University of Pittsburgh

Department of Anesthesiology

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: A Prospective, Randomized, Open-Label, Active-Comparator, Non-Inferiority study of the efficacy of Continuous nerve block vs Single block plus Intravenous Lidocaine for postoperative pain.

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SOURCE of SUPPORT: None

Why is this research being done?
We recommend a multimodal approach to pain management for primary abdominal surgeries that includes regional anesthesia (nerve blocks). In this institution, we routinely use a type of nerve block called the Quadratus Lumborum block) as standard-of-care. This block has been shown to give effective pain relief after theis type of surgery. It is easy to perform and low risk, as the local anesthetic is injected far away from sensitive structures such as the spinal cord and the lung. It is also common practice at this hospital to perform a continuous nerve block, where a small catheter is left at the nerve block site in order to give an infusion of local anesthetic and extend the block length after surgery. However, continuous blocks have some rare risks and limitations, including catheter dislodgement, movement, kinking and leaking at the site, increased risk of bleeding, especially when using blood thinning medications, and infection. They are also quite a bit more expensive than single nerve blocks due to higher supply and disposal costs.

The multimodal pain medication regimen that is used as standard-of-care at this hospital, and that everyone in this study will receive, includes the following medicines: gabapentin (100-300mg by mouth nightly), acetaminophen (1000mg by mouth every six hours), IV ketamine (5 mg/h, with escalation up to 10 mg/h if needed, for up to 48 hours), and (only if you are in the Intensive Care Unit) dexmedetomidine (0.2mg/kg/hour IV for 24 hours). Oral and IV opioids (oxycodone 5-10mg by mouth, hydromorphone 0.2-0.3mg IV) will be available on request for moderate to severe pain (pain level > 5/10).

Intravenous (IV) lidocaine (local anesthetic) is another medication that is very safe and has been shown to provide pain relief after surgery. It is thought that doing a single nerve block followed by an intravenous lidocaine infusion after surgery may provide the same benefits of a continuous nerve block while avoiding their risks and increased costs. However, there are no prospective studies comparing these two techniques directly. Therefore, the purpose of this study is to show that a single injection nerve block together with postoperative IV lidocaine is not worse than the standard-of-care continuous nerve block for primary thoracic and abdominal surgeries.

Who is being asked to take part in this research study?
You are being invited to participate in this research study because you will undergo primary one-sided thoracic or major abdominal surgery. People being invited to participate must be over 18 years of age.

What procedures will be performed for research purposes?

<u>Screening Procedures:</u>

There are no specific screening tests or procedures for this research study. Your medical records will be examined by your anesthesiologist to determine your eligibility for the study.

<u>Procedures:</u>

If you qualify to take part in this research study, you will undergo the procedures listed

below:

After you sign an informed consent form, you will be enrolled into the study. You will be randomized, or randomly assigned, in a 1:1 ratio (similar to flipping a coin) via a computer-generated number system, into either the control or intervention group. The control group will receive the hospital's standard of care intervention as indicated by the accepted protocol for major abdominal surgery, which consists of a multimodal pain management regimen, including continuous Quadratus Lumborum block. The intervention group will receive single injection Quadratus Lumborum block plus postoperative IV Lidocaine infusion, and will also receive a multimodal pain management regimen. Nerve block procedures will take approximately 10-20 minutes to complete. All nerve block procedures will be performed under strict aseptic (clean) technique using sterile equipment and gloves.

For the Quadratus Lumborum block, you will be positioned on the side with the side to be blocked facing up, and this side will be marked. An ultrasound probe will be used to identify the muscle layers on the side of the trunk just above the hip bone. After cleaning the area with sterile solution and numbing the skin, a needle will be placed between the appropriate muscle and tissue layers under real-time ultrasound visualization, and once correct placement is confirmed the local anesthetic medication will be injected.

If you receive a continuous nerve block, once the initial injection is complete a small catheter (about the size of fishing line) will be inserted at the site and confirmed to be in the correct place using ultrasound. It will then be taped to the skin underneath a sterile dressing. If you receive a single block, the procedure will be complete once the injection is finished--there will be no catheter placement.

You, as well as your doctors and nurses, will know which group you are in. However, the research team will not know which group you are participating in while on study.

Monitoring/Follow-up Procedures

Pain Level: Pain level will be measured at 6, 12, 24, 48, and 72 hours after surgery. Pain level will be measured on a scale of 0 to 10, with 0 meaning no pain and 10 meaning the worst pain imaginable.

Pain Medications Consumption: total opioid pain medications given in 24, 48, and 72 hours after surgery will be collected. Total amount of local anesthetic medicine given in 24, 48, and 72 hours after surgery and how it was administered (IV or via nerve block) will be collected.

Serum Lidocaine Levels: the amount of lidocaine (local anesthetic) in your blood will be measured at 24, 48, and 72 hours after surgery. Each measurement will involve a blood draw of one teaspoon or less that will be performed by properly credentialed nurses or phlebotomy staff at UPMC Shadyside.

Length of Hospital Stay – Total length of hospital stay will be collected.

Adverse effects – any incidence of adverse effects like nausea, vomiting, low blood pressure, and slow or fast heart rate will be collected.

What are the possible risks, side effects, and discomforts of this research study?
There are risks associated with your surgery, anesthesia, and hospitalization. These risks will be discussed with you by your surgeon and anesthesiologist and are independent of your participation in this research study.

Risks associated with Quadratus Lumborum block:
1. Pain or bruising at site of nerve block
2. Bleeding
3. Infection
4. Nerve damage resulting in persistent numbness, tingling, muscle weakness or paralysis
5. Local Anesthetic Toxicity

Risks associated with Intravenous Lidocaine infusion:
1. General fatigue, dizziness, or headache
2. Local Anesthetic Toxicity

Risks associated with randomization:
Since the treatments will be assigned randomly, the process of randomization will necessarily carry the associated risks and benefits of the specific type of treatment to be used here.

Risks associated with the multimodal pain management regimen will be discussed when you receive
anesthesia consent for the standard of care surgery procedure.

Your medical record will be accessed by the study team. Some of the information reviewed in the medical record include medical history, surgical and anesthesia record, medication record, and pain scores. All of your medical record and study-related information will be considered protected health information and will be kept confidential per HIPAA privacy act. There is, however, a possibility of breach of confidentiality. That is, in very rare cases, people not associated with this research study may inadvertently see your identifiable research results. We will do everything in our power to prevent this from happening by keeping all research records in locked files and identify all specimens and medical information by a research record number, rather than by your name or social security number. The codebook containing your name and number will be kept secure by the Study Team.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

You can speak with your anesthesiologist if you have any questions or concerns regarding the implications and frequencies of each risk.

What are possible benefits from taking part in this study?
You will not directly benefit from participating in this study.

What treatments or procedures are available if I decide not to take part in this research study?
If you decide not to take part in this research study, you will receive the standard of care anesthesia and post-operative care dictated by this institution.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
Some of the services you will receive during this study are considered to be "routine clinical services" that you would have even if you were not in the study. These include surgery, standard of care anesthesia, which may include a nerve block, and multimodal pain management. These services will be billed to your health insurance company or you, if you do not have health insurance. You will not be charged for study activities that are not part of "routine clinical services" such as serum lidocaine level measurement. You will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan.

You may want to get more detailed information about what "routine clinical services" your health insurance is likely to pay for. Talk to a member of the study staff and/or a UPMC financial counselor to get more information.

Alternative treatments
If you do not participate in this study, you will likely still participate in the standard protocol of post-operative care at UPMC facilities and will receive a nerve block according to your anesthesiologist's preference.

Will I be paid if I take part in this research study?
You will not receive any payment for participating in this research study.

Who will pay if I am injured as a result of taking part in this study?
University of Pittsburgh researchers and their associates who provide services at UPMC (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible

that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name. The information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results. We will attempt to preserve your medical record and participation in this study as confidentially as possible, but breach of confidentiality is a risk of participation.

In the future, the investigators may decide to share data with other investigators both within and outside of this institution. If that were to occur, we would de-identify all of the information prior to sharing any data in this way.

Will this research study involve the use or disclosure of my identifiable medical information?
This research study will involve the recording of past, current and/or future identifiable (pertaining to only you) medical information from your hospital and/or other health care provider (e.g. physician office) records. This information that will be recorded will be limited to diagnostic information, lab results, medications, and medical history. The information will be used to determine your eligibility for this study and to follow your care once you are enrolled in the study.

This research study will result in identifiable information that will be placed into your medical records held at UPMC and the UPMC Cancer Centers. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes response to study treatment including adverse events (side effects).

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of the study team, who are also part of the

Department of Anesthesiology and the Acute Interventional Perioperative Pain Service, will review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data.
Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for an indefinite period of time. Per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project.

May I have access to my medical information that results from my participation in this research study?
In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

Is my participation in this research study voluntary?
Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your anesthesiologist is involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another

doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your anesthesiologist.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study. Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you decide to withdraw from study participation after you have received the study drug, no study assessments will be done after your withdrawal.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers if, for example, you have an unexpected change, complication in your anesthesia or surgery or serious adverse reaction. If you are withdrawn from participation in this research study, you will still be treated for your post-surgical pain. Please consult your surgeon or anesthesiologist if you have any further concerns.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the principal investigator listed on the first page of this consent document at the telephone number given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and to authorize Dr. Kearns and the members of his research team to access my medical records and extract research data from them, as described in this document. Dr. Gabriel Wilner or a qualified member of his research team will sign this consent and a copy of this consent form will be given to me. Also, I further certify that no research component of this protocol was begun until after the consent form was signed.

_____

Participant's Signature

_____ _____

Printed Name of Participant Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date