

**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 “**Efficacy of incisional infiltration with local anesthetic during elective cesarean delivery for postoperative pain control: a randomized controlled trial**” 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 Dr. Jeffrey Bernstein.

You can reach Dr. Bernstein at:

**Office Address:**

Jack D. Weiler Hospital  
1825 Eastchester Road  
Bronx, NY 10461

**Telephone #: 718.904.2872**

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](mailto: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

**Concise Summary**

The purpose of our study is to determine if giving an injection of numbing medication at the incision at the end of your cesarean will help control your pain AFTER your cesarean delivery. The information we learn by doing this study may help us determine the best pain medication for cesarean deliveries.

Depending upon if you enroll in this study, you will be receiving the usual regimen of pain medication in your spinal anesthesia. At the end of your cesarean delivery, while you are still under the spinal medication, you will receive an injection at the incision of either numbing medication or sterile saline. After your cesarean delivery you will receive pain medications by mouth commonly given after a cesarean delivery. You will only be in the study during your hospital stay. You will also be asked multiple times during your stay by nursing, doctors, and anesthesia about your pain control. Benefits to you include improved pain control after your cesarean.

The greatest risk to participating in this study is that you will be randomized to one of three injections at the site of your incision- meaning that you and your doctor will not be able to choose which medication you receive. There is a risk of allergic reaction to any medication you are given. There is a small risk of systemic toxicity with the numbing medication. The most common risks of opioids (oxycodone) include nausea/ vomiting/ constipation.

We do not know which regimen is best for pain control AFTER your cesarean delivery which is why we are doing this study.

If you are interested in learning more about this study, please continue reading below.

### **Why is this study being done?**

The goal of this study is to determine if adding a local injection of numbing medication during your cesarean delivery will be better at controlling your pain AFTER your cesarean delivery so that you will need less narcotic pain medication.

The U.S. Food and Drug Administration (FDA) has approved bupivacaine as an anesthetic and for pain but the FDA has not approved bupivacaine to be given specifically for postoperative cesarean pain.

Acetaminophen and oxycodone are being used as part of routine clinical care for pain control after your cesarean. Fentanyl and duramorph are being used in your spinal anesthesia and are FDA approved for regional anesthesia and used for this purpose in routine clinical care.

### **Why am I being asked to participate?**

You are being asked to participate in this study because you are going to have a cesarean delivery under spinal anesthesia at Albert Einstein College of Medicine- Weiler or Wakefield Divisions.

### **How many people will take part in the research study?**

You will be one of about 276 women who will be participating in this study.

### **How long will I take part in this research?**

You will be in the study for the remainder of your hospital stay after your cesarean delivery. You will not need to make any other visits, participate in any telephone calls, or any communication after your hospital stay to participate in this study.

### **What will happen if I participate in the study?**

Depending upon if you enroll in this study, you will be receiving the common regimen of medications commonly given in your spinal during your cesarean delivery and possibly an injection at your incision of a local numbing medication. You will **not** know which medications you received during the study. The remainder of your care during your cesarean delivery will be the same as anyone getting a cesarean delivery in the hospital. After your cesarean delivery you will receive pain medications we usually give women after a cesarean delivery. These medications are oxycodone (an opioid/ narcotic) and acetaminophen (or more commonly known as Tylenol). These medications will be given to you "PRN" meaning that you will only get the medication if you are in pain and ask for it. Your nurse will ask you about your pain on a pain scale every few hours, but you can ask for pain medication at any time you need it. If you need more pain medication on top of what you are receiving in the study to control your pain, you may ask your nurse and she will ask the covering doctor. You will remain in the study for the

remainder of your hospital stay. You will be asked during the study about your satisfaction with your pain control. You will not be contacted after you leave the hospital about the study.

This study will **not** include any blood draws or tissue samples above what will be ordered by your treating physicians/ care team to care for you routinely during your cesarean delivery.

If you are eligible for the study, we will assign you by chance (like a coin toss) to one of three groups: under the skin injection of sterile saline group, under the skin injection of bupivacaine group or under the skin injection of bupivacaine + epinephrine group. You and the study doctor cannot choose your study group. You will have a 1 in 3 chance of being assigned to any of the groups.

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://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. No information will be collected that could later be used to identify you.

### **Genetic Testing**

This study will not involve genetic research or genetic testing.

### **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 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. Jeffrey Bernstein 718-904-2872

### 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 including “over-the-counter” remedies and nutritional supplements or herbs.
- 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 to the research study doctor.***
- You may carry out all your normal postoperative activities.

### 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.

Information about your participation in this study will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, the information will be available to all of your providers who participate in the EMR system. The purpose of this entry is to provide research information that has the potential to impact your medical care.

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.

**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. You will be asked multiple times during your hospital stay. You may feel uncomfortable answering questions about your pain. You can choose not to answer questions that make you feel uncomfortable. Risks of a local skin injection include redness, pain, infection, and allergy.

**Risks of Taking Opioids**

The medications that you receive during this study may cause drowsiness or sedation. You should not drive after receiving these medications. They may also lead to abuse or addiction if misused.

Risks of taking: Oxycodone

- Common side effects: constipation, nausea, vomiting, sleepiness, itching, dry mouth, sweating, weakness
- Less common side effects: loss of appetite, nervousness, inability to sleep, fever, confusion, diarrhea, abdominal pain, upset stomach, rash, anxiety, shortness of breath, chills, abnormal dreams, thought abnormalities, hiccups, twitching
- Rare side effects: enlarged lymph nodes, heart racing, ear ringing, abnormal vision, difficult swallowing, gas, mouth sores, chest pain, swelling, pain, thirst, withdrawal syndrome, allergic reaction, throat irritation, confusion, seizures, increased liver function tests, dehydration, seizures, fainting, tremor, agitation, feeling disconnected or detached from one's body and thoughts, difficulty remembering, headaches, cough, decreased libido, hallucination, trouble and pain urinating, dry skin, changes in voice, seizures, decreased muscle tone, prickling sensations, changes in taste

Risks of taking: Acetaminophen

- Common side effects: nausea, vomiting, headache
- Less common side effects: anemia, fatigue, swelling, increased liver function tests, difficulty sleeping, fever
- Rare side effects: breath sounds abnormal, weakness, fatigue, muscle cramping, constipation, muscle spasms, lockjaw, anxiety, shortness of breath, high or low blood pressure, lockjaw

Risks of taking: Bupivacaine Hydrochloride (Marcaine)

- Toxicity most commonly dose related from overdose or incorrect administration
- Common side effects: numbness, headache, backache
- Less common side effects: excitation and/or depression, restlessness, anxiety, dizziness, ringing in ears, blurred vision, drowsiness, nausea, vomiting, chills,

constriction of the pupils, difficulty breathing, swelling, hives, rash, decreased blood pressure

- Rare side effects: tremors, convulsions, unconsciousness, difficulty breathing, heart attack, changes in heartbeat or rhythm, paralysis of legs, loss of consciousness, difficulty breathing, inability to urinate, loss of urine or feces, numbness of the perineum, and sexual function, longer than expected numbness, prickling sensations, weakness, paralysis of lower extremities, infection or inflammation of the spinal membranes, cranial nerve issues

Risks of taking: Bupivacaine Hydrochloride and Epinephrine: see “Bupivacaine Hydrochloride” above; difficulty breathing, swelling, hives or rash to sulfites in epinephrine-containing solutions

Risks of taking: Fentanyl citrate injection

- Common side effects: nausea, vomiting, dizziness, sweating, itching
- Less common side effects: high or low blood pressure, slowing of heart beat, blurred vision, allergic reaction
- Rare side effects: difficult breathing or breathing failure, heart failure

Risks of taking: Morphine sulfate injection (Duramorph)

- Common side effects: itching, nausea, vomiting, constipation
- Less common side effects: difficulty urinating, headache, dizziness, sense of happiness or unhappiness, anxiety, decreased blood pressure, confusion, decreased libido, menstrual irregularities, depression of cough reflex, interference with temperature regulation, decreased urination, muscle spasm or twitching, difficulty breathing, swelling, hives, rash
- Rare side effects: convulsions, difficulty breathing or breathing failure

There may be other risks of any drug that are currently unknown.

### **Risks to Women Who Are Pregnant/ Breastfeeding**

All medications used in this study are medications commonly used and given to pregnant women at the time of their cesarean delivery or after their cesarean delivery for pain control.

### **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 the treating physician in the hospital immediately.

### **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 improved pain control after your cesarean delivery. We hope you will participate because the study will generate important information about postoperative pain control after cesarean deliveries.



**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. 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 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
	I		
Printed name of the person conducting the consent process	Signature	Date	Time
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