Study Title:

Effects of preoperative combined use of acetaminophen and ibuprofen on the control of pain following orthodontic treatment

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UNIVERSITY OF WASHINGTON
CONSENT FORM
Pre-emptive Use of Analgesics for Orthodontic Pain Reduction

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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

Orthodontic treatment creates an inflammatory process, which allows for the reshaping of bone around the teeth. The inflammation may also be a source for pain or discomfort during treatment that peaks within the first few days after treatment and is usually resolved within a week. Analgesics are medications that are used to relieve pain. Commonly used analgesics are acetaminophen (a.k.a. Tylenol®) and ibuprofen (a.k.a. Advil®). These drugs work by specifically inhibiting cyclooxygenase (COX) enzymes, which weakens the inflammatory response and therefor reduces the discomfort caused by orthodontic treatment. Acetaminophen and ibuprofen have both been shown in numerous studies to reduce the peak level and duration of discomfort associated with orthodontic treatment when taken before the appointment when compared to a placebo (sugar pill). The combination of both acetaminophen and ibuprofen is a widely accepted standard for mild to moderate dental pain relief. However, to our knowledge, the combination of acetaminophen and ibuprofen taken pre-emptively has not yet been investigated for pain reduction during orthodontic treatment.

This study is recruiting 180 participants in order to determine if orthodontic patients can benefit from decreased peak levels of discomfort and shorter duration of discomfort with pre-emptive administration of a combination of acetaminophen and ibuprofen compared to a single dose of each individual medication.

STUDY PROCEDURES

As a participant of this study, you will be given a brown envelope that contains two capsules. The contents of the two capsules will be one of the following:

- Acetaminophen (a.k.a. Tylenol®) (650mg),
- Ibuprofen (a.k.a. Advil®) (400mg),
- Acetaminophen (a.k.a. Tylenol®) (650mg) + ibuprofen (a.k.a. Advil®) (400mg)

Before the start of your appointment, you will be asked to take the provided medication, record the date and time, and answer a few short questions, which should take less than a minute.

You have the option to be given a paper workbook or online version that consists of visual analogue scales (VAS) which will help you record your level of discomfort at four different time points over the next few days. Each recording can be completed in one to two minutes. For your convenience, the requested dates and times for the recordings will be written on the top of each page:

- Immediately following drug administration
- 6 hours after the appointment
- The morning after the appointment
- The 2nd morning after the appointment

For each recording you will mark the horizontal line circle the appropriate number that corresponds to your level of discomfort. You may use the provided facial expressions, or written descriptions to help you determine an appropriate recording.

Each time interval will ask you to record your level of discomfort during three different scenarios:

- At rest: The teeth should be not touching and the jaw should be relaxed
- Lightly close: Gently bring your back teeth together until they touch
- Chewing: Chew a small piece of wax (~1/2 inch) for 5 seconds

During the study you will be asked to not take any additional analgesics. If you absolutely must take additional analgesics please record what you took, how much, when you took it, and if it was for dental pain.

If you have completed the paper version of the workbook, please bring it to your next appointment at the University of Washington and return it to the front desk upon check-in.

Participation in this study will have no effect on your treatment and you are not obligated to answer or complete any portion of the study against your will. You are free to refuse any portion of the study.

RISKS, STRESS, OR DISCOMFORT

The medication given to you will be randomly determined and will include one of the following:

- Acetaminophen (a.k.a. Tylenol®) (650mg),
- Ibuprofen (a.k.a. Advil®) (400mg),
- Acetaminophen (a.k.a. Tylenol®) (650mg) + ibuprofen (a.k.a. Advil®) (400mg)

The doses are determined from the U.S. Food and Drug Administration (FDA) recommended doses for each medication for ages 12+ and over 88 lbs. If you have not taken one of the medications before, there may be unanticipated side effects. These commonly taken medications

are available over-the-counter and side effects are often associated with long-term use at high doses. Although rare, it is possible that you may experience:

- Anemia
- Kidney failure
- Liver failure
- Edema
- Dizziness
- Blurred vision
- Headache
- Rash
- Heartburn
- Nausea
- Cardiovascular thrombotic events
- Ulcers
- Bronchospasms

Adverse effects typically occur in patients over the age of 60 or with one of the following conditions:

- Impairment of the heart, kidney, or liver
- History of peptic ulcer
- History of hypersensitivities to NSAIDs or acetaminophen
- Asthma
- Systemic lupus erythematosus

BENEFITS OF THE STUDY

The medication that you will be given may reduce your peak pain level and shorten the duration of discomfort associated with your orthodontic treatment.

CONFIDENTIALITY OF RESEARCH INFORMATION

The workbook that will be given to you will have a unique number associated with it that can be used at the conclusion of the study to determine which drug was administered. No personal identifiers will be recorded and your responses will be kept anonymous.

OTHER INFORMATION

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.

If you would like to enter the raffle for one of four gift cards, please tear off the raffle ticket on the last page of your workbook. If you completed the online version of the workbook, then your contact information will be automatically entered into the raffle once you have submitted your last recording. Fill out your contact information and return it to the front-desk of the Department of Orthodontics. At the conclusion of the study, four tickets will be randomly drawn to determine who will receive the $50 Visa gift cards, and contacted approximately at the end of June 2017. Prizes can be claimed at the front-desk of the Department of Orthodontics when convenient.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Andrew Keith right away at (206) 616-4338. 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 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

When subject is a minor:

Printed name of parent Signature of parent Date

Copies to: Researcher
Subject