KEY INFORMATION FOR: Intranasal Fentanyl vs Placebo as adjuncts to local analgesia for pain control in patients undergoing Emergency Department abscess incision and drainage

We are asking you to choose whether or not to volunteer for a research study about fentanyl versus placebo (sterile water) in addition to local pain medication injection for emergency department incision and drainage of an abscess. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. 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?
During the study, you will be given fentanyl OR sterile water through your nose before injection of lidocaine (a pain medication) in the area of the abscess. This may reduce the pain you experience during injection of lidocaine, as well as, during the drainage of the abscess. We will monitor your vital signs during the study. By doing this study, we hope to learn if fentanyl given through the nose is helpful in reducing pain during abscess drainage. Your participation in this research will last about 2 hours.
The purpose of this research is to gather information on the safety and effectiveness of fentanyl. This medication is FDA approved for pain control in adult cancer patients and is likely as safe in non-cancer adults treated for pain.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
You may or may not receive personal, direct benefit from taking part in this study. However, the medication may decrease in the amount of pain you are feeling. This research may benefit people who are experiencing pain during drainage of an infection in the emergency room.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
In this randomized clinical trial you have a 50/50 chance of receiving fentanyl or sterile water. It is possible that either of these medications will not reduce the pain you experience during the procedure.
Both medications are commonly used and have a low chance of causing significant side effects although if this happens it may be harmful. For a complete description of risks of please refer to the detailed 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 Benjamin Friedman, MD. 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 "**Intranasal Fentanyl vs Placebo as adjuncts to local analgesia for pain control in patients undergoing Emergency Department abscess incision and drainage"** 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 210th 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?

Abscess incision and drainage is a common and painful procedure performed in the emergency department. Injection of local pain medication into the abscess can often itself be painful and may not completely prevent pain during the procedure. The goal of this study is to compare medications given before the injection or the procedure to further prevent pain.

Fentanyl is a potent opioid medication which has been shown to reduce severe pain. It is used with caution because in rare cases it may cause low blood pressure, nausea/vomiting or if used often, addiction.

Alternatively, you may receive sterile water (placebo). This is simply water not containing any chemicals or potentially infectious organisms. This study will be done at two Montefiore emergency rooms: Jack D. Weiler and Moses. Both fentanyl and sterile water have been approved by the US Food and Drug Administration (FDA) for clinical use.

Why am I being asked to participate?

You have been asked to be a participant in this research study because you will undergo abscess incision and drainage in the Emergency Department and you are between 18 and 64 years old. You will be one of approximately 150 participants in this study.

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.

What will happen if I participate in the study?

We will spend 10 minutes right now asking you questions about your pain, your medical history, your age, and your ethnicity.

We will then determine randomly which medication you will get: either **fentanyl OR sterile water**. There is an equal chance (like flipping a coin) that you will get either one of these treatments. Neither you nor your treating provider will know now which medication you received. We will look to see which medication you received once we have completed the study one year from now. The medication will be given to you in your nose.

Prior to receiving the study medication, a research associate will check your vital signs. The research associates will return to check your pain level and your vital signs every 15 minutes for the entire two hour study period.

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.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Risks of Taking Sterile Water

There is a small chance the medication may go in your lung. This is unlikely to cause any harm but may cause some discomfort.

Risks of Taking Fentanyl

Common side effects: flushing, itching, nausea, vomiting, itching, dizziness, feeling light headed, drowsiness, constipation

Less common side effects: Low blood pressure, weakness

Uncommon side effects: This medication could make you stop breathing, which can be fatal

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. Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

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 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 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 your nurse.

Confidentiality

We will keep your information confidential. 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 secure manner 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 as long as they are useful for this research. Dr. Latev, the principal investigator, will keep your study information as long as it is useful for his research on acetaminophen and hydromorphone.

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, and 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.

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.

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.

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 are feeling**. This research may benefit people who are experiencing pain during drainage of an infection in the emergency room.

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. Your other choices are:

- To receive no medication in the nose in addition to local injection of analgesia. You may be given additional pain medication by mouth by the treating provider at your request at any time during the procedure.

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.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

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. You will remain in the study for 2 hours until its completion unless the clinician caring for you believes you are unable to follow the protocol or are not fit to participate.

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.

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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