Default Dosing Settings for Opioid Prescriptions to Adolescents and Young Adults After Tonsillectomy

NCT04066829

IRB Approval Date: December 6, 2020

********************DO NOT DELETE OR ALTER THIS PAGE********************

CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent** - *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

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Study ID: HUM00159821 / Continuing Review ID: CR00086077

Approval Date: 12/6/2020

Document Finalized: 12/7/2020 9:43 AM

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Pain Medication Prescribing and Use after Tonsillectomy in Adolescents and Young Adults

Principal Investigator: Kao-Ping Chua, MD, PhD

GENERAL INFORMATION

We're doing a study to learn more about how much pain medication adolescents and young adults need after having their tonsils removed, and how to make sure the amount of pain medication in prescriptions after surgery matches what patients need. To get information, we'd like you to answer three sets of surveys: a 10-15-minute survey now, daily 1-2 minute surveys during the 13 days after surgery, and a 10-15-minute survey 14 days after surgery. We expect the surveys to take less than 45 minutes in total.

Participation is voluntary. You don't have to participate if you'd rather not. If you participate, you can skip any questions that you don't want to answer, whatever the reason, and you don't have to tell us why. Choosing not to answer our survey won't affect the medical care you receive. It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

To keep your information confidential, we will take every precaution necessary and use strict security measures to protect your data and privacy. Your name will be replaced with a random code to hide your identity while the data is stored. We will use your name to combine the survey with electronic healthcare data. Under no circumstances will we intentionally release your name, date of birth, email address, address, phone number, or other identifying information publicly. The data is protected in special ways that are required for health information, as required by federal regulations governing all health care information in the United States.

If you disclose to us that you are having feelings of hurting yourself, a mental health professional on our team will contact you. If we learn that you are at immediate risk of hurting yourself and you're a minor, we may contact your parent or guardian. Otherwise, if you are bothered by mood problems or having thought about hurting yourself during the study, it's better to talk to your doctor or mental health professional. We suggest you make an appointment with your regular doctor as soon as possible. You can also call the University of Michigan Depression Center (734-764-0231 or 1-800-525-5188) to ask for counseling and other supportive services. For Urgent Care, please call Psychiatric Emergency Services at the University of Michigan Hospital at 734-936-5900 or dial 9-1-1.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if:
- There is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); or
- You have consented to the disclosure, including for your medical treatment; or
- It is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Drug Abuse, which is funding this project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of suspected or known sexual, physical, or other abuse of a child or older person, or threats of violence to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Answering our survey won't benefit you directly. We hope what we learn will help other people in the future.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

To thank you for participating, we'll mail you a gift card for $10 for each set of surveys that you complete. The University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed below (under Contact Information).

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers
- Other information

It's possible that the researchers or others will need access to information about you during or after this study. For example:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- The University of Michigan or a government agency may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to, make sure the study is done safely and properly, learn more about side effects, or analyze the results of the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- Federal or State law may require the study team to give information to the Food and Drug Administration (FDA) or other government agencies. For example, to prevent harm to you or others, or for public health reasons.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

As a rule, the researchers will continue to use information about you until the study is over and will keep it secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities. But use of this information would not reveal your identity.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information see http://www.med.umich.edu/hipaa/npp.htm. Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Kao-Ping Chua, MD, PhD Mailing Address: 300 N Ingalls St, SPC 5456, Room 6E18, Ann Arbor, MI 48109 Telephone: 734-615-8169 Email: chuak@med.umich.edu	Study Coordinator: Kendall Dubois Mailing Address: University Hospital South, Unit 2, 1505 Simpson Dr, Ann Arbor, MI 48109 Telephone: 734-232-0324 Email: OPATstudy@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID: _____ Date of Birth: _____

Legal Representative (if applicable):

Signature of Person Legally
Authorized to Give Consent _____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____

Check Relationship to Subject:

☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

[If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.]

Reason subject is unable to sign for self:

_____

_____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____