Cover Page for Approved Consent

NCT #: 04563494

Study Title: The effects of IV vs oral dexamethasone on postoperative nausea, vomiting, pain, and drug cost in children undergoing tonsillectomy: A randomized controlled prospective non-inferiority study.

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Principal Investigator: Jeremy Prager, MD
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Study Title: The effects of IV vs oral dexamethasone on postoperative nausea, vomiting, pain, and drug cost in children undergoing tonsillectomy: A randomized controlled prospective non-inferiority study.

You or your child are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about a medication, dexamethasone, also referred to as the study drug, that treats postoperative nausea and vomiting, as well as postoperative pain after your child's surgery. The medication is a routine medication that is given to every child who has this surgery, but it is currently unavailable world-wide due to the covid19 pandemic. The medication that is being studied is the same medication but in a different form – oral medication instead of intravenous (medicine that goes into the IV line). The goal is to learn as much as possible about the oral version of this medication, because it may be a good substitute for the intravenous version.

You are being asked to be in this research study because your child is having his or her tonsils removed and will be getting this medication to help prevent postoperative nausea and vomiting and also reduce pain postoperatively.

Other people in this study

Up to 160 people from your area will participate in the study.

Up to 160 people around the country will be in the study.

The study is a local study being performed at Children's Hospital Colorado only.

What happens if I join this study?

If you join the study, your child will receive all of the routine and normal care that he or she would normally receive while having a tonsillectomy. This includes administration of one (1) dose of this medication.

In addition to the routine care, as part of this study your child will be given an oral liquid prior to surgery that may or may not contain the medication. Your child will also be given an intravenous liquid during surgery, which may or may not contain the medication.

Your child will only receive the medication once (either by mouth or through the IV), which is routine for this patient population having this type of surgery.

Study participation is during your stay at the hospital, lasting through the first postoperative day. Outside of the oral medication given before surgery, all of the care will be routine and your child will receive the care we would normally perform for this surgery and anesthesia.

Additionally, information from your child's medical record will be collected if you join the study.

What are the possible discomforts or risks?

Discomforts your child may experience while in this study include annoyance or irritation being asked to take an oral medication

Other possible risks include that the oral medication form may not work as well as the intravenous (through the IV) form.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about identifying a substitute for the IV medication, which is currently on extremely limited supply and will not be available in a matter of weeks.

This study is not designed to treat any illness or to improve your health.

Are there alternative treatments?

There are no alternative treatments for this particular medication

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

The Children's Hospital Colorado Research Initiative is paying for this study as part of an emergency funding for covid19-related pediatric research studies. It is supported also by funding provided by Children's Hospital Colorado Foundation.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Jeremy Prager, immediately. His phone number is 720-201-1339.

If you are hurt by this research, we will give you medical care. Medical treatment will be provided at no cost to you or your insurance company for a research-related injury. The sponsor and the investigator will determine if your injury or illness is research-related. The term “research-related injury” means physical injury caused by drugs or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the trial.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Jeremy Prager MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Jeremy Prager, at 720-201-1339. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Jeremy Prager. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

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 Web site at any time.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- Children's Hospital Colorado (CHCO). CHCO shares a medical record system with the Barbara Davis Center and PedsConnect; therefore, it is also possible that your information could be viewed by healthcare professionals at these organizations.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Jeremy Prager, MD
Pediatric Otolaryngology - Head & Neck Surgery
13123 East 16th Avenue Box 455
Aurora, CO. 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

----------Use the following only if applicable----------

A signature of a witness is required for consent of non-reading subjects and consent using a short form.

Witness Signature: _____ Date:_____

Print Name:_____

Witness of Signature ☐

Witness of consent process ☐