The Effect of Vibration on Pain during Intravenous Injection of Propofol: A Randomized, Controlled, Single-blinded Study

Registered United States Food and Drug Administration (FDA) Clinical Trial (**NCT #03509857**)

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MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called “Vibration Analgesia in Propofol Infusion During Anesthesia Induction” 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 Aravind Pothula. You can reach Dr. Pothula at: **Office Address:** Montefiore at 1250 Waters Place 1250 Waters Place Bronx, NY 10461-2723 **Telephone #:** (718) 405-8444 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 Room 1002 Bronx, New York 10461

Why is this study being done?

We are looking for a way to make propofol infusion during anesthesia less painful. We want to see if vibration has any benefit in this regard.
Buzzy is registered as a class I FDA- approved therapeutic massager.

Why am I being asked to participate?

You are being asked to participate in this study because you are going to receive a propofol injection as part of the anesthesia for your surgery.

How many people will take part in the research study?

You will be one of about 100 people who will be participating in this study.

How long will I take part in this research?

You will only be asked to participate in this study for as long as it takes to administer the anesthesia.

What will happen if I participate in the study

If you are eligible for the study, we will assign you by chance (like a coin toss) to one of 2 groups. You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to one of the following groups: 1) Normal infusion of propofol without any intervention 2) Infusion of propofol with application of vibration

A description of all applicable clinical trials will be available on www.ClinicalTrials.gov, (NCT #03509857) 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.

Information Banking (Future Use and Storage)

We will store information about you in a “bank”, which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease, including genetic research. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. Information about me 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

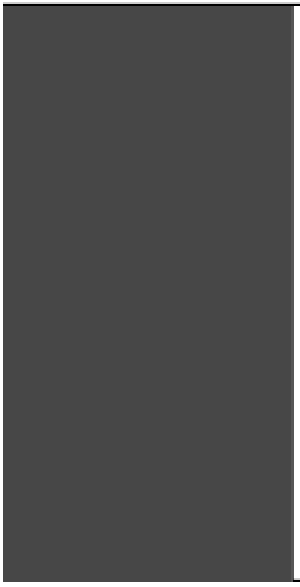
You will not receive any payment or other compensation for taking part in this study.

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

There will be no cost to you to participate in the study.

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. Aravind Pothula (Principal Investigator): 718-920-4800

  What else do I have to do?

• You must tell the doctor if you have any medical allergies or if you have had any adverse reactions to anesthesia.

Are there any risks to me?

There is no additional risk to you if you decide to be involved in this study beyond the standard risks involved in the administration of anesthesia and surgery.

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 as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them
- groups that review research (the Einstein IRB, and the Office for Human Research

  Protections**)**

  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 of vibrating device application

  Some patients may experience discomfort with application of the vibrating device. However, there are no known significant risks with regards to application of this device.

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 benefit of this study primarily involves a less painful propofol infusion.

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.

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.

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 Signature Date Time conducting the consent process