Consent to Take Part in a Research Study

Title: Quadratus Lumborum Blocks for Pain Control following Open Ventral Hernia Repair: A Randomized Control Trial

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We are asking you to participate in a random placebo-controlled study as part of a research project being done by Kaela E. Blake, MD, a surgeon at the University of Tennessee Graduate School of Medicine and University of Tennessee Medical Center to determine whether a Quadratus Lumborum (QL) block can improve postoperative care for patients having abdominal hernia surgery and reduce the amount of opiate pain medicine you will need.

Participants in this study will randomly be put in one of two groups, one that receives a Quadratus Lumborum (QL) block and the other will receive a placebo injection of saline into the same place. A block is the injection of a local anesthetic (medication to block pain), into a specific nerve or group of nerves to treat or prevent pain. In a QL block, local anesthetic is injected into the back above the hip on both sides. The block will be placed after you are sedated, and you should feel no pain during the block placement. After surgery both the active and placebo groups' pain management will be the same as typically prescribed now by their physicians. In addition, you will also be asked to keep a pain diary and take a survey that looks at how well you recover from your ventral hernia repair. This consent provides information for the research study in which you are being asked to participate. If you decide to participate in this study, you will be asked to sign this form. You will receive a copy of the signed form for your personal records. Taking part in this study is voluntary. You may choose not to take part in the study and saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time during your participation.

Why is this study being done?

The purpose of this study is to determine whether using a QL block is better than placebo in lowering the dose of opioids you needed for pain relief in the first 24 hours and if it improves your recovery following a ventral hernia repair.

How long will the study last?
You will be in this study for approximately 30 days following your surgery.

How many people will be in the study?
Up to 70 people will be included at UT Medical Center (UTMC).

What will happen to me during the study?
Before entering the operating room you will be randomly put in one of two groups, one group will receive a Quadratus Lumborum (QL) block with local anesthetic and the other group will receive a placebo injection of saline in the same place. This will be done using ultrasound guidance and the local anesthesia or saline placebo will be injected into your back above your hip on each side. Whether

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you receive the local anesthetic or saline placebo will be chosen randomly and you will not be told which one you received. All patients will receive the normally prescribed pain pills as needed after surgery.

There is a 50% chance you will receive a QL block, a 50% chance you will the placebo saline injection. This is being done so that we can determine if there is any real benefit from the QL block. All patients will receive the same pain medication as needed after your surgery that is normally prescribed by your physicians and the rest of your post operative care will also not be affected by your participation in the study.

If you qualify and agree to participate in this study, you will be asked to complete a questionnaire before surgery and again at their 30-day follow up. You will also be asked to complete a pain diary 24 hours after surgery and attend a follow-up visit approximately 30 days after surgery. We will call you at 24 hours to remind you to complete the pain diary. The pain diary will record the amount of medication you took and your average pain score for the day. The following information will be collected from you or your medical record:

- Pain medications given to you during surgery.
- Pain medications prescribed to you after surgery, including medication name, dose, units, and frequency.
- Pain levels during the first 24 hours after surgery.
- Your total hospital length of stay after surgery.
- Any complications that you may have experienced after surgery.
- Demographic information, medical history as well as details about your hernia repair surgery.

What side effects or risks can I expect from being in the study?

The greatest risks of the study are those commonly associated with receiving a nerve block. This includes bruising at the injection site which can happen in less than 0.5% of patients (1/500) and the uncommon risks/side effects of infection, bleeding, and persistent numbness each of which has a 0.01% (1/10,000) incidence.

There is a small risk that someone could get access to the stored data. We will use tight security measures and safeguards to protect your data, but we cannot guarantee that your identity will never become known. Identifiable data such as your name and Medical Record Number (MRN) will not be recorded in your research records, however; other identifiable data such as your date of birth, other medical illnesses and any related treatments will be.

Are there benefits to taking part in the study?

While there are no specific benefits to the participants for being in the study, the results of this study will have the potential to significantly decrease the post operative opioid use and improve recovery after surgery for patients having a ventral hernia repair.

Confidentiality:

We will be recording identifying information in your research record such as your age, gender, date of birth, medical history, and contact information. However, we will keep this information strictly confidential. We will keep your information locked in a private office under the supervision of the study team.

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Contact persons:
If you have any questions, concerns, or complaints about this study call:

- Kaela E. Blake, MD at (865) 305-7975
- Call the UT GSM IRB office (865) 305-9781 or (865) 305-6892 if you have any questions about your rights as a participant in this research study.

What other choices do I have if I do not take part in this study?
Patients may choose not to take part in the study and their anesthesia and post-operative pain will be provided as chosen by the anesthesiologist.

What will it cost me to be in the study?
You will not be charged for any assessments completed as part of this study. You or your insurance carrier will be charged for all routine costs associated with your medical care while you are seen by your regular providers, including copays.

Will I be paid for taking part?
You will not receive compensation for participating in this study.

Voluntary participation and withdrawal:
Your participation is voluntary, and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. The study Principal Investigator and/or the Study Coordinator may stop you from taking part in this study at any time if they decide it is in your best interest.

Is the investigator paid to do this study?
The investigator is not being paid to conduct this study.

What if I am injured in this study?
You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

It is important that you tell your study doctor, Dr. Kaela Blake, MD if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at (865) 305-9620.

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures the University of Tennessee does not have funds budgeted for compensation either for lost wages or for medical treatment.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Identifiable private information
Dr. Blake is a participant of the Abdominal Core Health Quality Collaborative (ACHQC). The ACHQC is an organization dedicated to quality improvement in hernia and abdominal core health and already receives protected health information from this institution as one of its HIPAA business associates for

routine healthcare operations. This pre-existing data collection effort, including with your consent, the collection of your protected heath information, will be utilized for the research study.
Kaela Blake, MD is a participant of the Abdominal Core Health Quality Collaborative (ACHQC). The ACHQC is an organization dedicated to quality improvement in hernia and abdominal core health. The ACHQC already receives health information from Kaela Blake, MD for its quality improvement efforts. With your consent, this ACHQC information will be utilized for the research study and sent securely from the ACHQC to Kaela Blake, MD.

Will my medical information be kept private?
All reasonable efforts will be made to keep your protected health information (PHI) private and confidential. PHI is health information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow federal privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the use and disclosure of your PHI. A decision to take part in this research means that you agree to let the research team use and share your PHI as described below, for the purpose of this research.

As part of the study, Kaela E. Blake, MD and her study team may share your personal data for the study. This includes, but is not limited to: your age, gender, date of birth, ethnic origin, information on your physical health or condition (that is, data from your medical records such as past and present health conditions, medications and health outcomes). These may be study or non-study related. They may also share portions of your medical record, with the groups named below:

- The Federal Government Office for Human Research Protections
- The University of Tennessee Graduate School of Medicine Institutional Review Board

At no time will the PI or study team members share your social security number, address, phone number, or medical record number with anyone outside of the study team. The greatest risk, although rare, is the loss of confidentiality caused by unauthorized release or misuse of information from your research records. We will do everything possible to make sure that the information in your research records is kept private. The study results will be retained in your research record for at least six years after the study is completed. At that time, the research information not already in your medical record will be destroyed, per the institutions policies. Any research information entered into your medical record will be kept indefinitely.

If you decide to withdraw your permission to use your data, we ask that you contact Kaela E. Blake, MD and let her know that you are withdrawing your permission in writing. The mailing address is Kaela E. Blake, MD, University of Tennessee Graduate School of Medicine, 1924 Alcoa Highway, U114, Knoxville, TN 37920. The results of this study may be published in a medical journal and shown at medical meetings. You will not be identified (by name or any other means, e.g., photo) in any of these publications.

CLINICALTRIALS.GOV: 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.

If you sign this authorization and decide later to withdraw this authorization, you will not be permitted to continue your participation in the study.

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CONSENT:
I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts, and side effects as well as the possible benefits (if any) of the study. I agree that my personal data, including data relating to my physical health or condition, and ethnic origin, may be used ONLY as described in this consent form. I freely volunteer to take part in this study and understand that I am free to withdraw at any time.

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

_____	_____	_____
Printed Name of Subject	Signature of Subject	Date/Time
_____	_____	_____
Printed name of person obtaining Consent	Signature of person obtaining consent	Date/Time
_____	_____	_____
Printed name of Investigator	Signature of investigator	Date/Time

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