University of California, Los Angeles

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

A Randomized Controlled Trial of Infraclavicular or Supraclavicular Nerve Blocks for Postoperative Pain Control in Operative Pediatric Lateral Condyle 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 use of "you" in this consent refers to your child. The research team is asking you (your child) to be in this study because your child has a lateral condyle 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 regional anesthesia versus not in patients, who are between 3.5 to 12 years old, who undergo surgery for lateral condyle 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 who received the regional anesthesia and who hasn't. This is to reduce any bias in the analysis of the data.

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. These procedures are standard of care for all patients undergoing surgery and are not performed for research purposes. This research study is focused on the use of an infraclavicular or supraclavicular nerve block in the surgery. A nerve block is an injection of anesthetic used to numb a region of the body, in this case the injured arm. Infraclavicular means below the collar bone. Supraclavicular means above the collar bone. The pain injection is similar, as is the pain control, but certain anesthesiologists prefer to place the injection above the collar bone,

and some prefer to place the injection below the collar bone. Both are affective at controlling pain. The approach of the block will be based on the discretion of the anesthesiologist.
There are two treatment groups included in this study. One group will receive an infraclavicular or supraclavicular nerve block prior to surgery, the other group will not. Your child will be randomized into one of the two groups. 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 form 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. If your child is selected for the no regional anesthesia arm of the study they will undergo our standard pre and postoperative protocol with the addition of a single needle stick. If your child is selected for the regional anesthesia group they will still undergo our standard pre and postoperative protocol with the addition of a one time nerve block to the affected extremity prior to surgery.

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.
- If your child is randomized to the regional anesthesia group they will receive a one-time nerve block to the affected extremity prior to surgery. The nerve block will be performed in the operating room by fellowship-trained anesthesiologists after your child is asleep from the general anesthesia. It involves injecting a numbing medication around the nerves that provide sensation to the arm. The goal of this nerve block is to help reduce the pain your child experiences after surgery.
- If they are randomized to the no regional anesthesia group they will undergo our standard preoperative protocol with the addition of a single needle stick. The single needle stick will be performed in the operating room after your child is asleep from the general anesthesia. The needle stick will be in the location of the nerve block, however no medication will be injected. The purpose of the needle stick is to ensure that neither you nor your child knows which intervention was performed.
- You (parent) will pick up the prescription for pain medication post-operatively while your child is undergoing surgery. You will be given acetaminophen (Tylenol), Ibuprofen and Oxycodone.
- 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, ibuprofen or oxycodone) in a log that we provide to you. You will record the type, dosage (amount given), time given, side effects 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 not know whether your child received the nerve block prior to surgery. All patients will have a soft dressing placed under the collar bone on the side in which your child had surgery. You will remove the dressing 24 hours after surgery and clean the area gently with soap and water.
- 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 side effects from oxycodone which can include nausea, vomiting, constipation, and respiratory depression (see medication information sheet for complete list).
- Possible risks of regional anesthesia include infection, hematoma formation, prolonged block, pneumothorax, nerve and blood vessel damage. A pneumothorax can be described as a collapsed lung, which may require treatment with placement of a chest tube, which allows for gradual re-inflation of the lung. A hematoma is a collection of blood that is caused by bleeding from a blood vessel.
- Possible risks of surgery include bleeding, infection, stiffness, pain, damage to nerves and blood vessels, the fracture not healing, need for further surgery.
- 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.

Are there any potential benefits if we participate?

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:
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 in the study. If you do not participate, you will be prescribed a typical compliment of pain medications – including acetaminophen (Tylenol), ibuprofen and oxycodone. If you do not participate in the study no regional anesthesia will be performed prior to surgery.

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, Lindsey Han (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?

You or your health plan may be responsible to pay for all the types of items listed below:

- *Items or services needed to give you study drugs or devices, <u>including the nerve block</u> (typically covered by most health plans)*
- *Items and services that would have been provided to you even if you were not in the study*
- *Health care given during the study as part of your regular care*
- *Monitoring for side effects or other problems*
- *Deductibles or co-pays for these items and/or services*

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: Lindsey Han at (213) 742-6537 or LLHan@mednet.ucla.edu

  If you choose to respond by email, do not include sensitive health information, as the confidentiality of emails cannot be guaranteed.

- **UCLA Office of the Human Research Protection Program (OHRPP):**
  If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail:10889 Wilshire Blvd, Suite 830 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 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