KEY INFORMATION FOR
A randomized placebo controlled trial of IV metoclopramide + dexamethasone versus IV metoclopramide + placebo for acute post-traumatic headache

This research study will compare two treatments for post-traumatic headache. All medicines used in this study are FDA approved. We are inviting you to take part in the study because you have post-traumatic headache and it is not known which treatment is best. 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 a medication called dexamethasone is helpful for people with post-traumatic headache. If you participate in this study, you will help us figure that out.
If you agree to participate:

- The study doctor will not pick which medications you will get. 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 one or two treatments for post-traumatic headache, either metoclopramide (Reglan) + dexamethasone or just metoclopramide (Reglan). We will not tell you which of the two medicines you get.
- This study will end 30 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 medication for post-traumatic headache. 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?

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. 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

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When the word "you(r)" / "my" / "me" / "I" appears in this consent form, we mean the participant (you or your child); "we" means the research study doctors and research staff.

Introduction

You are being asked to participate in a research study called "**A randomized placebo controlled trial of IV metoclopramide + dexamethasone versus IV metoclopramide + placebo for acute post-traumatic headache**". 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 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 emergency room to get treatment for a post-traumatic headache. Unfortunately, doctors and scientists do not yet know what types of medication are best for acute post-traumatic headache. This study will be one of the first research study to try to figure out what treatment to use for patients who come to an emergency room with post-traumatic headache.

We are using two medications in this study. The first medication we are using in this study is called Reglan (metoclopramide). It is a very effective medication for migraine headaches and tension-type headaches and in one study it was effective for post-traumatic headache. Reglan is approved by the FDA for treatment of nausea. The FDA has not approved it for treatment of headache, though it is used commonly in emergency rooms for this purpose. The second medication we are using is called dexamethasone. It is also effective for migraine headaches and is approved by the FDA for treatment of inflammation.

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.

Why am I being asked to participate?
You have been asked to be a subject in this research study because you have a moderate to severe post-traumatic headache and your emergency doctor plans to treat you with an intravenous (IV, through the vein) medication.

How many people will take part in the research study?
You will be one of 162 people who will be participating in this study, which is being conducted only at Montefiore Medical Center.

How long will I take part in this research?
It will take you about **two hours today** to complete the treatment phase of this research study. We will then call you on three future dates to ask you more questions about your headaches and how you are feeling. **We will call you in two, seven and 30 days**. During each of these phone calls, we will ask you questions for about five minutes.

What will happen if I participate in the study?
We will spend 10 minutes right now asking you questions about your headache, your medical history, your age, and your ethnicity.

Then we will treat your headache with metoclopramide (Reglan). At the same time, we will determine whether you will be given **dexamethasone or placebo**. There is an equal chance (like flipping a coin) that you will get either one of these treatments. Placebo is not a medication. It is an inactive solution (water + sodium chloride) that is made to look like medication. Neither you nor we will know whether you received dexamethasone. We will look to see which medication you received once we have completed the study. However, if the research study doctor needs to find out in the case of an emergency, the research study doctor can do so.

We will give you the medications or placebo through an IV. It will be given over 15 minutes. If one hour goes by and you still do not have enough relief from your headache, your doctor will choose a different pain medication for you.

We will call you by telephone in 2, seven and 30 days to ask you approximately 15 questions about your pain and your experience with the study medication.

Information Banking (Future Use and Storage)
Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

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 cost you anything. The study drug will be 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 must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking.
- If you do not feel well at any time, tell your nurse.

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.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

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 Metoclopramide (Reglan)
Common side effects: Drowsiness, restlessness, fatigue, sedation, mood swings, and anxiety. Metoclopramide may impair the mental or physical abilities to drive or operate machinery. Patients with Parkinson's disease can experience worsening of symptoms with metoclopramide.

Less common side effects: Insomnia and depression.

Uncommon side effects: The most serious side effects of metoclopramide are involuntary muscle movements, facial grimacing, and muscle spasms, which may be permanent. No one has ever had this happen after only one dose of this medication, but it is theoretically possible.

Risks of Taking Dexamethasone
Common side effects: Dizziness, nausea, pain at the injection site

Less common side effects: Elevation of blood pressure, mood swings, depression, water retention, bloating, elevated blood sugar, susceptibility to infection, menstrual irregularities, increased appetite, worsening of pre-existing infection

Uncommon side effects: Destruction of bone, changes in skin color around the injection site, destruction of the hip, which would require surgery to fix

Risks to Women Who Are or May Become Pregnant
Reglan (metoclopramide) and dexamethasone are commonly used in pregnant women. These medications are considered safe in pregnancy.

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.

THE STUDY MEDICATIONS MAY MAKE YOU VERY DROWSY. YOU SHOULD NOT DRIVE YOURSELF HOME AFTER PARTICIPATING IN THIS STUDY.

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 research study include **possible decrease in the amount of pain you feel from the headache**. The information learned from this study may, in the future, benefit other people who suffer from post-traumatic headache.

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. If you do not enroll in this study you will probably be treated with Reglan (metoclopramide).

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?
No, it cannot. 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 to answer questions for 30 days 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 person conducting the consent process	Signature	Date	Time

CONSENT TO PARTICIPATE For Children <18 years

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 (not applicable for participants under age 13)	Date	Time
Printed Name of Parent or Guardian (when applicable)	Signature of Parent or Guardian (when applicable)	Date	Time
Printed name of the person conducting the consent process		Date	Time