University of Pittsburgh

Department of Anesthesiology

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY TITLE:

ESP vs. PVB Nerve Blocks for Video Assisted Thoracoscopic Surgery (VATS)

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SOURCE OF SUPPORT: UPMC Department of Anesthesiology

Why is this research being done?
You are being asked to participate in this research study because you are at least 18 years of age and you are scheduled to have a video assisted thoracoscopic surgery. Thoracic surgery can cause significant pain, which makes it difficult for you to breath. Nerve blocks are part of several ways to manage pain after surgery and by helping you breathe they also help decrease complications after the surgery. When we do nerve blocks, we inject local anesthetics (numbing medication) around the nerves that give you sensation to site where you had surgery, "numbing" the area.
There are several nerve blocks that we use to achieve pain relief. With this study we are comparing 2 techniques that we use routinely to evaluate efficacy and also safety.
Before agreeing to be in this study, it is important that you understand that studies like this include only people who choose to take part. An investigator will explain the research study to you. Your participation is voluntary; you can choose not to participate. Please read this informed consent carefully and ask about any words or information that you do not clearly understand. It tells you what you need to know about this research study. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about this study, its risks, and that you want to take part in this study.

Why is this research study being done?
We are trying to study the difference of two similar but different nerve blocks for

videothoracoscopic surgery. A nerve block is a procedure where we use an ultrasound machine to guide a needle so we can place a solution of pain medication around your nerves, so we can "numb" the nerves. This causes a numbing sensation in the painful area, thus reducing your discomfort and making your more comfortable. Under the current standard of care, multiple types of nerve blocks are used including thoracic epidural nerve catheter infusions, paravertebral nerve block catheter (PVB) infusion and erector spinae block catheter infusions (ESP). PVB and ESP are both nerve block techniques for which ropivacaine and bupivacaine are FDA approved for. The hope of this study is to determine if the ESP can provide comparable pain relief compared to PVB, while at the same time also decreasing the unwanted side effects or risks of other nerve blocks.

While previous studies have demonstrated that the PVB has not been inferior to thoracic epidurals for pain relief, no formal studies comparing PVB to ESP have been made. Additional pain medications will be available to you if needed, regardless of which group you are assigned to.

Who can I talk to if I have questions?

Your physician is involved as an investigator in this research study. Before agreeing to participate, 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 physician. If you have questions, concerns, or complaints, or think that the research has hurt you, you should contact the principal investigator – Dr. Neal Shah at Passavant Hospital: 412- 367-6700; or call on weekdays between 7 am – 4 pm
Answering Service: 412-692-2333 to speak with the anesthesia provider on call.

If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll -free at 866-212-2668. Please use this number if you feel that your questions, concerns, or complaints are not being answered by the research team, you have questions about your rights as a research subject or want to get information or provide input about this research.

How long will the research last?

Your involvement in this research study is expected to last for up to 5 days after your nerve block. We will be collecting data until 60 patients have been enrolled and fully evaluated.

How many people will be studied?

We anticipate that approximately 60 patients will be included in this research study. All patients will be from UPMC Passavant Hospital.

What happens in this research study?

If you agree to participate in this study, you will be randomly assigned (by every other enrollment to treatment group) to one of two groups:

> **Paravertebral Nerve Block Catheter** – This group will receive pain management via a paravertebral nerve block catheter. This will include ultrasound guidance. All standard multimodal pain medications will be included as well.

Erector Spinae Block Catheter – This group will receive pain management via an erector spinae nerve block catheter. This will include ultrasound guidance. All standard multimodal pain medications will be included as well.

The procedure for both of the above types of nerve blocks are essentially the same for you. Both nerve blocks can take between 10-60 minutes to perform. They will either occur in the preoperative holding area or a designated block area or in the operating room. The difference between the two types of nerve block is the target, which is within a few centimeters of each other. To perform this procedure, we ask you to sit at the edge of your hospital bed. We use a marker to mark the spot on your back where the needle will enter your skin. We clean your back, and place sterile drapes over the area to protect it from infection. We inject lidocaine (numbing medicine) into the skin to make the procedure painless. We then use an ultrasound machine to identify the location of the target nerves. We then place a needle into your back in the area of the numbing medicine. We use the ultrasound to guide the needle into place. We then inject more numbing medicine (ropivacaine) into your back to improve your pain. We then thread a very small plastic catheter into your back, and remove our needle. We provide more numbing medicine through the plastic catheter. We then tape the catheter to your skin, and lay you back in bed. We hook the catheter to a medicine pump, that will continuously deliver more numbing medicine (bupivacaine) for the duration of your treatment. After the treatment period, we remove the catheter which does not cause any pain. We cover the area with gauze and tape, and continue to provide pain medicine with oral and IV medications as needed.

During your treatment with the nerve block catheter, the pain management team adjusts the amount of pain medication given through the catheter to promote comfort. Every hour, your nurse can give you an extra dose of bupivacaine if needed for pain control. We remove the catheters based on how well you tolerate the nerve block in combination with other pain medicines, after no more than 5 days. Most catheters remain for approximately 72 hours (3 days).

Regardless of which group you are assigned to, follow-up assessments will occur:

During the next 3 days after your nerve blocks. You will be followed-up post-procedure at 15 minutes, 60 minutes; post-procedure day 1 at 9:00AM; post procedure day2 at 9:00AM and post-procedure day 3 at 9:00AM.

Items that will be assessed at these time intervals include:

- Your verbalized pain scores from 0-10 at rest and with breathing
- The amount and types of opioid pain medications you require
- The time you first request extra opioid medications
- Total local anesthetic utilized
- Your vital signs
- Presence or absence of complications including pneumothorax, bleeding, dislodgment of catheter, needing for re-dressing of catheter, or block site infection.
- Presence or absence of signs of local anesthetic toxicity including perioral numbness, ringing in your ears, and/or metallic taste in your mouth

The medications utilized for the PVB and ESP will include ropivacaine and/or bupivicaine. Ropivacaine and bupivacaine are FDA approved local anesthetics for nerve block procedures. A total of 25mL of 0.5% Ropivacaine will be used with 25mL allocated to the nerve block site. An infusion of up to 12 ml/hr of .0625% bupivacaine along with an option 3ml requested bolus will be ordered. This is a standard dose for this surgery for nerve block infusions.

Potential health information that will be used and/or disclosed:

Your age, gender, race, height, weight, body mass index, ASA classification (measure of your level of health according to the American Society of Anesthesiologists), number of rib fractures, and anti-coagulation status.
Any medical comorbidities (other medical problems) that you may have including any history of chronic opioid use
Your verbalized pain scores from 0-10 at rest and with movement
The amount and types of postoperative pain medications you require The time you first request extra opioid medications
Your vital signs
Presence or absence of complications including pneumothorax, bleeding, dislodgment of catheter, needing for re-dressing of catheter, or block site infection.
Presence or absence of signs of local anesthetic toxicity including perioral numbness, ringing in your ears, and/or metallic taste in your mouth

What happens if I say no, I do not want to be in this research?

Participation in this research is voluntary. You may decide not to take part in the research and it will not negatively impact your care in any way. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. This is not a treatment study. Your alternative is not to participate. Should you not participate, we will provide alternative means to control your pain to the best of our abilities. This may include a nerve block, even if you do not want to participate in the study. You are not under any obligation to participate in any research study offered by your doctor.

What happens if I say yes, but I change my mind later?

You can, at any time, withdraw from this research study. You can also withdraw your authorization for us to use your identifiable medical information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above. Should you decide to withdrawal, any information already obtained will still be used in the study, but no new information will be obtained. Should any new findings develop during the course of the research that may be related to your willingness to continue participation, it will be provided to you in a timely manner. **To formally withdraw from this research study**, you should provide verbal notification to the study team or the principal investigator. Contact information is available on this form. **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.

What are the study risks?

Risks associated with screening procedures and access to private health information includes:

Loss of confidentiality:
- Access to health information
- Screening procedures
- Follow-up

Special care will be taken to ensure anonymity in this study and only a study number will be used to identify you. Only necessary information will be collected and any questions asked will be done so in a respectful manner in a private area. Should any unforeseen loss of confidentiality occur, you will be informed in a timely manner. Although every reasonable effort has been taken to de-identify your research information, confidentiality cannot be guaranteed and it is possible that re-identification of research data may occur.

Risks associated with the Paravertebral Nerve Block (PVB) include:

Bleeding
Infection
Damage to surrounding
structures Pneumothorax
Epidural spread of medication
Tenderness at insertion site
Block failure

Risks associated with the Erector Spinae Plane Block (ESP) include:

Bleeding
Infection
Damage to surrounding
structures Pneumothorax
Tenderness at insertion
site Block failure

There is a very low risk of experiencing one or more of the possible side effects above if you are in either group assigned. These risks are minimized by performing the procedure in a sterile fashion, ensuring appropriate dosing, and using an ultrasound machine which allows us to directly visualize where we are going. You may have some discomfort while having the nerve block placed as this utilizes a needle to penetrate the skin and structure until at the correct site. Prior treatment to the proposed insertion site with local anesthetic may be used or sedation at disclosure of the attending anesthesiologist. As with any experimental procedure, there may be adverse events or side effects that are currently unknown and certain of these unknown risks could be permanent, severe or life-threatening.

Risks associated with ropivacaine/bupivacaine include:

Patient:

- Restlessness
- Anxiety
- Dizziness
- Tinnitus
- Blurred vision
- Tremors
- Depression of the myocardium: decreased cardiac output, heart-block, hypotension, bradycardia, ventricular arrhythmias
- Allergic type reactions.

Considering that the medications used in the nerve blocks are continuously flowing, the risks displayed above are continuous while the nerve block is in place. The medical staff is trained to identify any adverse drug effects and can quickly shut off the nerve block if you experience any

side effect. You will also have continuous cardiac and respiratory monitoring while the nerve block is in place. The doses used in this study are standard, and have been administered to many thousands of patients worldwide. The risks of adverse drug effect are very low.

There may be some inconvenience to you associated with the follow-up that is planned for this study. However, this is standard procedure for a; patients receiving nerve blocks under the interventional pain service. This a safety measure to ensure adequate treatment and limitation of side effects. Again, there is a small risk for loss of confidentiality which will be minimized as described above.

What are the benefits of the study?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits from participation may include improved post-traumatic pain control, decreased need for post-traumatic pain medications, standardized nerve block recommendations and decreased incidence of opioid related side effects such as nausea, vomiting, pruritus (itching), and sedation. This will help determine which nerve block is safer and more appropriate for patients in your situation.

If I do not want to participate in this study, how will my pain be managed?

If you do not want to participate in the study it will not affect you care. You will have access to the standard of care which includes oral, intravenous, and topical pain medications in combination with nerve blockade for patients who can tolerate them. It is often best to include a nerve block to complete what we call multi-modal analgesia, but it is not always wanted or possible. We use medications like opioids, NSAIDS, tylenol, ketamine, gabapentin, lidocaine patch, among many others, for pain control. Either the ICU / medical / pain management physicians will manage the rib fracture pain with a variety of the above agents to promote comfort.

Will my information be kept confidential?

Your identity and medical records and data related to this study will be kept confidential, except as required by law and except for inspections by the University of Pittsburgh Research Conduct and Compliance Office. Once enrolled, you will be given a research number to identify you in the study. This research number (not your name) is what will be used to keep track of any personal information or data collected on you. All such data and information will be maintained in a password protected computer and/or locked file cabinet. A single document linking all research numbers to specific patient names will be kept in a separate, secure location accessible only by the primary investigator of this study. Results of the research may be published for scientific purposes or presented to scientific groups, however, your identity will not be revealed. Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project. Your de-identified research data may be shared with secondary investigators with similar research interests.

Can I be removed from the research without my okay?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff, breach of protocol, alteration of your clinical condition or required surgical plan including the need to have a surgery or additional procedures which may alter pain results.

Are there costs of participating in this study?

For this study, you will not be charged for any additional costs for having enrollment or nerve block type other than standard billing procedures per department protocol. You or your insurance will be billed for all procedural requirements and all medications required for pain management, which is the same for patients who are not enrolled in this study.

Will I be paid to participate in this study?

You will not be paid for your participation in this research study.

What if I am injured while taking part in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is 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. Your insurance provider may be billed for the costs of this emergency treatment, but none of those 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. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form

Authorization to use and disclose individually identifiable health information for a research study

Before you can take part in this research study, the University of Pittsburgh is required to obtain your authorization to use and/or disclose (release) your health information. This section describes how, and to whom, your health information will be used and/or disclosed (shared) while you are participating in this research study. It is important that you read this carefully. The University of Pittsburgh and its researchers are required by law to protect your health 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 will be used to determine your eligibility for this study and to follow your response once you are enrolled in the study.

The following is a list of entities that may use and/or disclose your health information as part of this study:

Those who oversee the study will have access to your health information, including the following:

- The University of Pittsburgh
- The University of Pittsburgh Conduct and Compliance Office

Government agencies such as the Department of Health and Human Services who have oversight of the study or to whom access is required under the law.

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. It is possible that collected data may also be shared with secondary investigators with similar research interests, but only in a de-identified fashion (your name and other identifying information will not be shared).

In order to participate in this study, you must agree to share your health information with the persons and organizations listed above. If these persons or organizations that you authorize to receive and/or use protected health information, are not health plans, covered health care providers, or health care clearinghouses subject to federal health information privacy laws, they may further disclose the protected health information and it may no longer be protected by the federal health information privacy laws.

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.

Expiration of Authorization

This authorization will not expire unless you revoke it in writing. You may revoke or end this authorization by writing to the Principal Investigator:

Neal Shah, M.D.
Department of Anesthesiology
Universirty of Pittsburgh Medical Center
200 Lothrop Street
Pittsburgh, PA 15213

If you revoke your authorization, you will also be removed from the study. Revoking your authorization only affects the use and sharing of your health information after the written request is received. Any health information obtained prior to receiving the written request may be used to maintain the integrity of the study.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my participation in this research study, I am encouraged to ask questions about any aspect of this research study including the use and disclosure of my identifiable medical record information. Such future questions will be answered by the investigators listed on the first page of this form.

Any questions I have about my rights as a research participant or the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study and for the use and disclosure of my medical record information for the purposes described above. A copy of this consent form will be given to me.

_____ _____

Signature of subject Date/Time

_____

Printed name of subject

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, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Investigator signature Date/Time

_____

Printed name of investigator