Quadratus lumborum block versus transversus abdominus plane block for pain management after donor nephrectomy

NCT 03476850

May 2, 2019

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April 17, 2019

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Quadratus lumborum block versus transversus abdominus plane block for pain management after donor nephrectomy

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. 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. The purpose of this study is compare two types of nerve blocks used to manage pain after surgery. The two nerve blocks being compared are the transversus abdominis plane block (TAP) and the quadratus lumborum block (QL). The TAP block is done approximately 6 inches to the side of the belly button and the QL block is done approximately 10 inches to the side of the belly button. Both of these blocks are used routinely for patients having nephrectomy. You are being asked to participate in this study because you are having a nephrectomy and you elected to have a nerve block. In completing this study, we hope to determine if one of the blocks provides longer and better pain control after your surgery than another. The investigator in charge of this study is Eric Bolin, M.D. The study is being done at The Medical University of South Carolina. Approximately 52 people will take part in this study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. The researchers will check your medical records to gather information from your chart to make sure you are eligible to participate.

2. If the chart review shows that you are eligible for the study, you will be randomly assigned to receive one of the two blocks: quadratus lumborum block (QL) or

transversus abdominis plane block (TAP). This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. .

3. Once you are sedated, a trained anesthesiologist will place the block.
4. The study team will collect data from your chart such as how much pain medication you received after your surgery, the amount of pain you are in after surgery, and the length of time you were in the hospital.

C. DURATION

Participation in the study will take place from the time your block is placed until you are discharged from the hospital.

D. RISKS AND DISCOMFORTS

There is no increased medical risk for participating in the study as the risks for both blocks are the same. The risks are bleeding, infection, damage to surrounding structures, nerve damage, and failed blocks. There is a risk of a loss of confidentiality, as the research team will be looking in your medical record. However, all paper information will be kept in a locked cabinet in a locked research office and all electronic data will be kept on MUSC's password protected serve. The research team will decrease this risk as much as possible by following confidentiality standards.

E. BENEFITS

There is no direct benefit to you for participating in this study.

F. COSTS

There will be no additional cost to you as a result of participation in this study. However, you or your insurance company will be responsible for all costs related to your medical care, including the nerve block you will receive.

G. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

H. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is either a QL or TAP block depending on your anesthesia provider's preference.

I. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

J. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

K. CLINICAL TRIALS.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.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your

insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Eric Bolin at (843) 792-2322. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

Participant's Personal Representative (if applicable):

_____

Name of Personal Representative (Please print)

_____

Signature of Personal Representative Date