DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Comparison of TAP, Anterior QL, or ESP
Block for Elective Cesarean Section

Concise Summary

This is a research study to find out if injection of numbing medication (local anesthetic) in one of three different locations (either in your abdomen or back) will help to decrease your need for pain medication after cesarean section.

If you enroll in this study, you will be randomized to receive a nerve block, or an injection of local anesthetic (numbing medication) in one of three specific locations in your abdomen or back. This injection will take place after your baby has been delivered at the end of your surgery. We will be evaluating how this injection impacts the amount of strong narcotic pain medication, such as oxycodone, medication you need to control your pain after surgery. We believe these injections have the potential to decrease the amount of strong narcotic pain medication you will need after surgery and improve your pain management. The rest of your anesthesia care, including your spinal anesthesia and postoperative pain medication, will be the same as it would be without participating in the study. You will be enrolled in this study for 48 hours.

The risks of this study are described in this document. Some risks include: minor pain or discomfort; infection at the needle insertion site; injury to arteries, veins, or nerves affecting the abdomen, back, or legs; residual numbness, weakness, or paralysis; reaction to numbing medication.

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

You are being asked to take part in this research study because you are scheduled for an elective cesarean section. 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.

Amanda Kumar, MD, will conduct the study and it is funded by the Duke University Hospital Department of Anesthesiology.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Kumar 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.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn if injecting a numbing medication (local anesthetic) in one of three

locations (close to nerves in either your abdomen or back) will help to decrease your need for pain medication after your cesarean section. Strong narcotic medications, such as oxycodone, are often prescribed after cesarean section as part of a pain regimen. However, many people experience side effects from narcotics including nausea, vomiting, constipation, or sedation. These injections (nerve blocks) have been shown to decrease narcotic use after other abdominal and thoracic surgeries, but no studies have specifically looked at the benefit after cesarean section.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
This is a single institution study, meaning that it is only being performed at Duke University Hospital. Seventy-five (75) subjects will take part in this study at Duke University Hospital.

WHAT ARE MY RESPONSIBILITIES DURING THE STUDY?
Being in this study, it is important that you:

- Tell the study doctor about your medical and medication history;
- Tell your doctor and/or study team your pain scores during your hospitalization;
- Report any possible side effects, such as leg weakness or irritation around the injection site to your doctor and/or study team.

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. If you do not sign this consent form, you will continue to receive your regular care, but not as a part of this study.

To participate in this study, you must be medically able to undergo a nerve block. Be sure to report to the study team if you have any medical conditions, infections, or allergies. You will not be eligible for this trial if you have a history of allergy to local anesthetics (such as lidocaine or Novocain), have a blood thinning disorder (such as hemophilia or von Willebrand disease), are taking blood thinners (such as heparin), or have a condition that would make it difficult for you to communicate with your doctor.

The typical anesthetic plan for elective cesarean section at Duke University Hospital is for patients to receive a spinal anesthetic or a combined spinal epidural anesthetic in the operating room immediately before surgery, which will numb your abdomen and legs. It is standard for patients to be awake during elective cesarean sections. After surgery, a detailed pain regimen of intravenous and oral pain medications are used during your hospital stay.

Before your surgery, you will be randomized (like picking a number out of a hat) to receive one of three nerve blocks. You will receive either a transversus abdominis plane block (two injections in the abdomen), an anterior quadratus lumborum block (two injections in the back), or an erector spinae block (two injections in the back) with ropivacaine (numbing medication). The nerve block will be performed AFTER your baby has been delivered at the end of your surgery. This block will interrupt skin to skin time for the duration of the procedure (5-10 minutes) to ensure safety for both mom and baby during positioning of the nerve blocks. After the block is complete, there will no limitations concerning

positioning, mother/baby bonding, or breastfeeding.

After surgery, we will monitor the amount of strong narcotic pain medication, such as oxycodone, medication that you need to manage your pain. We will also record your pain scores at various points immediately following surgery until 48 hours later. Additionally, we will contact one time via email or telephone after hospital discharge to complete a survey regarding your experience and satisfaction. The nerve block is in addition to the normal pain regimen and care you would normally receive had you not been in the study.

If your treating anesthesiologist determines it is best for you to receive additional medication through a combined spinal epidural anesthetic during your cesarean section, you will be withdrawn from the study post-consent and will not receive any of the above mentioned blocks. Instead, you will receive standard of care post-operative care.

HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for 48 hours, however we may contact you via telephone one time after hospital discharge to complete a survey. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
You should discuss the risks of the study with the study doctor. As a result of your participating in this study, you are at risk for the following:

Risks Associated with Nerve Block:
Risks associated with the nerve block include minor pain or discomfort; bruising; infection at the needle insertion site; injury to arteries, veins, or nerves affecting the abdomen, back, or legs; residual numbness, weakness, or paralysis; headache; muscle soreness. If you are allergic to the local anesthetic (ropivacaine) or have an adverse drug reaction, you could possibly have a reaction that is severe enough to cause cardiac arrest (the heart stops beating) and/or respiratory arrest (you stop breathing). If there is injection of local anesthetic into a blood vessel, you could possibly have loss of consciousness, seizure, or cardiac arrest.

There have been rare case reports of hip or knee weakness after quadratus lumborum block. Therefore, we recommend having someone with you to help you out of bed the first time after the nerve block is performed.

Drug and Food Interactions:
For your safety, you must tell the study doctor or nurse about all prescribed 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.

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

There is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. You may stop your participation in this study at any time.

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. You may experience improved pain control after surgery, but it is not yet known if this will be the case and this potential benefit cannot be guaranteed. It is not known how long this benefit may last after surgery. Improved pain control may result in the decreased need for strong narcotic pain medication, such as oxycodone, after surgery and thus decreased side effects like nausea, vomiting, constipation, or sedation. We hope that in the future the information learned from this study will benefit other people undergoing cesarean section.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
If you choose not to participate in the study you will receive the Duke University Hospital standard of care for elective cesarean section.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to Duke University Hospital Department of Anesthesiology and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of Duke University Hospital Department of Anesthesiology, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain procedures performed. Some of these procedures would have been done as part of your regular care. The study doctor will use these results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the Duke University Hospital Department of Anesthesiology. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your

medical record.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. Additionally, information and data resulting from this study may be used for future unspecified research, however your name and other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with *Dr. Kumar***.** At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

WHAT ABOUT COMPENSATION?
You will not be compensated for your participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Hospital in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke University Hospital physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Kumar at (216) 385-5529 during regular business hours, after hours, and on weekends and holidays.

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 unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

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 University Hospital.

If you do decide to withdraw, we ask that you contact Dr. Amanda Kumar in writing or by telephone and let her know that you are withdrawing from the study. The mailing address is Department of Anesthesiology, DUMC Box 3094, 2301 Erwin Road, Durham, NC, 27710. The telephone number is (216) 385-5529.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

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.

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. Kumar at (216) 385-5529 during regular business hours, after hours, and on weekends and holidays.

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.

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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

_____
Subject's Printed Name

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time