THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

TITLE: Post-operative pain management in Supracondylar Humerus Fractures: A randomized, double-blinded, prospective study.

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1. KEY INFORMATION:

A person who takes part in a research study is called a research or study subject. In this consent form "you" refers to the research subject and/or the parent/legal guardian. You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

The purpose of this study is to determine if using the combination of acetaminophen (also known as Tylenol) and ibuprofen (also known as Motrin or Advil) will provide equal or better pain control as compared to acetaminophen-hydrocodone (also known as Lortab), in children with broken elbows who need surgery. The acetaminophen, ibuprofen, and acetaminophen-hydrocodone are in liquid form and will be given orally.

We want to know if using the combination of acetaminophen and ibuprofen can provide pain control as well as or better than acetaminophen-hydrocodone so that doctors might be able to prescribe less acetaminophen-hydrocodone (which can be addictive) to children in the future. Currently, the standard of care for pain control following this kind of elbow surgery is acetaminophen-hydrocodone.

Procedures:
In this study, we will randomize subjects between different treatments to compare their success and safety.

You will be randomly assigned (like the flip of a coin) to receive acetaminophen and ibuprofen or acetaminophen-hydrocodone. You have a 1 in 2 chance of receiving acetaminophen and ibuprofen, the experimental treatment. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide

which you receive. It is not known whether the experimental treatment is as good as, better than, or worse than the standard treatment.

Neither you, the principal investigator, nor any personnel giving you the study medicines will know which treatment you will receive or have received. This is important for the research design so that neither you, the principal investigator, nor anyone giving you the study medicines, will know about the developing trends in the research information being gathered. However, in case of an emergency, the principal investigator can find out which treatment you have received. Your participation in this study will last approximately 4 days. This includes your time spent in the hospital and a one-time phone call 2-3 days after you are discharged.

The following procedures are being performed for research purposes only:

- Being randomized to receive either acetaminophen and ibuprofen or acetaminophen-hydrocodone
- The collection of information from your medical record, such as pain scores, medications received, date and time of surgery, anesthesia records, total amount of intravenous (IV) medication received, complications
- Receiving a telephone call to fill out a questionnaire after you are discharged from the hospital.

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLLOWED.

Risks:

The most common side effects of acetaminophen are dizziness and heartburn. The most common side effects of ibuprofen are dizziness and heartburn. The most common side effects of hydrocodone are nausea and vomiting.

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:

If you are randomized to receive standard therapy, it is likely to be as safe and effective in treating your pain as it is when given outside the research setting. If you are randomized to receive acetaminophen and ibuprofen, its safety and effectiveness in treating pain may be the same as, better than, or worse than standard treatment. The benefits of the study drugs are less certain because it is still being tested for the treatment of your condition.

The results of this study may help children with broken elbows in the future by helping their pain after surgery without using medicines that can be addictive.

Alternatives:
You may receive acetaminophen and ibuprofen without participating in this study.

If you decide not to enter this study, there are other choices available. These include acetaminophen-hydrocodone and ibuprofen. Ask the study staff to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

You will receive medical treatment for pain following elbow surgery whether or not you participate in the study.

Voluntary Participation:
Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Deciding to not take part in this research study will not change your regular medical care in any way.

2. DETAILED PROCEDURES TO BE FOLLOWED:

150 subjects will be participating in this study.

The study will take place at Le Bonheur Children's Hospital, 848 Adams Ave., Memphis, Tennessee 38103.

Prior to Surgery:

- Information such as your age, weight, height, medical history, total amount of intravenous (IV) medication received, and pain scores will be copied from your medical record. You will be randomized to receive either the standard or experimental treatment.

After Surgery:

- Information such as pain scores, medications received, date and time of surgery, anesthesia records, medications, total amount of intravenous (IV) medication received, complications, etc. will be copied from your medical record.
- You will receive either acetaminophen **and** ibuprofen or acetaminophen-hydrocodone every 6 hours for pain, and either medicine you receive will be flavored with cherry syrup.
- You will receive intravenous (IV) morphine for additional pain relief if needed.
- If you receive the experimental medicine (acetaminophen **and** ibuprofen), and you need 2 doses of additional pain relief in a row, you will be switched to standard of care pain medicine (acetaminophen-hydrocodone).

- You will receive instructions for post-operative pain management at home and prescriptions for pain medication if needed.

After Discharge from Hospital:

- Follow up information will be collected by telephone 48-72 hrs (2-3 days) after you are discharged from the hospital. This will include up to 10 questions about how your child felt after going home from the hospital and will take about 5 minutes.

Your participation in this research study may be stopped by the study staff without your consent for any of the following reasons:

- If the study medications are not controlling your pain
- If your diagnosis changes
- If you do not follow the study staff's instructions

If you decide to stop taking part in this research study, you should tell your study staff, and any information that you have already provided will be kept in a confidential manner

3. RISKS ASSOCIATED WITH PARTICIPATION:

All drugs can have side effects. Although not all or none of these side effects may occur, if they do occur, they may need medical attention. You must notify your study staff about all symptoms, side effects, complaints, illnesses, or injuries which you experience during the course of the study regardless of whether or not you think these are related to the study drug. You should discuss these with your study staff as well as your regular health care provider, if you choose.

As a result of your participation in this study, you are at risk for the following side effects.

Acetaminophen may cause some, all, or none of the side effects listed below.

Occasional (6-20%)

- Dizziness
- Heartburn

Rare (1-5%)

- Itching
- Constipation
- Nausea
- Vomiting

- Agitation
- Collapsed lung
- Headache
- Sleeplessness

Very Rare (less than 1%)

- Heart attack
- Heart failure
- High blood pressure
- Kidney failure
- Liver failure

Ibuprofen may cause some, all, or none of the side effects listed below.

Occasional (6-20%)

- Dizziness
- Heartburn

Rare (1-5%)

- Itching
- Constipation
- Nausea
- Vomiting
- Agitation
- Collapsed lung
- Headache
- Sleeplessness

Very Rare (less than 1%)

- Heart attack
- Heart failure
- High blood pressure
- Kidney failure
- Liver failure

Hydrocodone may cause some, all, or none of the side effects listed below.

Occasional (6-20%)

- Nausea
- Vomiting

Rare (1-5%)

- Constipation
- Dizziness
- Headache
- Sleeplessness
- Tiredness
- Ringing in the ears
- Inability to sleep
- Decreased appetite
- Agitation
- Collapsed lung

If you are not randomized to the experimental treatment, you will not be exposed to the risks (listed above) associated with the study drug, Ibuprofen while you are in the hospital.

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

4. CONFIDENTIALITY:

Research records

All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Your private information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

Medical Records
Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record; as such, this information could be made available to your employer or insurer.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

Limits to Confidentiality
Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) or other government agencies
- Le Bonheur Children's Hospital
- Your medical insurance provider
- Campbell Foundation which sponsors and provides funds for this research
- Campbell Clinic

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the principal investigator. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

5. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee, Le Bonheur Children's Hospital, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Le Bonheur Children's Hospital do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Le Bonheur Children's Hospital do not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study doctor, Derek Kelly, MD, immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

6. QUESTIONS:

Contact Jonathan Rowland, BS at 901-287-5413 if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury or a reaction to the study drug, contact Derek M. Kelly, MD, at 901-759-3100 (24-hour/7-day answering service).

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

7. PAYMENT FOR PARTICIPATION:

You will not be paid for participation in this research study.

8. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study. The Campbell Foundation will provide the study drug free of charge during this study. Tests and procedures that are done only for research purposes will not be billed to you or your insurance company.

9. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____
Printed Name of Minor Research Subject (Ages 4-13)

_____ _____ _____
Signature of Parent/Legal Guardian **Date** **Time**

_____
Printed Name of Parent/Legal Guardian

Check Relationship to Minor:

- ☐ **Parent**
- ☐ **Court-Appointed Legal Guardian**

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

_____
Printed Name of Person Obtaining Consent

In my judgment, the parent/legal guardian has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____ _____
Signature of Investigator **Date** **Time**

Assent Discussion for Subjects 8-13 Years of Age

A. Assent Obtained:

The assent discussion was initiated on _____ (date) at _____ (time).
The information was presented in age-appropriate terms.

_____ _____
Minor Subject's Printed Name (8-13 years) **Minor Subject's Date of Birth**

_____ _____ _____
Minor Subject's Signature (8-13 years) **Date** **Time**

*** Please note that the parent/legal guardian must sign the consent signature page above.**

I hereby certify that I have discussed the research project with the minor subject and/or his/her parent/legal guardian. I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the research subject was encouraged to ask questions and that all questions were answered.

_____
Printed Name of Person Obtaining Assent

_____ _____ _____
Signature of Person Obtaining Assent **Date** **Time**

B. Assent Not Obtained, but Minor Subject was Enrolled:
Assent of the minor subject was NOT obtained for the following reason:
☐ Minor is cognitively or emotionally unable to participate in an assent discussion (e.g., minor has either a psychiatric or developmental disorder; minor received narcotics within the last 4 hours; minor is sedated; etc.).

C. Assent Was Obtained, but Minor Subject was Unable to Sign:
☐ The minor assented to participation, but has an incapacity that prevents applying a signature (e.g., the subject's dominant hand is incapacitated, the subject is illiterate, etc.). The assenting subject's inability to sign the assent document has been duly noted in the research record.