Title: **The PAIN (Pelvic Area Injection for Numbness) Study**

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KEY INFORMATION FOR A RANDOMIZED CONTROLLED TRIAL OF BUPIVACAINE FOR LOCAL PAIN CONTROL FOLLOWING PERINEAL LACERATION REPAIR IN PATIENTS WITH PRE-EXISTING EPIDURAL ANALGESIA

We are asking you to choose whether or not to volunteer for a research study about women pain control during perineal laceration repair with both an epidural and local pain numbing medication. 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?

By doing this study, we hope to learn if further pain control medication is needed for women undergoing vaginal tear repair with epidural in place. Your participation in this research will last about 7 days.

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

This study will not include a direct benefit to you. However, 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?

Participants may NOT want to volunteer for the study due to concern of receiving the placebo instead of the pain medication or concern regarding the very unlikely, but possible side effects of the numbing medication. For a complete description of risks, refer to the Consent Document below. 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. Fatima A Estrada Trejo, PI.** If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 718-904-2767 and 1825 Eastchester Rd, Bronx, NY 10461.

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.ed

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 controlled trial of Bupivacaine for local pain control following perineal laceration repair in patients with pre-existing epidural analgesia."** 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." Her name is **Fatima A Estrada Trejo.** You can **reach Dr. Estrada at: Office Address: 1825 Eastchester Rd, Bronx, NY 10461** **Telephone #: 718-904-2767** 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, by e-mail at irb@einstein.yu.edu, 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 Department of OBGYN & Women's Health Albert Einstein College of Medicine/Montefiore Medical Center	

Why is this study being done?

The goal of this study is to identify if further pain control medication is needed for women undergoing vaginal tear repair with epidural in place. The current standard of care is not to provide any local pain medication in women who already have an epidural. This study would like to answer the question if women will be more comfortable at time of perineal repair if they had both an epidural and local pain medication.

The U.S. Food and Drug Administration (FDA) has approved bupivacaine with epinephrine to provide local pain control.

This study will use bupivacaine with epinephrine as the local pain medication to help with pain control when stitches need to be placed due to a vaginal tear in women who already have an epidural in place.

Why am I being asked to participate?

You are being asked to participate in this study because you are 18 years of age or older delivering your baby at the Montefiore Jack D. Weiler Hospital, have an epidural, and may have a vaginal tear during your delivery that needs repair.

How many people will take part in the research study?

You will be one of 60 people who will be participating in this study.

How long will I take part in this research?

It will take you about 7 days to complete this research study. During this time, we will ask you questions on the first and second day after your delivery and we will call you one week after your delivery.

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 the placebo group or the bupivacaine with epinephrine group. You will have an equal (50-50) chance of being assigned to the bupivacaine with epinephrine group and the placebo group. Neither you nor the study doctor can choose your study group, or will know which group you are in, until the study is over. However, if there is a need to know for medical reasons such as a side effect or reaction to medications, this information can be made available right away. This research study will compare injection of bupivacaine with epinephrine to injection of placebo into the area of your laceration that is undergoing repair.

- The dose of bupivacaine plus epinephrine is the same as you would receive if you did not have an epidural.
- The placebo looks exactly like bupivacaine with epinephrine but contains no drugs

During this study you may get a placebo instead of bupivacaine with epinephrine. Placebos are used in research studies to see if the results are due to the study drug or due to other reasons.

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.

As part of this study, we will review your medical records and put the information we collect in our research records.

Genetic Testing

This study will not involve genetic research or genetic testing.

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?

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?
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?

Unfunded Research
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 because 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. Estrada at 718-904-2767.

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
- 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 immediately after the drug is injected for vaginal tear repair. Please inform your symptoms to your delivering doctor and they will let the research study doctor know.***
- You may carry out all your normal daily activities.

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 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?
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 local injection of bupivacaine with epinephrine

Rare side effects:
- restlessness,
- anxiety,
- lightheadedness,
- numbness and tingling of the mouth and lips,
- metallic taste,
- ringing of your ear,
- dizziness,
- blurred vision,
- tremors or twitching,
- drowsiness

Very, very rare side effects:
- arrhythmias,
- cardiac arrest, and
- death

There may be other risks of bupivacaine with epinephrine that are currently unknown.

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, please let your labor and delivery doctors and nurses know immediately.

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 better pain control during vaginal tear repair and postpartum.

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 the standard care treatment which is no local injection.

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. The researchers may continue to use and share the information they have already collected.

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 she 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 conducting the consent process	Signature	Date	Time