Consent to Take Part in a Research Study

Title: Erector Spinae Plane Block (ESP) versus Control for Pain Control Following Percutaneous Nephrolithotomy: A Randomized, Double-Blind, Placebo Controlled Study.

Principal Investigator: Jason Buehler, MD

The purpose of this study is to look whether or not an erector spinae plane (ESP) block can reduce post-operative pain after a percutaneous nephrolithotomy (a surgical procedure is used to remove kidney stones when they are too large, or the body cannot pass them on its own). A block is the injection of a local anesthetic like Novocain, into a specific nerve or group of nerves to treat or prevent pain. Participants in the study, will receive either an ESP block or a placebo-saline block placed after general anesthesia is started while you are asleep, so no pain will be felt during the block placement. After surgery, both groups will have the standard pain management as ordered by their physicians. The study will also include four, thirty-minute, twenty question follow-up phone calls at 24 hours, 48 hours, 7 days, and 30 days after their surgery at which time participants will also be asked about their pain levels and opioid use. Other data will be collected from their standard hospital record. The total study time is 30 days. The greatest risks of the study are those associated with receiving a nerve block. This includes pain, tenderness and bruising at the block site, and uncommon risks/side effects of infection, bleeding, and persistent numbness. 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 improve post-surgical care, and if the block is proven to be effective, it will decrease the need for patients to have opioid pain medications in the future.

If you would like to learn more about this study, please read below.

You are being asked to take part in a research study. The information below will tell you about the study. Please read this form in full. Your taking part in the study is your choice. Saying no will not change your rights to health care or services. You are free to leave this study at any time.

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Please take the time to read over this consent form. You will have the chance to sign this consent form and ask any further questions at your pre-anesthesia appointment.

What is the purpose of the study?

The purpose of this study is to determine if an erector spinae plane (ESP) block is more effective than a placebo block in lowering pain after a percutaneous nephrolithotomy (a procedure that removes kidney stones when they are too large, or the body cannot pass them on its own).

How long will I be in the study?

You will be in the study for 30 days. The study will conclude after a 30-minute phone call to assess pain and opioid use 30 days after your surgery.

What will happen to me during the study?

The following tests or procedures that are required in this study for research purposes are:

After we begin your general anesthesia we will place either an Erector Spinae Plane block or a normal saline placebo block while you are asleep. We are using the placebo control because it is the only way that we can determine whether or not the active block is effective in helping control post-surgical pain and reduce the need for use opioids. There is a 50/50 chance that you will receive an active or placebo block.

Pain control after your surgery will be ordered after your surgery by your physician and will not be affected by your participation in the study.

Study personnel will follow-up follow up with you after surgery with a 30-minute, twenty question phone call 24 hours, 48 hours, 7 days, and 30 days after your surgery and will also assess your pain levels and pain medicine use.

A pregnancy test will be done for all females of child-bearing age as part of routine care.

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The study will end after assessing your pain and opioid use on day 30.

What are the side effects or risks from being in the study?

The potential risks to you from being in the study are:

Enrollment Risks:

Less Likely:

Loss of Confidentiality.

Block Risks:

Likely:

Discomfort or bruising at the injection site.

Block Failure.

Less Likely:

Infection.

Nerve Damage.

Headache.

Damage to surrounding structures.

Rare but Serious:

Punctured lung (pneumothorax).

Persistent weakness.

To minimize risks:

1. Proper aseptic technique will be used to minimize risk of infection.
2. Proper positioning and the use of an ultrasound-guided technique will help minimize the risk of block failure, pain or bruising at the injection site, and pneumothorax.
3. The use of data security to prevent the loss of confidentiality.

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What are the benefits to taking part in the study?

The potential benefits to you include:

There are no direct benefits to you for participating in the study but your participation will help us determine if and which nerve blocks provide better pain control after surgery.

What other choices do I have if I do not take part in this study?

If you choose not to participate in the research, you will have the pain control prescribed by your doctors.

How many people will be in the study?

About 128 people will be in this study at UT Medical Center (UTMC).

What will it cost me to be in the study?

Service	Charges
Preoperative Evaluation	This is billed with anesthesia for surgery
Medical History and Physical	This is billed with anesthesia for surgery
Regional Anesthetic	This service is for research only and is not billable
Local Anesthetic medication	This service is billed with usual medical care for surgery
Surgery Anesthesia	This is billed with usual medical care for surgery
Global Surgical Fee	This is billed with usual medical care for surgery
Facility Fee	This is billed with usual medical care for surgery
Associated medications	This is billed with usual medical care for surgery
Follow-up Survey	This service is for research only and is not billable
Pregnancy Test	This is billed with usual medical care for surgery for females of childbearing age.

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Will I be paid for taking part?

No, you will not be paid.

Is the Investigator paid to do this study?

No, the investigator is not being paid to enroll people in 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 treatment.

Tell your study doctor, Dr. Jason Buehler, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at (865) 305-9220 during normal business hours (8:30AM-4:30PM).

You are not waiving any legal rights or freeing the University of Tennessee or its agents from liability for negligence. If you are injured as a result of the research procedures, the University of Tennessee does not have funds for payment. This includes lost wages and medical treatment.

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

Who do I call if I have questions about the study?

Questions about the study: Dr. Jason Buehler

University Anesthesiologists
1924 Alcoa Highway, Box 109
Knoxville, TN 37920
Phone: (865) 305-9220

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Questions about your rights as a research subject: You may contact the UT Graduate School of Medicine Institutional Review Board (IRB) at 865-305-9781. The IRB is a group of people that reviews studies for safety and to protect the rights of study subjects.

Can I stop being in the study?

You may leave the study at any time. Your treatment, payment, or enrollment in any health plans or eligibility for benefits will not be affected.

Could I be removed from the study?

You could be removed from the study. Reasons could be:

- The doctor in charge of the study may feel it is in your best interest to change treatments.

Identifiable private information or identifiable biospecimens:

Identifiers might be removed from the identifiable private information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

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 kept 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 uses and disclosures of your PHI. By taking part in this research study, you agree to let the research team use and share your PHI as described below. It will be used for the purpose of this research.

As part of the study, Dr. Jason Buehler and his study team may share the results of your fifteen question *Quality of Recovery-15* (QoR-15) questionnaire, visual analog pain scale scores, amount of opioid medication used, Face, Leg, Activity, Cry, Consolability (FLACC) behavioral

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pain assessment scores, level of sedation in the post anesthesia care unit, level of sedation after going to the hospital floor, how long it takes you to first pass gas. 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
- Insurance companies for billing purposes

Federal privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal health information private and confidential. The sponsor may give your PHI that will not contain your name to others. They may also use it for research purposes other than those listed in this form. When using your PHI, the sponsor, Dr. Jason Buehler and staff, will keep your information in strict confidence. They will comply with any and all applicable laws in regard to the confidentiality of such information.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research information not already in your medical record will be held for six years after the study is finished. Any research information entered into your medical record will be kept until further notice.

Unless otherwise stated, this permission to use or share your PHI does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr. Jason Buehler in writing and let him know that you are withdrawing your permission. The mailing address is 1924 Alcoa Highway, Box 109, Knoxville, TN 37920. At that time, we will stop further collection of any information about you. The health information taken before this withdrawal may still be used for reporting and research quality.

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.

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CONSENT OF SUBJECT:

I have read or have had read to me the information about the research study. The investigator or his representative has explained the study to me. They have 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 will receive a copy of this form after it is signed.

I freely volunteer to take part in this study.

_____	_____	_____
Printed Name of Subject	Signature of Subject or Authorized Representative	Date & Time

_____	_____
Printed Name of Representative	Relationship to Subject

_____	_____	_____
Printed name of person Obtaining Consent	Signature of person Obtaining Consent	Date

_____	_____	_____
Printed name of Investigator	Signature of Investigator	Date

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