

A Randomized Controlled Trial of Acetaminophen and Ibuprofen Versus Acetaminophen and Oxycodone for Postoperative Pain Control in Operative Pediatric Supracondylar Humerus Fracture

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CONSENT FOR PARENT AND PARENTAL PERMISSION FOR MINOR TO PARTICIPATE IN RESEARCH

A Randomized Controlled Trial of Acetaminophen (Tylenol) and Ibuprofen Versus Acetaminophen (Tylenol) and Oxycodone for Postoperative Pain Control in Operative Pediatric Supracondylar Humerus Fractures

Rachel Thompson, MD, and Mauricio Silva, MD, from the Department of Pediatric Orthopaedic Surgery at the University of California, Los Angeles (UCLA) are conducting a research study.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because your child has a supracondylar humerus fracture (a type of common elbow fracture in children) that requires surgery. Your participation in this research study is voluntary.

Why is this study being done?

The study is being done to determine differences in pain control using oxycodone and Acetaminophen (Tylenol) vs ibuprofen and Acetaminophen (Tylenol) in patients who undergo surgery for supracondylar humerus fractures.

The following definitions may help you understand how this research study is designed: Double-blinded randomized control trial: this means that the patient (and the family) and the doctors who do the surgery do not know which medications you have been given after surgery. This is to reduce any bias in the analysis of the data.

This study is being funded by Orthopaedic Institute for Children Foundation

What will happen if we take part in this research study?

Before you begin the study:

Before you begin the study, you will need to be seen in our Orthopaedic Institute for Children Urgent care, have x-rays done, be placed in a splint and need surgery for your fracture. No labs are needed prior to the surgery, unless you require medical clearance by your doctor before undergoing anesthesia.

You will be randomized into one of two treatment groups. One group will receive acetaminophen and ibuprofen to manage their pain while the second group will receive acetaminophen and oxycodone. For randomization, sealed envelopes will be used, sequentially numbered on the outside, but with a random sequence written on a

letter-sized sheet of paper inside, which will be concealed such that it will be unreadable from the outside. The nurse or coordinator will open the envelopes after consent of each patient/family to determine the treatment for the given patient. The probability of being assigned to each of the two arms of the study will be 50%, or 1 in 2.

During the study:

If you take part in this study, the researcher(s) will ask you to do the following:

- Your child will be asked to rate his/her pain level using a scale that we provide you with prior to surgery.
- You (parent) will pick up the prescription while your child is undergoing surgery. You will be given acetaminophen (Tylenol) and a study drug (either ibuprofen or oxycodone). You will not know which study drug is given, but the medication information for both study drugs will be given to you by the pharmacist.
- Your child will have his/her pain level recorded after surgery per usual post-operative protocol. Pain medication will be given per usual post-operative protocol and recorded by the researchers.
- At home, you will record all medications (either tylenol or study medication) in a log that we provide to you. You will record the type (either acetaminophen (Tylenol) or study medication), dosage (amount given), time given and your child's pain level at the time of administration. This will be done until your child no longer requires pain medication.
- You will also record your child's pain level at 24 and 48 hours after surgery.
- You will be asked to fill out a survey on your satisfaction with the surgery and the subsequent pain control prior to your first clinic visit after surgery.

How long will we be in the research study?

Participation will take a total of about 2 weeks.

Are there any potential risks or discomforts that we can expect from this study?

- Possible risks include inadequate pain control with the study medication, possible side effects from oxycodone (if your child receives it) which can include nausea, vomiting, constipation, and respiratory depression (see medication information sheet for complete list). If your study medication does not provide adequate pain control, you may contact the pharmacy for the alternative study medication.
- Risks of oxycodone include nausea, vomiting, dizziness, drowsiness, lightheadedness, fainting, constipation, anxiety, restlessness, itching, respiratory depression, or death.
- Risks of ibuprofen include bleeding, liver/kidney damage, vision problems, higher risk of heart attack or stroke.
- Treatment assignment is by chance rather than based on a clinical decision, you may not get the treatment you prefer, the treatment you are assigned to may be less effective or have more side effects than the treatment you would have received if you were not participating in the research

Unknown risks and discomforts:

The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

WHAT IF THE STUDY MEDICATION DOES NOT WORK:

If the medication you were prescribed does not work (e.g. your child's pain is not alleviated), you can do the following:

- If it's during pharmacy hours at Orthopaedic Institute for Children (Monday through Friday, 8am to 5pm), you may call the pharmacy at (213)742-1128 and ask them to dispense you the other medication that you were not prescribed (e.g. if you were given ibuprofen, you can receive oxycodone). You will need to pick up the medication during the above pharmacy hours.
- If it's not during pharmacy hours, you can contact the orthopaedic surgery resident on-call by calling the hospital at (310)319-4000 and ask to page the pediatric orthopaedic surgery resident on call. They can provide assistance over the telephone. They will be able to tell you the study medication; if your child was given oxycodone, you will be able to pick up ibuprofen over-the-counter. If your child was given ibuprofen, you will either need to go to the emergency room or wait until the pharmacy opens the next morning (please note: prescriptions for narcotics cannot be "called-in" or prescribed electronically).

Are there any potential benefits if we participate?

You and your child may benefit from the study by possibly avoiding exposure to narcotic medication, which has side effects (nausea, vomiting, constipation, addiction, respiratory depression).

Possible benefits to others or society:

There will be no direct benefit to you from participating in this study. The results of the research may help further our understanding of pain control after pediatric elbow surgery and potentially avoid unnecessary narcotic exposure in children in the future.

What other choices do we have if we do not participate?

You can choose to not participate and know what medications are being prescribed. If you do not participate, you will be prescribed a typical compliment of pain medications – including acetaminophen (Tylenol), ibuprofen and oxycodone. And if you do choose to participate, but the study medication you receive does not provide adequate pain control, you may contact the pharmacy to receive the other study drug in addition to the medication that your child was initially given.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:

The patient's personal information (name, age, gender, date of birth, medical record number) will be linked with the data we collect (date of injury, date of surgery, pain scores, amount and type of pain medication taken, survey scores) in a password-protected, secure datasheet, only accessible by the researchers.

How information about you will be stored:

All information will be stored in a secure, password protected datasheet, which is only accessible by members on our research team.

People and agencies that will have access to your information:

Dr Thompson, Dr Silva, Dr Takamura, Dr Gajewski, Jared Alswang (research coordinator), Dr Ebramzadeh

The research team, authorized UCLA personnel, regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

How long information from the study will be kept:

Research records will be kept until the study is published.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

There will be no additional cost to you or your health plan as a result of your participation in this study. Items and services described in this consent form would have occurred regardless of your participation in this study or, if research-related, will be provided to you at no cost.

What are my rights if I take part in this study?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you or your child, and no loss of benefits to which you or your child were otherwise entitled.
- You and your child may refuse to answer any questions that you do not want to answer and still remain in the study.

Researcher Financial Interests in this Study

There are no financial interests by any of the members of this study team.

Who can I contact if I have questions about this study?

- The research team:**

If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact: Jared Alswang at jalswang@mednet.ucla.edu or (213)742-1000, extension 6537.

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

Public Information about this Study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

You will be given a copy of this information to keep for your records.

SIGNATURE OF PARENT OR LEGAL GUARDIAN

Name of Child

Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian

Date

SIGNATURE OF PERSON OBTAINING CONSENT AND PARENTAL PERMISSION

Name of Person Obtaining Consent and
Parental Permission

Contact Number

Signature of Person Obtaining Consent
and Parental Permission

Date