain medication at a set rate. The rate will be fixed and give the medicine at a defined controlled rate. The catheter will be removed once the reservoir is empty which is usually 2-3 days after surgery. There are set instructions that will be given to you on how to remove the catheter. If you are uncomfortable removing this yourself you can have it removed in the office.

For participants in the single shot group:

The medicine will be delivered through an injection by the anesthesiologist. The anesthesiologist will cleanse the inner mid-thigh region on the operative side with an antiseptic solution. He or she will use both anatomical landmarks and an ultrasound machine to find the desired location for the adductor canal/saphenous nerve block in the groin region. Once the best location is found the anesthesiologist will slowly insert a needle the size of a paperclip through the skin. Your anesthesiologist will utilize ultrasound to guide the needle to the proper location near the nerve. When the location and/or response are optimal, the anesthesiologist will inject the long acting Novocaine-like medicine (Bupivacaine) in multiple small doses which will numb the front of your thigh and knee. This procedure takes only a few minutes to perform. The numbness and weakness from the block usually lasts from 16-24 hours and occasionally greater than 24 hours. You will also be given pain medication to take in addition to the block or for when it feels like the block is wearing off. You may have some discomfort behind and below your knee. This is normal.

You will also be assessed in person, after the procedure. Following that, you will be sent surveys via email that ask a few simple questions regarding your pain, opioid use and sleep quality. Sleep will be assessed by asking if you have had any disturbances in your sleep or trouble falling asleep because of the pain in your surgical knee over the past 24 hours.

You will be asked to rate those variables on a scale from 1-10. You will also be asked how many of your pain pills you have taken in the past 24 hours. This survey should only take an estimated 5 minutes to complete.

You will also be contacted via telephone on post-operative day 1, 2, 3, 4 and 7 to assess for any side effects from the procedure. Lastly you will be asked to attend a follow-up appointment to see the orthopedic surgeon. The follow up appointment will be anywhere between 10-14 days after your procedure.

What are the risks of the research study? What could go wrong?

Risks associated with single shot adductor canal block

Peripheral Nerve Injury

- This is a rare complication that is usually temporary and goes away with time. The estimated incidence is 0.5% for any nerve irritation after the procedure. The risk of injury to the nerve that is permanent in 1/10,000is very rare in part due to the implementation and success of ultrasound use for guidance of the needle and/or catheter during nerve blockade.

Local Anesthetic System Toxicity

- Ranges from mild symptoms of metallic taste, agitation, and numbness around the mouth to more severe findings such as seizure, respiratory arrest, cardiac arrhythmias (irregular heartbeat).
- If this happens, it will typically appear 1 to 5 minutes after the injection, but onset may range from 30 seconds to as long as 60 minutes.
- Subjects will be monitored in the post anesthesia recovery unit until they are deemed stable and ready for discharge. Any abnormalities will be noted by the nurse taking care of the patient who would inform the anesthesiologist and surgeon. This is standard protocol at our institution when any regional blocks are given for post-operative patients.

Local Infection

- For single shot adductor canal blocks the risk of infection is very low, and is minimized by using sterile technique perioperative antibiotics that are standard protocol for ACL reconstruction regardless of catheter insertion or not.

Risks associated with continuous peripheral nerve catheter placement:

Block Failure

- Occasionally, there are instances when the catheter is passed easily but the nerve block fails to provide adequate anesthesia or analgesia.

Accidental Catheter Migration/Removal

- The incidence of accidental catheter removal is about 1%.

Localized Infection

- Localized inflammation is infrequent (0–10%), and local infection (0–3%), abscess formation (0– 0.9%), and sepsis occur even more rarely.

Local Anesthetic System Toxicity

- Subjects will be receiving a fixed rate of flow of local anesthetic to the nerve site for 48-72 hours and have a low risk of a reaction to the anesthetic, with symptoms that may include metallic taste, agitation, and numbness around the mouth to more severe reactions such as seizure, respiratory arrest, cardiac arrhythmias.
- If this happens, it will typically appear 1 to 5 minutes after the injection, but onset may range from 30 seconds to as long as 60 minutes.

- Subjects will be monitored in the post anesthesia recovery unit until they are deemed stable and ready for discharge. Any abnormalities will be noted by the nurse taking care of the patient who would inform the anesthesiologist and surgeon. This is standard protocol at our institution when any regional blocks are given for post-operative patients.

Randomization:
Your group may receive less effective treatment or have more side effects than the other group.

Loss of confidentiality:
We will be collecting information that can identify you. Therefore there is a risk of breach in confidentiality. However the researchers have taken measures to reduce this risk.

What are the benefits of this research study?
You may or may not benefit from participation. Your group might receive more effective treatment and/or have fewer side effects than the other treatment group(s).

Your participation in this research project may help us measure and determine if one of these options has superior effects than the other treatment group.

If you do not want to take part in this research study, what are your other choices?
Each treatment option can still be offered to you for post-operative pain control. You also have the option of declining to use any regional anesthesia (nerve block). Regional anesthesia has been shown to be an effective option for decreasing pain after ACL reconstruction.

Are there any costs for being in this research study?
There are no additional costs to you. All costs will be billed to you and your insurance company in the usual way, as part of your standard care if you agree to have regional anesthesia, regardless of if you agree to participate in the study.

Will you receive any payments for participating in this research study?
There are no payments for participating in this research study.

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study. If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study, you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?

You will be told of any new findings that may change your decision to continue to participate.

What information will be collected and used for this study?

If you agree to be in this study, we will collect health information about you. We may collect data from questionnaires and interviews. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?

Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health.

Investigators will share information collected from this study with:

- clinical staff not involved in the study who may be involved in participant's treatment

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies such as the Food and Drug Administration (FDA)
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversee research at this institution)

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

Will you be able to access your records?

If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You

have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Randy Cohn
Address: Medical Education
888 Old Country Rd Plainview, NY 11415

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
A description of this clinical trial will be available on http://www.Clinical Trials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Will my information be used for research in the future?

Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified data to be used by future researchers without additional consent

Does the investigator of this study receive money if you take part?
The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, side effects, or injury you may call the research coordinator Prashant Matai at 929-666-9993 or Dr. Cohn at 516-396-7846 or Co-Investigators: Dr. Nicholas Frane 763-439-5741, Dr. Erik Stapleton 813-220-6777, Dr. Zachary Aberman 336-255-6995, If you need emergency care, dial 911 or go to the nearest Emergency Room. If you

have questions about your rights as a research participant, or concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516)465-1910. A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____ _____

Signature of Adult Participant/Parent/Legally Authorized Representative Date

_____

Printed Name of Adult Participant/Parent/Legally Authorized Representative

_____ _____

Signature of Witness Date

_____

Printed Name of Witness

(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement

In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____

Investigator's signature **Date**

_____

Investigator's printed name

Northwell Health

Campus: Plainview/Valley Stream/Huntington/Long Island Jewish/North Shore University Hospital

Assent to be in a Research Study

Title: Randomized adductor canal single shot versus continuous peripheral nerve block after ACL reconstruction and effects on opioid use, pain, sleep quality.

My name is _____

1. We are asking you to take part in a research study because we are trying to see if one treatment intervention is better than another in reducing painkiller use, improving pain and sleep The intervention may or may not only help you but the results can be used and applied to future patients to help provide better care.

2. If you decide to be in this study, we will be giving you the painkiller medication in one of the 2 ways, either as a single shot after the surgery, or as a drug delivery system implanted in your thigh, that will deliver the medication in a fixed dose over the next few days. We will be comparing this with a single dose of numbing medication given in the operating room after surgery. We will also give you telephone numbers to call doctors throughout the study.

3. Sometimes things that don't feel good happen in research studies. Some things that could happen may hurt you, make you feel yucky, or make you feel upset. You might have allergy to the medicine, persistent pain at injection site, local skin irritation, failure of the pain pump. Ear pain, numbness around the mouth, metallic tastes, confusion, seizures. Some of the things might happen to you or they might not. Or things might happen that we don't know about yet.

4. People may also have good things happen to them when they are in research studies. Your participation in this research project will help us measure and determine if one of these options has superior effects than the other method of giving the pain medication.

5. Please talk to your parents about this before you decide whether or not to be in this research study. We will also ask your parents to give their permission for you to be in this study. But even if your parents say "yes," you can still decide not to be in this research study.

6. If you don't want to be in this study, you don't have to. Each of these treatment options have are available on choice, which will be given before the surgery. You can also refuse the numbing medication.

7. You may stop being in this study any time. Remember, being in this study is up to you and no one will be upset if you don't want to take part in this study or even if you change your mind later and want to stop.

8. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me on 516-396-7846 or ask me next time you come in for an appointment. You may call me at any time to ask questions about your disease and treatment

9. Putting your name at the bottom means that you have decided to be in this study. You and your parents will be given a copy of this form after you have signed it.

Name of Subject	Sign your name here ↑	Date
Witness' Printed Name	Witness' Signature	Date
Investigator's Printed Name	Investigator's Signature	Date