KEY INFORMATION FOR

A randomized study of topical diclofenac and oral ibuprofen for acute non-radicular low back pain

This research study will compare two pain medications. We are inviting you to take part in the study because you have low back pain and it is not known which pain medication is better. This page is designed to give you key information to help you decide whether to participate. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

We do not know if pills or creams are better for low back pain. By doing this study, we hope to learn which medicine is better at improving pain.
If you agree to participate:

- The study doctor will not pick which drug you will take. We will use a computer to place you in one of the two study groups. The group the computer picks is by chance, like a flip of a coin. You will have an equal chance of being in either group. If you want more information about randomization, we will show you a brief video.
- You will receive either ibuprofen by mouth or diclofenac by cream or both. We will not tell you which of the two medicines you get.
- This study will end seven days after you leave the emergency room.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There is no guarantee that you will benefit personally from being in this study. However, you will definitely be treated with at least one standard medication for low back pain. Some participants appreciate knowing they have contributed to research that may benefit others in the future. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

All medicines used in this study are FDA Approved to treat pain. You should not participate in this study if you do not want to leave the choice of medicine up to chance. The study computer picks which medicine you receive instead of a doctor choosing. The Detailed Consent provides a list of possible risks for each study medicine.

You do not have to participate in the study to receive medication for your pain but if you don't participate, you will probably be treated with the same medications anyway.. If you decide not to be in the study, your doctor will choose a treatment he/she thinks is best for you. For a complete description of alternate treatment/procedures, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Benjamin Friedman. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: 718-920-6626

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu.

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **"A randomized study of topical diclofenac and oral ibuprofen for acute non-radicular low back 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, benefits, or access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Benjamin Friedman, MD. You can reach Dr. Friedman at: **Office Address: 111 East 210 Street 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.	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
Support for this research study is provided by **Montefiore's Department of Emergency Medicine**	

Why is this study being done?

Like you, many people across this country go to an ER to get treatment for low back pain. More than twenty different medications are used to treat low back pain but research shows that many of these medications don't really help patients with low back pain but they do cause side effects. The purpose of this research study is to compare two commonly used anti-inflammatory medications: ibuprofen tablets and diclofenac gel. If you participate in this study, you will be treated with ibuprofen tablets taken by mouth or diclofenac gel applied on the skin. You might also get both. These medications are part of a class of medications called non-steroidal anti-inflammatory drugs. They are approved by the US Food and Drug Administration for the treatment of pain.

Why am I being asked to participate?
You are being asked to participate because you are being treated in the ER for low back pain.

How many people will take part in the research study?
You will be one of 198 people who will be participating in this study at Montefiore Medical Center.

How long will I take part in this research?
This research study lasts 7 days. It will take you about twenty minutes today to complete the study paperwork and questionnaires. We will give you the medication, which you will take for the next two days only as needed for low back pain. We will then call you in two days and seven days. During each of these phone calls, we will ask you questions for about ten minutes.

What will happen if I participate in the study?
First, you must sign this consent form. Then we will spend 20 minutes asking you questions about your low back pain, your medical history, your age, and your ethnicity. We will then randomly (like flipping a coin) determine which of the following medication you will receive: a) ibuprofen pills and placebo gel; b) diclofenac gel and placebo pills; c) ibuprofen pills and diclofenac gel.

There is an equal chance that you will be assigned to these treatments. You might also receive a gell or a pill without any medication in it called a “placebo”. Neither you nor we will know now which treatment you received. We will look to see which medication you received once we have completed the study. However, the research study doctor can find out what medication you received, in case of an emergency. We will give you one vial of medication containing 8 capsules and one tube containing the topical gel. The two medications should always be taken together, at the same time, every 6 hours on a full stomach **only as needed** for low back pain. You will need to use the strip we provided to measure the right amount of the gel each time you apply it to your lower back.

Information Banking (Future Use and Storage)
We will destroy the information about you when the study is complete.

Will I be paid for being in this research study?
No. 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 will be given free of charge. You or your insurance company will receive the usual bill for your emergency visit and physician services.

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 Montefiore, 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. Benjamin Friedman at 718-920-6626.

What else do I have to do?

You will need to schedule a follow-up appointment with your doctor following your discharge from the emergency department. If you do not feel well at any time, tell or 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 team. The telephone number is on the front page.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any risks to me?

Risks of Taking Ibuprofen or Diclofenac (NSAIDs)

Common side effects: rash, abdominal pain, nausea, fluid retention, stomach upset
Less common side effects: ringing in the ears, headaches, dizziness
Uncommon side effects: NSAIDs reduces the ability of blood to clot and therefore may increase bleeding after an injury. NSAIDs also may cause stomach and intestinal bleeding and ulcers. NSAIDs may impair function of the kidneys. Individuals with asthma are more likely to experience allergic reactions to NSAIDs. Fluid retention, blood clots, heart attacks, hypertension, and heart failure have also been associated with the use of NSAIDs. Intestinal bleeding, heart attacks, and blood clots can kill people.

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. If you are having trouble breathing, tell your nurse immediately or if at home go to the nearest emergency department.

Risks to Women Who Are or May Become Pregnant

Ibuprofen is commonly used in pregnancy but may cause miscarriage or fetal malformations. Because of these risks, women cannot take part in this study if they are:

- Pregnant
- Trying to become pregnant

Special precautions for using the topical gel

In order to reduce the risk of skin reactions and other adverse events, avoid applying the provided gel to open wounds, avoid exposure to sunlight of the treated area, and avoid applying lotions or skin products on the same area as the gel. To maximize the effectiveness of the gel, avoid washing or bathing the treated area for 1 hour after application and avoid wearing clothes over the treated area for 10 minutes after application.

Questionnaire

You can choose not to answer questions that make you feel uncomfortable.

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. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. Your participation will generate important information that will benefit other people who suffer from low back pain.

What choices do I have other than participating in this study?
You can refuse to participate in this 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.

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.

Can the study end my participation early?
After you have consented to participate and have been determined to be eligible, you will be randomly assigned to receive specific study medications. After that point you will remain in the study unless you choose to end your participation.

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 research associate conducting the consent process	Signature	Date	Time
Printed name of the provider conducting the consent process	Signature	Date	Time i r e