UNIVERSITY OF WASHINGTON
CONSENT FORM

Effect of Post-operative Ibuprofen after Surgery for Chronic Rhinosinusitis

Researchers:

Craig Miller, MD	Resident	Otolaryngology – Head & Neck Surgery	206-314-8781
Greg Davis, MD, MPH	Associate Professor	Otolaryngology – Head & Neck Surgery	206-543-5230
Ian Humphreys, DO	Assistant Professor	Otolaryngology – Head & Neck Surgery	206- 583-1863

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Chronic rhinosinusitis (CRS) is a common clinical disease. Following sinus surgery, patients are typically prescribed a combination of acetaminophen, also known as Tylenol, and an opiate narcotic medication, such as oxycodone, or a single combination pill of both medications. We are interested in investigating the impact of other pain medications on sinus surgery pain. One medication specifically, ibuprofen, also known as Motrin or Advil, is an over-the-counter medication. We are conducting a study investigating the use of ibuprofen in the post-operative period following sinus surgery. We are hoping to find out if ibuprofen is a safe and effective option for pain control in post-operative sinus surgery patients as this could help to reduce opiate exposure and prescribing. Currently, surgeons who perform sinus surgery avoid the use of ibuprofen due to a theoretical risk of increased bleeding following sinus surgery. We aim to perform a well designed study to evaluate this theoretical risk.

This investigation will be aimed at reducing the number of opioid pills prescribed and taken following sinus surgery. The first step in this process is evaluating the effect of ibuprofen on pain levels following surgery. This study will have two arms and participation in either arm is your choice entirely. One arm will consist of the standard pain regimen without the addition of ibuprofen, the other will have the same regimen with the addition of ibuprofen 400 mg every 6 hours while awake until cessation of need for scheduled pain medication.

STUDY PROCEDURES

We will also ask you to let us record information from your medical record for research. We want to record information about your medical history, nasal cultures, previous surgeries, CT scans of your sinuses, and any questionnaires that you complete in the clinic related to your chronic sinus disease.

We are giving you information about this study because you are being treated for chronic sinus disease. Treatment for you sinus disease will be decided by your physician and is independent of this study. If you are willing to participate, we will have you decide in which arm you would like to be enrolled, standard or ibuprofen. Following sinus surgery, we will have you complete a short questionnaire each day for seven days. You have the choice of using a paper diary to complete this or using an online, secure website. If you elect to use the paper diary, you will receive a quick reminder call on the 1st, 3rd and 7th day following surgery to remind you to complete your questionnaire. If you choose the online recording tool, an email with a link to the questionnaire will be sent to you daily for the first seven days following surgery. The table below outlines the pain management schedule for the two arms of the study. Acetaminophen or acetaminophen and ibuprofen combination will be taken on a scheduled basis while you are awake until your pain is managed well enough to no longer needed scheduled pain medication. The "control group" is the normal pain control that will be prescribed even if you are not interested in participating in the study. The addition of ibuprofen is the experimental aspect of this study.

Control group (normal pain control regimen)	Study group (ibuprofen)
Acetaminophen 650 mg q6 hrs	Acetaminophen 650 mg q6 hrs
Oxycodone 5 mg q3hrs PRN	Oxycodone 5 mg q3hrs PRN
	Ibuprofen 400 mg q6hrs (alternating every 3 hrs with acetaminophen)

All sinus surgery patients are seen in clinic approximately two weeks following surgery. At that time, we will have you bring back your diary and will give you a $20 gift card for your participation in the study. The diary must be complete to receive the gift card. Additionally, at your first post-operative visit, we ask that you bring in your remaining oxycodone pills for us to count how many you have left and calculate how many you took during the post-operative period. All remaining pills will be returned to you. All patients involved in the study will be seen by a study team member at the first post-op visit.

RISKS, STRESS, OR DISCOMFORT

Risks for this study include all risks of sinus surgery that your surgeon discussed with you prior to signing your surgical consent. For the study specifically, the standard pain regimen arm has no further risks beyond sinus surgery. Ibuprofen is a commonly used medication, but there are a number of potential adverse effects including nausea, dyspepsia, gastrointestinal bleeding/ulceration, raised liver enzymes, diarrhea, constipation, increased nose bleeding, headache, dizziness, rash, and hypertension. The short duration and low dose of the medication used in this study make these adverse effects unlikely. Currently, there is not enough data to

draw conclusions on whether the use of ibuprofen is safe in this population and this is why we are performing the study. Due to this lack of substantial data, there is a possibility that there may be increased bleeding following surgery. We anticipate that this will be minimal, but we have provided contact information for our clinic and on-call physician if you have any concerns post-operatively. If you elect to be in the control arm, we will ask that you do not take ibuprofen in the post-operative period. This may place you at an increased for opioid exposure compared to what you would experience if you did not participate in this study. There is a risk to your confidentiality when your medical records are accessed and used for research. Information about how we will protect you health information is outlined in the Confidentiality section below.

Not all patients are eligible for this study. Exclusion criteria includes: any contraindication to ibuprofen, or its class of medications known as NSAIDS (including but not limited to chronic kidneys disease, peptic ulcer disease, Sampter's triad), previous history of bleeding disorder, sinus cancer, cystic fibrosis, current use of blood thinning medication, history of chronic pain condition, fibromyalgia, or opioid addicition, contraindication to acetaminophen, also known as Tylenol, or daily use of pain medication for any other reason including ibuprofen, other NSAIDs, acetaminophen/Tylenol, opioid medication or other analgesics. If you feel any of these apply to you, please notify the person discussing this study with you or your surgeon.

BENEFITS OF THE STUDY

We do not know if ibuprofen will help the subject need less opioid medication. The subject will not benefit directly but we hope that this study may help others in the future.We will be using information gained from this study to advance knowledge and understanding of sinus disease, as well as evidence-based prescribing on narcotic medication.

CONFIDENTIALITY OF RESEARCH INFORMATION

The researchers will keep your study information confidential. We will assign a study code to your study information. We will keep any information that will identify you in a secure location, separate from the study information. If we publish the results of this study, we will not use any information that will identify you. We may use the study information for other studies after we destroy any link to your identity.

Government and university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

OTHER INFORMATION

Taking part in this study is voluntary. You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. As with medications typically prescribed following sinus surgery, you or your insurance will be responsible for the cost of ibuprofen. We will provide you with $20 remuneration via gift card upon successful completion of your portion of this study.

RESEARCH-RELATED INJURY

If at any time you would like to withdraw from this study, contact the University of Washington Otolaryngology Clinic at (206) 598-8545 during regular business hours or ask to have the ENT resident on-call paged through the University of Washington Medical Center operator at (206) 598-3300 after hours right away. He/she will notify the study team of your desire to withdraw. If at any time you feel that you have been harmed by participating in this study, contact Dr. Craig Miller at Craigmil@uw.edu. He will treat you or refer you for treatment.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject