

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

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## Study Summary

<b>Title</b>	Erector Spinae Plane Block versus Control for Pain Control Following Percutaneous Nephrolithotomy: A Randomized, Double-Blind, Placebo Controlled Study.
<b>Methodology</b>	Randomized, double-blind, controlled study
<b>Study Duration</b>	1 year
<b>Study Center(s)</b>	University of Tennessee Medical Center
<b>Objectives</b>	<p><b>Primary:</b> Determine if there is a significant effect on post percutaneous nephrolithotomy morphine milligram equivalents (MME) consumption with the usage of an ESP block vs. saline control.</p> <p><b>Secondary :</b> Determine if there is a significant effect on reported pain levels with the use of an ESP block vs. saline control in post percutaneous nephrolithotomies</p>
<b>Number of Subjects</b>	128
<b>Diagnosis and Main Inclusion/Exclusion Criteria</b>	<p><b>Inclusion Criteria</b> All participants will require full consent, be willing and able to comply with all study requirements and will meet the following inclusion criteria: -Adults, male and female greater than or equal to age 18 and undergoing non-emergent percutaneous nephrolithotomy Monday-Friday from 6:00AM-4:00PM. -Female volunteers of childbearing potential will be required to provide a negative pregnancy test. -Ability to understand and teach back consent for the procedure. -Willingness to sign consent for procedure. -English Speaking.</p> <p><b>Exclusion Criteria</b> -Emergent surgery status. -Local infection. -Allergy to local anesthetics. -Recreational drug use. -Inability to provide informed consent. -Pregnancy or breastfeeding. -History of Guillain-Barre' Syndrome. -Underlying medical conditions that would pose a significant risk to the patient.</p>
<b>Study Product, Dose, Route, Regimen</b>	The erector spinae plane block, while it is a standard procedure, is the independent variable for this study. The ESP block is an ultrasound-guided paraspinal fascial plane block that involves the injection of 30mL of 0.5% ropivacaine with 4mg of dexamethasone anterior to the erector spinae muscle and posterior to the thoracic transverse processes.
<b>Study Endpoints</b>	Primary study endpoint is the opioid consumption (MME) in the first 24 hours postoperative. Secondary study endpoints are hospital LOS, mean VAS score in the 24 hours after surgery, new persistent postoperative opioid use at 30 days, and QoR-15 at 24, 48, and 168 hours.

## Protocol Version 1.5

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

### **Investigator names:**

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**Location:** University of Tennessee Health Science Center- Knoxville

### **Objectives / Specific Aims**

The purpose of this study is to investigate the use of the erector spinae (ESP) block in reducing the morphine milligram equivalent (MME) consumption post percutaneous nephrolithotomy.

#### *Objectives:*

1. Determine if there is a significant effect on post percutaneous nephrolithotomy MME consumption with the usage of an ESP block vs. saline control.
2. Determine if there is a significant effect on reported pain levels with the use of an ESP block vs. saline control in post percutaneous nephrolithotomies.

Hypothesis: The Erector Spinae Plane Block will be associated with reduced opioid consumption in the first 24 hours compared to the control following percutaneous nephrolithotomy.

## **Background and Significance:**

Renal pain associated with percutaneous nephrolithotomy is a well-documented phenomenon due to sensory nerve transmission occurring through the renal nerve plexus, splanchnic nerves and thoracic sympathetic nerve ganglia. The erector spinae plane has the potential to provide a benefit of visceral analgesia through the spread of local anesthetic to the sympathetic fibers in the space between the thoracic vertebra [1, 2]. Due to this, the local anesthetic effects of the erector spinae plane block on renal visceral innervation may provide superior postoperative analgesia and in recent studies has shown a decrease of opioid consumption in the first 48 hours compared to control blocks [1, 3, 4].

Current data from the University of Tennessee Medical Center:

1. Quality improvement (QI) data demonstrates an average time to first opioid in patients who received a ESP block at the time of their percutaneous nephrolithotomy is 15.5 hours; average first pain return is 15.3 hours; On a five point scale (0 totally dissatisfied, 5 completely satisfied), average patient satisfaction with pain control is a 4.8; 100% would request a repeat block if they had the surgery again.

The current procedure for determining if an ESP block should be used is as follows:

1. The surgeon identifies patients who may benefit from block placement.
2. The day of surgery, the risks and benefits of a block are presented to the patient by the anesthesiologist.
3. If the patient decides on having a block placed, the anesthesiologist obtains consent for block placement.
4. Blocks are placed either in preoperatively or during surgery depending on the patient and the procedure.

In this study, potential subjects will have the opportunity to review all pertinent information regarding the risks and benefits to receiving a nerve block prior to pre-anesthesia testing so any questions can be answered before obtaining consent.

## **Interventions to be studied: ESP versus Control Block in Percutaneous Nephrolithotomy**

### ***Erector Spinae Plane Block- Independent Variable***

The erector spinae plane block, while it is a standard procedure, is the independent variable for this study. The ESP block is an ultrasound-guided paraspinous fascial plane block that involves the injection of 30mL of 0.5% ropivacaine with 4mg of dexamethasone anterior to the erector spinae muscle and posterior to the thoracic transverse processes.

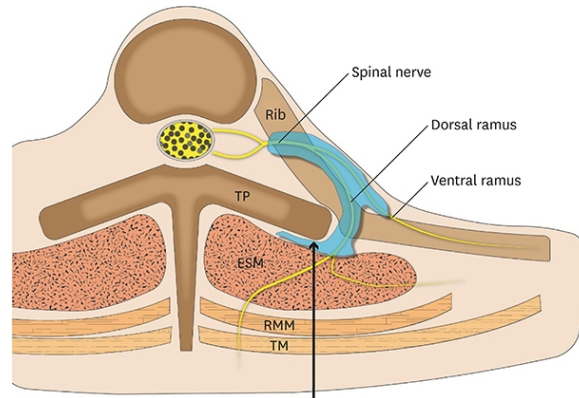


Figure 1. The Erector Spinae Block [5]

Approximately 20 ESP blocks are currently being performed per month at the University of Tennessee Medical Center for surgeries involving the thoracic cavity, kidney and/or flank

*Potential Regional Anesthetic-related Complications: [1, 6]*

- 2 cases of pneumothorax have been described in the literature.
- Nerve Damage
- Bruising and discomfort at injection site
- Infection
- Headache
- Hematoma at injection site
- Persistent weakness

The following will be utilized to minimize the risk of complications:

- Proper aseptic technique will be used to minimize risk of infection.
- Proper positioning and ultrasound-guided technique will help minimize the risk of pneumothorax, hematoma at injection site, paralysis, and block failure.
- Continuous monitoring of vital signs during surgery and in the PACU to assess for changes in clinical presentation.
- At the 48-h post operation phone call, study staff will assess for side effects.

*Benefits [1, 7, 8]: Whereas there are no specific benefits to the subjects for participating in the study it is hoped that we will be able to determine that an ESP block will be superior to the placebo and offer the following benefits*

- Reduction in opioid consumption.
- Reduction in Visual Analogue Scale (VAS) pain score.
- Reduced hospital stay.
- Prolonged analgesia.
- Improved ventilation and tissue perfusion status.
- Studies have demonstrated ESP safety and effectiveness with no cases of bleeding or hemodynamic effects currently identified [1].

### ***Control/Placebo***

The control block containing preservative free normal saline will be performed by a regional anesthesiologist. Post procedure analgesia will be available as ordered by the subject's physician performing the percutaneous nephrolithotomy.

### **Study Endpoints**

- Primary study endpoint is the opioid consumption (MME) in the first 24 hours postoperative.
- Secondary study endpoints are hospital length of stay (LOS), mean Visual Analog Scale (VAS) score in the 24 hours after surgery, new persistent postoperative opioid use at 30 days, and QoR-15 at 24 hours, 48 hours, 7 days and 30 days.

### **Number of subjects**

Based upon power analysis, sample size is 128 subjects undergoing an elective percutaneous nephrolithotomy with 64 participants in each arm of the study.

### **Inclusion / Exclusion Criteria**

Inclusion and exclusion criteria will be determined through chart review, the history and physical at pre-anesthesia testing as well as the day of surgery, and the ability and willingness to sign consent.

#### **Inclusion Criteria**

All participants will require full consent, be willing and able to comply with all study requirements and will meet the following inclusion criteria:

- Adults, male and female greater than or equal to age 18 and undergoing non-emergent percutaneous nephrolithotomy Monday-Friday from 6:00AM-4:00PM.
- Female volunteers of childbearing potential will be required to provide a negative pregnancy test.

- Ability to understand and teach back consent for the procedure.
- Willingness to sign consent for procedure.
- English Speaking.

### **Exclusion Criteria**

- Emergent surgery status.
- Local infection.
- Allergy to local anesthetics.
- Recreational drug use.
- Inability to provide informed consent.
- Pregnancy or breastfeeding.
- History of Guillain-Barre' Syndrome.
- Underlying medical conditions that would pose a significant risk to the patient.

### **Contraindications:**

Contraindications are the contraindications for receiving a nerve block. They are determined through chart review and the history and physical at pre-anesthesia testing as well as the day of surgery.

### **Absolute Contraindications**

- Lack of patient consent.
- Skin infection at the site of needle insertion.

### **Relative Contraindications**

- Coagulopathy.
- Systemic infection.
- Anatomical distortion.
- Neuropathy.

### **Drugs/Device usage within 7 Days of Randomization if any:**

- Anticoagulants

### **Recruitment Methods**

- Participants will be recruited through chart review of potential subjects scheduled for a percutaneous nephrolithotomy.
- Through chart review, subjects who meet all inclusion and exclusion criteria will be selected to be asked to consent to enter the study.

### **Consent process**

The physician performing the surgery will approach potential subjects at their in-office appointment prior to surgery. The physician will provide an overview of the study and a copy of the consent form to take home and read. The physician will:

- Explain all the risks and benefits of the study.
- Answer any questions at that time.

At the subjects' pre-anesthesia testing appointment, a member from the supporting Research Staff will:

- Explain all the risk and benefits of participation in the study.
- Review the consent form and assess the subject's ability to teach back in their own words the risks and benefits of the procedure, the ability to state their own decision, the ability to explain how the information applies to oneself, and the ability to compare and infer the outcomes of their choices.
- Only obtain consent from the participant.

In order to decrease the possibility of coercion or undue influence, the research staff will discuss how pain will be controlled both within the study and outside of the study to ensure participants understand that post-operative pain will be treated according to their physician's orders, regardless of study participation. Medical care will be provided in the event any unforeseen circumstance arises, regardless of study participation.

### **For Cognitively Impaired Adults**

Decision making ability will be assessed when obtaining consent. Study personnel will assess for the subject's ability to teach back in their own words the risks and benefits of the procedure, the ability to state their own decision, the ability to explain how the information applies to oneself, and the ability to compare and infer the outcomes of their choices.

### **Methodology**

This is a double-blind, randomized control trial involving 128 subjects undergoing an elective percutaneous nephrolithotomy. All subjects who meet all inclusion and exclusion criteria will be equally randomized on the day of the procedure by operating room



pharmacy into either the ESP block or the control block. An interim analysis at the sample size required for a large effect size ( $n = 52$ , with  $n = 26$  in each treatment arm) will be performed. In order to blind the anesthesiologist performing the block, the control arm will be equally randomized by the pharmacist at the time of distributing the pre-filled syringes for the ESP block procedure. Randomization will occur with the use of a random number generator with 1:1 ESP:Control allocation ratio.

Subjects will be followed at Pre-op and the 24-h, 48-h, 7 days and 30 days post operatively to assess the quality of recovery utilizing the *Quality of Recovery-15* (QoR-15) questionnaire, VAS pain scale, and opioid consumption. Intraoperative MMEs, PACU MMEs, total MME's, FLACC scores at 30 minutes/1 hour VAS scores at 1 hour/2 hours/6 hours/24 hours, PACU LOS, hospital LOS, time to first flatus will be documented in patient chart, reviewed by study personnel and uploaded into a password protected database on the UTMCK server.

#### Research Procedures:

All aspects of the study and consent forms will be IRB approved prior to implementation. Potential candidates will be selected for consent based on chart review and surgery scheduling.

- The Surgeon will initially approach potential subjects and provide them with a copy of the consent form to take home and read prior to pre-anesthesia testing.
- At the subject's pre-anesthesia testing appointment, the research staff will explain the risks and benefits of the study, answer any questions, and obtain consent to participate.
- The Biostatistician will randomize the subjects with a random number generator. Once randomized, a blinded package labeled "ESP" or "Control" will be delivered to the regional anesthesia team containing the following:

#### ESP

##### Active group:

1. One 30mL syringe containing 29mL of 0.5% ropivacaine and 4mg of dexamethasone- labeled "ESP Block"
2. One 30mL syringe containing 30mL of preservative free normal saline-labeled "wound infiltration"

##### Sham group

1. One 30mL syringe containing 30mL of 0.5% ropivacaine- labeled "wound infiltration"
2. One 30mL syringe containing 30mL of preservative free normal saline-labeled "ESP Block"

- The pharmacist will create a table pre-populated with the randomization assignments with space to fill out patient information and medication information on the day of surgery. This chart will be in paper form and kept in a research binder in the OR pharmacy. When a patient is consented for the RCT, the treatment group will be chosen based on the numbers assigned a priori. Each qualifying patient will be documented on the subsequent row in the table, maintaining the original order of randomization as dictated by the statistician. Based on the assignment, the pharmacy technician will be instructed as to which products to make in the sterile hood. The pharmacist will verify that the products were made appropriately and will label the syringes according to assignment.
- Operating room pharmacy will hand the anesthesiologist a blinded package with one prefilled syringe for the regional block that will either contain 30mL of 0.5% ropivacaine with 4mg of dexamethasone or preservative free normal saline.
- The regional anesthesiologist will perform the ESP block using standard protocols and procedures.
- Age, BMI, duration of operation, EBL, intraoperative MMEs, PACU MMEs, 48 hours post-operative MMEs, total MME's, FLACC scores at 30 minutes/1 hour VAS scores at 1 hour/2 hours/6 hours/24 hours, PACU LOS, hospital LOS, time to first flatus will be documented in patient chart and reviewed by study personnel.
- QoR-15, MME consumption, and VAS will be assessed at Pre-op, 24-h, 48-h, 7 and 30 days by study staff. Data will be uploaded into a database kept on secured password protected computers on the UTMCK server.
- All patient identifiers will be removed prior to data analysis.

#### Non- Research Procedures:

- Consent for anesthesia will be obtained prior to performing any regional or general anesthesia.
- Standard safety and aseptic measures prior to performing for all regional blocks will be followed.
- Pregnancy test for all women with child bearing potential.

#### ESP Block Procedure:

- The subject will be put to sleep with general anesthesia.
- The anesthesiologist will identify proper anatomy for the block.
- Lidocaine will be used to numb the injection site.
- The Anesthesiologist will use ultrasound-guided technique and inject 30mL of 0.5% ropivacaine with 4mg of dexamethasone or saline placebo control into the erector spinae muscle, superficial to the tips of the thoracic transverse processes

Procedures performed to lessen the probability or magnitude of risks:

1. Proper aseptic technique will be used to minimize risk of infection.
2. Proper positioning and ultrasound-guided technique will help minimize the risk of pneumothorax, hematoma at injection site, paralysis, and block failure.

Data Collection:

Data will initially be collected to determine inclusion and exclusion criteria through chart review.

The day of procedures, a member of the study staff will interview the potential subjects and perform a pre-operative QoR-15 and VAS questionnaire.

Other data to be collected are: Age, BMI, duration of operation, estimated blood loss (EBL), intraoperative MMEs, PACU MMEs, 24 hours post-operative MMEs, total MME's, FLACC scores at 30 minutes/1 hours and VAS scores at 1hour/2 hours/6 hours/, PACU LOS (length of stay), hospital LOS, and time to first flatus.

At 24 h, 48-h, 7 and 30 days post-operation, subjects will be contacted by study staff with repeat QoR-15 and VAS scores. Chart review will also take place to document opioid consumption. Data will be input into a secure, password protected database.

Tools Utilized:

Face, Legs, Activity, Cry, Consolability (FLACC) scale: This tool is used to express pain for individuals who are not able to communicate what their pain status is.

Table 1. FLACC Scale

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractible	Difficult to console or comfort

Quality of Recovery -15 (QoR-15) Questionnaire: This tool measures the quality of recovery after surgery and anesthesia through 15 outcome measure questions.

### Table 2. QoR-15 Patient Survey QoR-15 Patient Survey

Date: \_\_/\_\_/\_\_

Study #: \_\_\_\_\_

Preoperative

Postoperative

**PART A**

**How have you been feeling in the last 24 hours?**

(0 to 10, where: 0 = none of the time [poor] and 10 = all of the time [excellent])

- |   |                  |                      |                 |
|---|------------------|----------------------|-----------------|
| 1. Able to breathe easily                                 | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 2. Been able to enjoy food                                | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 3. Feeling rested   | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 4. Have had a good sleep                                  | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 5. Able to look after personal toilet and hygiene unaided | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 6. Able to communicate with family or friends             | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 7. Getting support from hospital doctors and nurses       | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 8. Able to return to work or usual home activities        | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 9. Feeling comfortable and in control                     | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |
| 10. Having a feeling of general well-being                | None of the time | _____                | All of the time |
|   | 0                | 1 2 3 4 5 6 7 8 9 10 | 10              |

**PART B**

**Have you had any of the following in the last 24 hours?**

(10 to 0, where: 10 = none of the time [excellent] and 0 = all of the time [poor])

- |                                |                  |                     |                 |
|--------------------------------|------------------|---------------------|-----------------|
| 11. Moderate pain              | None of the time | _____               | All of the time |
|                                | 10               | 9 8 7 6 5 4 3 2 1 0 | 0               |
| 12. Severe pain                | None of the time | _____               | All of the time |
|                                | 10               | 9 8 7 6 5 4 3 2 1 0 | 0               |
| 13. Nausea or vomiting         | None of the time | _____               | All of the time |
|                                | 10               | 9 8 7 6 5 4 3 2 1 0 | 0               |
| 14. Feeling worried or anxious | None of the time | _____               | All of the time |
|                                | 10               | 9 8 7 6 5 4 3 2 1 0 | 0               |
| 15. Feeling sad or depressed   | None of the time | _____               | All of the time |
|                                | 10               | 9 8 7 6 5 4 3 2 1 0 | 0               |

Visual Analogue Scale (VAS): This tool measures pain intensity by associating a perceived pain numeric value with a facial expression of pain.

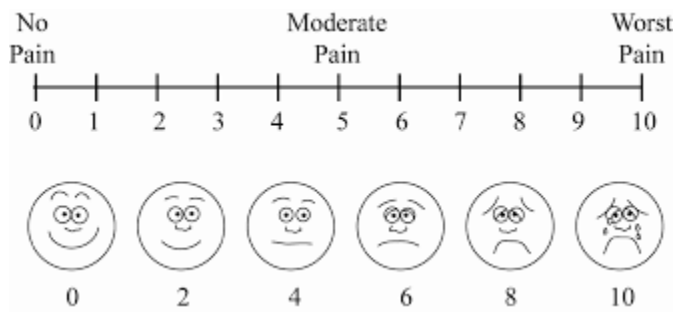


Figure 1. Visual Analog Scale

## Risks to subjects

*Adverse event (AE)* means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

*Life-threatening adverse event or life-threatening suspected adverse reaction.* An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

*Serious adverse event or serious suspected adverse reaction.* An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

*Unexpected adverse event or unexpected suspected adverse reaction.* An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended

(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32>)

The physical reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects are related to obtaining an ESP block and not specifically related the subjects' participation in the research. These risks include:

### Common Foreseeable Risks:

- Bruising and discomfort at injection site
- Block Failure

### Uncommon Foreseeable Risks:

- Pneumothorax
- Nerve Damage
- Infection
- Headache
- Hematoma at injection site
- Persistent weakness
- Loss of Privacy

Unforeseeable risks are associated with the blocks themselves and are not related to study participation

### ***Data Management***

#### Statistical Power/Sample Size

The researchers hypothesized a moderate effect size related to the difference in MMEs at 24 hours associated with ESP versus Control. Using a two-tailed hypothesis, the effect size of  $d = 0.5$ , an alpha value of 0.05, a beta value of 0.20, and a 1:1 allocation ratio to the two treatment arms, a total of  $n = 128$  participants would be needed for adequate power ( $n = 64$  in each treatment arm). The researchers plan to perform an interim analysis at the sample size required for a large effect size ( $n = 52$ , with  $n = 26$  in each treatment arm).

#### Statistical Methods

The statistical analysis for the study will be performed in an “intention-to-treat” fashion. Data missingness will be assessed using the MCAR (missing completely at random) analysis. Statistical assumptions of the statistical analyses will be assessed before choosing the correct statistical test (normality, homogeneity of variance, etc.).

Descriptive and frequency statistics will be used to describe the sample’s demographic and clinical characteristics. The following outcomes will be compared between the two treatment arms using either independent-samples t-test or Mann-Whitney U, depending upon the meeting of statistical assumptions: Age, BMI, duration of operation, EBL, intraoperative MMEs, PACU MMEs, 48 hours post-operative MMEs, total MME’s, FLACC scores at 30 minutes/1hour, VAS scores at 1 hour/2 hours/6 hours/24 hours, PACU LOS, hospital LOS, time to first flatus, Quality of Recovery 15 scores at 48 hours post-operation, MMEs at 30 days post-discharge, and the primary outcome MMEs in first 24 hours post-operation. Chi-square analysis will be used to compare the treatment arms on the categorical parameters of interest, including gender, ASA status, and post-operative nausea/vomiting, readmission rates, and new persistent postoperative opioid use. Statistical significance will be assumed at an alpha value of 0.05 and all analyses will be performed using SPSS Version 26 (Armonk, NY: IBM Corp).

The Principal Investigator will be responsible to ensure the study is conducted in accordance with the protocol, Good Clinical Practice, applicable regulatory requirements, and that the data recorded is valid. To achieve this, the study will be continuously monitored and reviewed via a monthly monitoring log

(Appendix 1.) that addresses adverse events as well as protocol and regulatory adherence on a monthly basis by Dr. McLoughlin, Dr. Allen, and the Study Coordinator and submitted for review to the Principal Investigator .

The collection of personal patient information will be limited to the amount necessary to achieve the aims of this research, so that no unneeded sensitive information is being collected. Data will be collected through chart review and medical records for inclusion criteria and follow-up. Pharmacy will maintain the code that identifies which patients receive which arm of the study while the Research Coordinator will maintain the decoder on a password protected computer. All hard copies of documents will be kept in a locked cabinet in the Research Coordinator's office. All hard copy documents will be shredded within six years after the completion of the study. Data will be input into the REDCAPS database stored on the University of Tennessee Medical Center server. When data is used for statistical analysis, it will be de-identified and input SPSS.

### Withdrawal of Subjects

- Subjects will be withdrawn from the research without their consent, including stopping participation for safety reasons, if the appropriate anatomy cannot be safely identified on ultrasound at the time of the regional anesthetic block.
- Subjects will be withdrawn from the research without their consent, if any contraindications are present on the day of surgery.
- All subjects have the right to withdraw from study participation at any time during the study. If a participant requests to withdraw prior to study completion, the data associated with that participant will be removed from the database and not utilized in statistical analysis. Subjects must notify study staff in writing, speak face-to-face, or call (865) 305-9220 within business hours (8:30 AM-4:30PM) in order to withdraw from the study.

### References

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5. Kwon WJ, B.S., Sun WY, *Erector Spinae Plane Block for Effective Analgesia after Total Mastectomy with Sentinel or Axillary Lymph Node Dissection: a Report of Three Cases*. Journal of Korean Med Sci, 2018. **33**.
6. De Cassai A, B.D., Correale C, Sandei L, Tulgar S, Tonetti T., *Erector spinae plane block: a systematic qualitative review*. Minerva Anesthesiol, 2019. **85**(3): p. 308-319.
7. Tulger S., S.O., Ozer Z., *Clinical experience of ultrasound-guided single and bi-level erector spinae plane block for postoperative analgesia in patients undergoing thoracotomy*. Journal of clinical anesthesia, 2018. **50**: p. 22-23.
8. Ugras, M.Y., et al., *Instillation of skin, nephrostomy tract, and renal puncture site with ropivacaine decreases pain and improves ventilatory function after percutaneous nephrolithotomy*. J Endourol, 2007. **21**(5): p. 499-503.



Appendix 1. Monthly Monitoring Log  
(Adapted from the CDC Monitoring Log and the King's Health Partners)

**Monthly Monitoring Log**

<b>Investigator and Trial Monitoring Visit Report IRB #</b>
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**Trial Details**

<b>Trial Title:</b>	
<b>Site Investigator Name:</b>	
<b>Department:</b>	
<b>Site:</b>	
<b>PI:</b>	

**Monitoring Summary**

<b>Date of Visit(s):</b>	
<b>Report Produced on:</b>	
<b>Follow-up Correspondence Sent:</b>	

**Patient Recruitment Status**

	<b>Confirmed</b>
<b>Randomised/Entered Study Arms:</b>	
<b>Dropped Treatment due to Adverse Events:</b>	
<b>Number of SAEs at Site To Date:</b>	

	YES	NO	NA*
<b>1. INFORMED CONSENT AND SUBJECT STATUS</b>			
1.1. Does the Investigator maintain logs of screened and enrolled subjects, including subject identification log?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:						
1.2. Has/have there been any subject(s) discontinued from treatment or from the clinical trial (include details of any discontinuation for non-serious adverse events)?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:						
1.3. Has/have there been any subject(s) lost to follow-up (according to the protocol) since the last monitoring visit report?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:						
<b>2. PROTOCOL ADHERENCE, MEDICAL RECORD REVIEW AND SDV</b>						
2.1. Did all the subjects reviewed meet the eligibility criteria?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:						
2.2. Has/have there been any significant deviation(s) from the final version of the protocol and protocol amendment(s) (if any)? *List all deviations on the deviation log.				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:						
2.3. Have all SDV/data queries raised during this visit been resolved?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:						
<b>2.4. SAE/AE</b>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have all site SAEs, including follow up information, been appropriately reported to the Sponsor? Please list SAE status of all the reported SAEs and any outstanding queries. *A separate sheet can be attached to the report if appropriate.						
Comments:						
<b>SAE number</b>	<b>Status (Open/Closed)</b>	<b>SDV performed (Y/N)</b>	<b>Outstanding Queries</b>			
2.5. Have all Serious Adverse Events been appropriately reported to the PI?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:						