

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

INFORMED ASSENT FOR PARTICIPATION IN A RESEARCH STUDY

STUDY TITLE: Sciatic Peripheral Nerve Blockade for Pain Control Following Hamstring Autograft Harvest in Adolescents: A Comparison of Two Techniques

SPONSOR NAME: Department of Anesthesia

SPONSOR STUDY NUMBER: AANA Foundation

INVESTIGATOR INFORMATION:

James Furstein

Principal Investigator Name

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Telephone Number 24 hr Emergency Contact

INTRODUCTION

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things. Being in research is your choice. You can say yes or no. Whatever you decide is OK. We will still take good care of you. Ask us any questions you have at any time. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about how to best provide pain control after ACL reconstruction. Peripheral nerve blockade is a way of numbing the leg to decrease pain after surgery. We want to know if a single injection of numbing medicine or continually giving numbing medicine give you better pain control after ACL reconstruction. Both ways of numbing the leg have been used for a long time, we just do not know which one works best for pain control after ACL reconstruction.

We are asking you and other children who are having ACL reconstruction to be in the research study, because we want to better understand how to provide the best pain control after surgery.

WHO IS IN CHARGE OF THE RESEARCH?

James Furstein is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study.

WHO SHOULD NOT BE IN THE STUDY?

You can not be in this study if you have any of the following:

- You have an allergy to local anesthetic medications;
- You are spending the night at the hospital after surgery;
- You are having surgery on other parts of your body at the same time you are

- having ACL reconstruction;
- You are less than 10 years old or older than 18 years old.

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain the study to you and give you a handout that explains the study in more detail. You will be able to ask questions to make sure that you understand what will happen.

If you qualify and decide you want to be in the study, you will come to CCHMC the day of surgery. Somebody will go over the data collection diary that you will keep for the first three days when you go home. You or your parents will get a phone call once a day from a research coordinator for three days after after you go home.

If you agree to be part of this study you will be picked to be in one of two groups of patients; those who receive a single injection of numbing medicine for the back of the leg and those who are continually given numbing medicine to the back part of the leg. Your leg will be made numb while you are asleep for surgery. After surgery you or your parents will keep a diary of your pain, medication use, and leg movement during the first three days after surgery. Somebody will be in touch with you once a day to get the information you wrote down on your diary.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

We still have a lot to learn about pain control after ACL reconstruction. We hope that this study will help you feel better or help to reduce your pain after ACL reconstruction, but we don't know if it will. When we finish the research, we expect that we will know more about pain control after ACL reconstruction. This may help other children who need ACL reconstruction later on.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Both ways of numbing the back of your leg in this study have been around for a long time and are used every day to help decrease the pain in kids after surgery. Neither way of numbing the back of you leg is new or experimental, so nothing bad can happen directly related to participating in this study. Sometimes, after a patient has their leg numbed they complain of:

- Itching
- Skin irritation where the numbing medicine was placed
- A bruise where the numbing medicine was placed
- Feeling sick to their stomach
- A temperature after surgery

You may be asked questions that make you uncomfortable or cause you to remember situations that were upsetting to you. You do not need to answer any questions that you do not wish to answer and you can stop the study at any time. If you become very upset during the study at any time, we will end the study. We will also offer to have you speak to someone about what you are feeling.

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it.

WHAT ELSE SHOULD YOU KNOW ABOUT THE RESEARCH?

Take all the time you need to make your choice. Ask us any questions you have.

Remember, it is also okay to ask more questions after you decide to be in the research study. You can ask questions at any time.

SIGNATURES

After you have read this form and talked about this research with your parents and the doctors or nurses you need to decide if you want to be in this research.

If you want to be in this research you should sign or write your name below.

Child's Assent

Date

Signature of Person Obtaining Assent

Date