DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study

Wound infiltration with the ON-Q pump for analgesia after Cesarean Delivery

You are being asked to take part in this research study because you are pregnant and plan to deliver your baby at the Duke Birthing Center by a cesarean section under a spinal or combined spinal epidural anesthetic. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

If you decide to participate, Dr. Ashraf Habib will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

The study is funded by Halyard Sales, LLC and sponsored by Dr. Habib.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if the infusion of the local anesthetic ropivacaine (a numbing medicine) and the non-steroidal anti-inflammatory drug ketorolac (a pain killer similar to ibuprofen) through a catheter placed along the cesarean delivery incision, will reduce the pain you experience after your cesarean section and your need for narcotic pain medicine. It is important that your pain after surgery is well controlled so that you will be able to assume your daily activities and look after your newborn with little discomfort. If post-surgical pain is not well controlled, between 10 to 18% of subjects can continue to experience persistent pain after surgery.

Pain after cesarean section is usually controlled with intravenous and oral narcotic pain medicine, but these drugs can cause drowsiness, nausea, vomiting, itching and constipation. The infusion of a mixture of ropivacaine (a local anesthetic) and ketorolac (a non-steroidal anti-inflammatory drug) along the incision is not FDA approved for this indication and is considered investigational for this study. The word “investigational” means the study drug is still being tested in research studies.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 100 people will take part in this study at DUMC.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. Then following this you will have the following tests and procedures to make sure that you are eligible:

- Medical history
- Vital signs (blood pressure, pulse, breathing rate and temperature)
- Blood tests - We will review the blood tests done as a part of your routine preoperative care for cesarean delivery. These include your blood count or hemoglobin concentration and your blood group. No additional blood tests will be ordered for this study.

Then you will be randomly (like drawing numbers from a hat) assigned to one of two groups. You will receive either ropivacaine and ketorolac or normal saline (placebo) through a catheter placed along the cesarean delivery incision. Your surgeon, while closing the incision, will place this catheter. A pump called an ONQ pump will be used to infuse medication into your incision. Infusion of study medication will start after the skin is sutured and will continue for 48 hours after your cesarean delivery. Neither you nor your anesthesiologist or surgeon will be aware of which group you are in. Prior to entering the operating room, one of the study doctors will conduct a brief test of your response to a stimulus. This test is done by tapping your forearm within a small area with a small, bendable, plastic filament and asking you to rate the sensation on a number scale. The test takes less than a minute.

When you arrive in the operating room you will undergo spinal or combined spinal epidural anesthesia, which is the standard anesthetic for this procedure.

You will be monitored very closely. In addition to frequent blood pressure measurements, you will also have your heart rate and rhythm monitored using an electrocardiogram (electrical tracing of your heart) and your oxygen levels monitored using a pulse oximeter (all are standard of care at Duke).

After surgery, we will collect information about the occurrence of pain, nausea, vomiting, and itching at 2, 24, and 48 hours after surgery. Your postoperative pain will be managed according to our standard of care at Duke University. The remainder of your postoperative care will also be according to our standard of care at Duke Birthing Center and will involve treatment for any symptoms of nausea, vomiting, or itching that you might experience as needed.

You will also be contacted by phone for a 10-minute follow-up interview at approximately 8-weeks and 6-months postpartum following discharge from hospital.

Your decision not to be in this study will not involve any penalty or loss of benefits to which you are otherwise entitled. If you do not sign and date this consent form, you will continue to receive care, but not as a part of this study.

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HOW LONG WILL I BE IN THIS STUDY?

You will be enrolled in this study before you have your caesarean section and your participation will last until 48 hours after your surgery. You will also be contacted by phone for a 10-minute follow-up interview at 8-weeks and 6-months postpartum.

You can choose to stop participating at any time.

WHAT ARE THE RISKS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

The main potential side effect that might occur with the use of the ONQ pump is leakage of fluid from the wound. There is also a risk for infection. Side effects of ropivacaine can include feeling anxious, restless, confused, or like you might pass out; problems with speech or vision; ringing in the ears, metallic taste, numbness or tingling around your mouth, or tremors; seizure (convulsions); weak or shallow breathing; slow heart rate, weak pulse; or fast heart rate, feeling unusually hot. Those side effects occur if ropivacaine goes into a blood vessel. Side effects of ketorolac when given through a vein include bruising, nausea, vomiting and upset stomach.

You will have a spinal or combined spinal epidural anesthetic for your cesarean section and this is the standard anesthesia technique used at the Duke Birthing Center for cesarean section. The risks of this spinal or combined spinal epidural anesthesia will be provided when you give consent for your anesthesia.

There are no known risks to the fetus associated with the drug used in this study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

DRUG INTERACTIONS:

An infusion of ropivacaine and ketorolac is not known to interact with any commonly used drugs. For your safety, you must tell the study doctor or nurse about all the prescription medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you if you receive the combination of ketorolac with ropivacaine. The benefit might include improved pain control

after your cesarean section but we do not know if this will happen. If you receive placebo, there are no expected benefits beyond those provided by your usual care. We hope the information learned from this study will benefit other pregnant women having spinal anesthesia in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law or for your care, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file securely at DUHS.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the representatives from the Food and Drug Administration (FDA) and Duke University Health System Institutional Review Board. If your research records are reviewed by any of these groups, they may also need to review your entire medical record.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

As part of this study, you will not have any additional laboratory tests or studies that would not otherwise be done as part of your regular care. These test results will be recorded in your medical and research record. Some information collected about you only for this research study may be kept in a research study record separate from your medical record, and some research information may also be part of your medical record. You will not have access to this research information until the end of the study. However, it will be available to your physicians if needed for your care.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

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A description of this clinical trial will be available on 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.

WHAT ARE THE COSTS?

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. All of the procedures done in this study are part of routine care.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Ashraf Habib in writing and let him know that you are withdrawing from the study. Their mailing address is Duke University Medical Center, Box 3094, Durham, NC 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. If this occurs, you will be notified and your study doctor will discuss other options with you.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Ashraf Habib at (919) 970-3775.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by

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Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study related injury.

For questions about research-related injury, contact Dr. Ashraf Habib at (919) 970-3775.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time