Usefulness of the medication 'celecoxib' in pain relief after tonsillectomy

INFORMATION FOR PARENTS / GUARDIANS

Introduction

You are invited to allow your child to take part in a research study into new pain relief methods after tonsillectomy. This research study will investigate whether adding a medication called celecoxib to the current medications used to treat pain after tonsillectomy will create more effective pain relief for children than using only the current medications. We encourage you to discuss this research with your child if they are old enough, and for them to read this information statement as well as the age appropriate one that has been provided. If your child is old enough to understand what the study involves, then it should be a joint decision with them whether they participate in the research.

What is the research about?

Celecoxib is a medication that is widely used for pain relief. We want to find out if it can be used after tonsillectomies in children to help control the pain. To do this research, we will be splitting people who agree to take part into two groups randomly, like flipping a coin. One group will receive celecoxib and the normal medications, the other group will receive the normal medication and a liquid that looks like the new treatment but does not have any treatment value from active ingredients. If you choose to participate, we will send you a survey to log details about your child's pain and recovery after their surgery so that we can compare the pain in children who have celecoxib and those who do not.

Where is the research being done?

The study is being conducted within Gosford Hospital, Gosford Private Hospital and the University of Newcastle by

Dr Shashinder Singh, Ear Nose and Throat Surgical Consultant at Gosford Hospital
Dr Michael Zhang, Ear Nose and Throat Surgical Registrar at Gosford Hospital

In addition to

Naae Kim, Medical Student, University of New England
Chloe Douglas, Medical Student, University of New England
Renee Thou, Medical Student, University of New England
Vanessa Pitts, Medical Student, University of Newcastle

as part of the requirements for a Bachelor of Medical Science, Doctor of Medicine double degree under the supervision of Dr Singh and Dr Zhang. The students will be involved in analysing the results of the survey under the supervision of Dr Singh and Dr Zhang.

Who can participate in the research?

We are seeking children aged 3-16 who are undergoing a tonsillectomy at Gosford Hospital to participate in this research.

If your child is having a tonsillectomy with or without adenoidectomy, insertion of grommets or turbinate diathermy at the same time as their tonsillectomy, this study is suitable for them.

If your child;

- Is already taking NSAIDs on a regular basis (NSAIDs are non-inflammatory pain medication such as ibuprofen (e.g. Nurofen or Aspirin)
- Is already taking opioids (e.g. Oxynorm) or paracetamol (e.g. Panadol or Tylenol) on a regular basis
- has allergies to NSAIDs, opioids, paracetamol, sulfomethoxazole or trimethoprim
- takes medications that interact with opioids, paracetamol or NSAIDs
- has any history of peptic ulcers or gastrointestinal bleeding
- is pregnant or nursing
- has a disease which may make them unable to be treated with Celecoxib (Celebrex), opioids or paracetamol

Then this study is not suitable to them.

If you are unsure if your child falls into one of these categories, you can ask your child's doctor.

What Choice do you and your child have?

Participation in this study is entirely voluntary. You may discuss the study and what it involves with your child. You do not have to agree for your child to take part in this research and your child's refusal to take part will also be respected. If you and your child do decide to take part, you can withdraw your child at any time without having to give a reason. You can ask that any data collected concerning your child also be withdrawn from the study. Whatever your decision, please be assured that it will not affect your child's medical treatment or your relationship with the staff who are caring for your child.

What would your child be asked to do if you and your child agree to participate?

If you agree to allow your child to participate in this study, you will be asked to sign the Parent/Guardian Consent Form. Your child may also sign this form. You and your child will then be asked to complete questionnaires on day 3, 5, 7, 10 and 14 after their surgery. These will seek information on their pain levels and recovery process. They will take about 5 minutes to do.

What are the risks and benefits of participating?

Risks

All medical procedures - whether for diagnosis or treatment, routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. Despite all precautions, your child might develop medical complications from participating in this study.

The risks of participating in this study are limited only to the risks associated with taking celecoxib, as any other medications your child is prescribed are the normal post-tonsillectomy medications.

Celecoxib is not a new medication and has already been safely used and studied. However, some side effects that might be experienced are:

Common side effects (>1%)

- Nausea
- Indigestion
- Stomach ulcers or Bleeding
- Diarrhoea
- Headaches
- Dizziness
- Fluid retention
- Raised blood pressure

Infrequent side effects (0.1-1%)

- Oesophagus ulcers
- Rectal irritation
- Heart failure
- Raised Potassium
- Kidney impairment
- Confusion
- Rash
- shortness of breath, wheeze or cough

Rare side effects (<0.1%)

- Kidney dysfunction
- Allergic reaction
- Severe rash
- Sun burn
- Stroke
- Heart attack
- Liver inflammation
- Ringing ears
- Inflammation of the meninges

Benefits

While we intend that this research study furthers medical knowledge and may improve treatment of post tonsillectomy pain in the future, it may not be of direct benefit to your child.

Will the study cost you anything?

Participation in this study will not cost you anything, nor will you or your child be paid. Celecoxib in a liquid form will be provided free of charge.

How will your privacy be protected?

All the information collected from you and your child for the study will be treated confidentially, and only the researchers named above will have access to it. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

Your child's personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

If you wish to remove your child from the study throughout the duration of the research your child's data will be withdrawn and destroyed. Once the study is published, we will be unable to withdraw your child's data. However, anything we publish will be about the groups data not individual children's results and no identifying features will be discussed within the publication.

Further Information

When you have read this information, the Celecoxib Research team will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on CCLHD-ENTResearch@health.nsw.gov.au

This information statement is for you to keep.

Ending

Thank you for considering this invitation.

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1. # HNE Ethics and Governance statements

Ethics:
This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2021/ETH11236.

Governance:
The conduct of this research has been **authorised** by the Hunter New England Local Health District to be conducted at the Gosford Hospital and Gosford Private Hospital.

Complaints about this research:
Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact the **HNE Research Office,** Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305. Telephone: 02 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number: **2021/ETH11236**

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INFORMATION FOR ADOLESCENTS

Introduction

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What is the research about?

Celecoxib is a medication that is widely used for pain relief. We want to find out if it can be used after tonsillectomies in children to help control the pain. To do this research, we will be splitting people who agree to take part into two groups randomly, like flipping a coin. One group will receive celecoxib and the normal medications, the other group will receive the normal medication and a liquid that looks like the new treatment but does not have any treatment value from active ingredients. If you choose to participate, we will send you a survey to log details about you pain and recovery after their surgery so that we can compare the pain in children who have celecoxib and those who do not.

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- have any history of peptic ulcers or gastrointestinal bleeding
- are pregnant or nursing
- have a disease which may make them unable to be treated with Celecoxib (Celebrex), opioids or paracetamol

Then this study is not suitable to them.

If you are unsure if you fall into one of these categories, you can ask your doctor.

What Choice do you have?

Participation in this study is entirely voluntary. You may discuss the study and what it involves with your parents. You do not have to agree to take part in this research and your refusal to take part will also be respected. If you do decide to take part, you can withdraw yourself at any time without having to give a reason. You can ask that any data collected concerning you also be withdrawn from the study. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

What would you be asked to do if you agree to participate?

If you agree to participate in this study, you will be asked to sign the Consent Form. Your parents will also be asked to sign this form. You will then be asked to complete questionnaires on day 3, 5, 7, 10 and 14 after their surgery. These will seek information on your pain levels and recovery process. They will take about 5 minutes to do.

What are the risks and benefits of participating?

Risks

All medical procedures - whether for diagnosis or treatment, routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. Despite all precautions, you might develop medical complications from participating in this study.

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Child Information Sheet

Usefulness of the medication 'celecoxib' in pain relief after tonsillectomy

This information sheet has been put together to help you decide if you would like to take part in our research project.

Why are we asking you?

We are asking you to take part in this project because:

- We want to find out if a new medicine called 'celecoxib' can make you feel better after your surgery.

Why are we doing this project?

After your surgery it can take a few weeks for you to feel better. We want to make these weeks less painful for children who have had this surgery by giving them a different medicine.

How the Project works...

After the surgery you will be put into group 1 or group 2 randomly, like flipping a coin. One group will be given all the normal medicines and the new medicine. The other group will just be given the normal medicines.

With the help of your parents, you will be asked to fill out a questionnaire about your pain after the surgery and answer questions about your pain.

Do I have to take part?

No you don't. If you say no, that is ok. It is up to you.

If you say yes, and then change your mind later on, that is okay as well. All you need to do is tell the researcher that you don't want to take part anymore. You also don't need to answer any question that you don't want to as well, that is okay too.

Good and bad parts of the project

Some bad things that could happen in the project are: Sometimes the medicine can make people feel sick.

Some good things that can happen in the project: The new medicine can make people feel less pain after the surgery.

Anything else?

You can talk about the project with your parents and ask questions about the project before making a decision.

If you would like to know more about this project, or would like to take part, you or your mum, dad, or usual caregiver can email a member of the research team at celecoxibresearch@gmail.com

If anything happens whilst you are in this research tell your mum, dad or caregiver and they will know who to talk to.

Thank you for reading this letter.

Health
Central Coast
Local Health District

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PARENT/GUARDIAN CONSENT FORM

I, ... [name of parent/guardian]

of .....…….[address],

Parent/Guardian of …….. [name of child]

have read and understand that the study will be conducted as described in the Information Statement, a copy of which I have retained. I have discussed this research with my child.

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I understand that participation in this study will allow the researchers to have access to my child's medical record, and I agree to this.

I agree to my child participating in this study and understand that I can withdraw them at any time without providing a reason.

I understand that my child's personal information will remain confidential to the researchers.

I and my child have had the opportunity to have questions answered to our satisfaction.

I hereby agree to my child's participation this research study.

I **would / would not** like to receive a summary of the results. The summary should be sent to;

_____ [Email or Address]

NAME OF CHILD _____

CHILD'S SIGNATURE: _____

NAME OF PARENT/GUARDIAN: _____

SIGNATURE: _____

DATE: _____

Declaration by person conducting the consent process
I, the undersigned, have fully explained this research to the patient named above.

NAME: _____

SIGNATURE: _____

DATE: _____