

STUDY TITLE: PRE-EMPTIVE GENOTYPING OF CHILDREN AND ADOLESCENTS AT RISK FOR SURGERY AND SUBSEQUENT PAIN MANAGEMENT**STUDY NUMBER: 2013-0853****FUNDING ORGANIZATION: The National Institutes of Health and the Department of Anesthesia.**Senthilkumar Sadhasivam, MD, MPH
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513-636-7963**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 how doctors use gene tests to pick pain medicines. We also want to learn how doctors use gene tests to decide how much pain medicine you need if you have surgery. Most important, we want to learn if knowing some of your genes can help pain medicines work better if you need them.

We are asking you and other children to be in the study because you might have surgery that involves taking pain medicine. We believe knowing certain genes before choosing pain medicines will help people after surgery.

WHO IS IN CHARGE OF THE RESEARCH?

Senthilkumar Sadhasivam 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 :

1. Are younger than 2 years or are 22 years old or older
2. Have significant comorbidities (ASA 4 and 5)
3. Have liver or kidney disease
4. Have a neurodegenerative disease
5. Have a severe pulmonary (lung) disease (e.g. cystic fibrosis)
6. Are known to take medicine or drugs for fun

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain each visit to you. 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 for up to two study visits.

These are the things that will happen to you while you are in the study:

- We will collect some blood from you. If you are afraid of needles, we will collect spit from you instead of blood.
- We will get information from your medical records and may talk to your doctors and nurses about how you are doing.
- If you are older than 5, need surgery and need to stay at the hospital for a few days, we will ask you to fill out a form to find out how you feel when you are in the hospital.. If we cannot see you while you are in the hospital we may call you to find out how you feel.
- If you need surgery but will go home that same day we will ask you and your parent to fill out a pain diary. The diary will ask you about how you feel, how much you sleep and how much you eat after your surgery.

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

Being in this study may not help you right now. When we finish the study, we hope that we will learn how knowing children's genes can help doctors choose medicines for pain after surgery. This may help other children later on.

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

- Having your blood drawn may hurt when the needle passes through your skin.
- The information we learn about you in this study may be discovered by others. However, we will try very hard to protect your study information. We will not share your information with anyone outside the study. For example, your teachers, friends, brothers or sisters will not know your answers in the survey or what researchers collect from your medical record.
- If we find out new things that are different from what we currently know, this may make you confused. We do our best to make sure that this does not happen.

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. You can ask questions at any time. It is also ok to say you do not want to be in the research no matter what you decide we will still take good care of you.

SIGNATURES

After you have read this form and talk 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