ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called "Comparative efficacy of 4 oral analgesics for the initial management of acute musculoskeletal extremity pain." Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Dr. Andrew Chang. You can reach Dr. Chang at:
Office Address: 111 East 210th Street
City, State Zip: Bronx, NY 10467
Telephone #: 718-920-6626
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Support for this research study is provided by the Department of Emergency Medicine

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Why is this study being done?

The goal of this study is to find out which, if any, of four pain medicines provides the best pain relief for patients who come to the emergency department with acute arm or leg injury.

The four pain pills are: oxycodone/ acetaminophen (Percocet), hydrocodone/ acetaminophen (Vicodin), codeine/ acetaminophen (Tylenol #3) and ibuprofen/ acetaminophen (Motrin & Tylenol). All four pain medications used in this study are approved by the U.S. Food and Drug Administration (FDA) to treat acute pain and are commonly used in the Montefiore emergency departments.

Why am I being asked to participate?

You are being asked to participate in this study because your physician plans to give you a pain medication to treat your acute pain and your physician thinks you need an x-ray.

How many people will take part in the research study?

You will be one of about **400** people who will be participating in this study. All research subjects will be enrolled from the Moses and Weiler adult emergency departments of Montefiore Medical Center.

How long will I take part in this research?

It will take you about 2 hours to complete this research study. You will need to remain in the ED for a minimum of 1 hour after taking the study medication. If you are discharged before 2 hours, we will call you at the 2 hours and ask you about your pain level.

What will happen if I participate in the study?

If you are eligible for the study, we will spend about 10 minutes asking you questions about your medical history (including medications that you take or have taken), your age, gender, and ethnicity and we will take your vital signs. If you are a woman, you may not participate if you are pregnant or breastfeeding. You will be asked to rate your pain on various pain scales. We will then assign you by chance (like a coin toss) to the oxycodone/acetaminophen group, the hydrocodone/acetaminophen group, the codeine/acetaminophen group, or the ibuprofen/acetaminophen group. You and the study doctor cannot choose your study group. You will have equal chance of being assigned to one of these 4 study groups. You will receive 3 tablets that have been coated to prevent you, the research study doctor, the research associate or the nurse from knowing which of the four medicines you are receiving. However, if the study doctor needs to find that out in an emergency, he can do so. If you require a rescue pain medication, you will receive oxycodone 5 mg, which is an opioid pain medication. The study will end 2 hours after you receive the study medicine.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Will it cost me anything to participate in this study?

Taking part in this study will not involve added costs to you. All study drugs (a single dose divided into three tablets) will be given free of charge by the research study. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.

- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Andrew Chang at 718-920-6626.

What else do I have to do?

- You must tell the research personnel about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- You must take your study drug as instructed.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- ***Drugs may cause a reaction that, if not treated promptly, could be life-threatening. It is important that you report all symptoms, reactions and other complaints to the research personnel.***

Are there any risks to me?

- All pain medications have side effects, which include but are not limited to the following:
  - Common, not serious: blurred vision; constipation; difficulty breathing; dizziness; drowsiness; flushing; lightheadedness; mental/mood changes; nausea; vomiting.
  - Rare, but serious: Severe allergic reactions (rash; hives; itching; difficulty breathing; chest tightness; swelling of the mouth, face, lips, or tongue); anxiety; change in the amount of urine; change or loss in hearing; fear; interrupted breathing; mental or mood changes; unusual tiredness, gastrointestinal bleeding, kidney impairment, hypotension (low blood pressure), bradycardia (low heart rate), respiratory depression (slowed breathing), and oxygen desaturation (decreased oxygen carried by your blood).
- There may be other risks of the four study drugs that are currently unknown.

Confidentiality
We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept by the principal investigator, Dr. Andrew Chang, as long as it is useful for his research on pain.

The only people who can see your research records are:

- the research team and staff who work with them

- clinicians and staff at Montefiore who review your records for your care
- groups that review research (the Einstein IRB, the Office for Human Research Protections, and the US Food and Drug Administration)

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Risks to Women Who Are or May Become Pregnant
The effect of the study drugs on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these unknown risks, women cannot take part in this study if they are:

- Pregnant
- Trying to become pregnant
- Breastfeeding or sharing breast milk

If you are a menopausal woman and have not had a menstrual period for the past 12 months or more, you will not need to have a pregnancy test. Also, you will not need to have a pregnancy test if you have had a hysterectomy (surgical removal of your uterus and/or ovaries). All other female subjects must have a negative pregnancy test (either by blood or urine) before starting the study drug. In the case of a blood test, approximately 1 tablespoon would be drawn.

Allergic Reaction to Study Drug
Any drug can cause an allergic reaction which could be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. However, when most opioids (hydrocodone, oxycodone, codeine) cause hives (an itchy rash) they do so through a non-allergic mechanism. If you are having trouble breathing, tell a nurse or the study doctor immediately, or if you have already left the ED, call 911 immediately.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include being assigned to a group whose medication results in better pain relief. In addition, the information learned from this study may, in the future, benefit other patients who receive pain medication while in the ER.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you. It is very likely that you will receive one of the same pain pills even if you don't participate in this study.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time