Quadratus Lumborum Block versus Control for Total Hip Arthroplasty

Study Protocol & Statistical Analysis Plan

NCT03408483

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Birmingham, AL 35294

Human Subjects Protocol (HSP)

Form Version: February 1, 2017

- You are applying for IRB review of the research described in this form.
- To avoid delay, respond to all items in order and include all required approvals and documents. For more tips, see the UAB IRB website.
- To complete the form, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck.
- All responses should be Times New Roman, Bold, and Underlined.
- Submit all materials to AB 470, 701 20th Street South, Birmingham, AL 35294-0104.

Indicate the type of review you are applying for:

☒ Convened (Full) IRB ***-OR-***

☐ Expedited - See the Expedited Category Review Sheet, and indicate the category(ies) here:

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

1. IRB Protocol Title: Quadratus Lumborum Block versus Control for Total Hip Arthroplasty

2. Investigator and Contact Person

a. Name of Principal Investigator: **Promil Kukreja, M.D., Ph.D.**

Degree(s)/Title: **M.D., Ph.D.** BlazerID: **pkukreja**

Dept/Div: **Anesthesiology** Mailing Address: **JT 862** UAB ZIP: **6810**

Phone: **996-7025** Fax: **996-4489** E-mail: **pkukreja@uab.edu**

b. Name of Contact Person: **Betty Herard** Title: **Program Coordinator**

Phone: **205.934.0045**

E-mail: **bherard@uabmc.edu** Fax: **205.975.0761**

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and all key personnel comply with reporting requirements of the UAB Conflict of Interest Review Board;
- Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;
- Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
- Verifying that all key personnel listed on the protocol have completed initial IRB training and will complete continuing IRB training as required;
- Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
- Certifying that I and all key personnel have read the *UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies* and understand the procedures for reporting;
- Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;
- Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator: _____ **Date:** 4/16/18

3. Protocol Personnel

Including the PI, list all key personnel (each individual involved in the design and conduct of this protocol). See the Key Personnel Flowchart.

Complete the UAB (3.a.) and non-UAB (3.b) tables, as applicable. Use the checkboxes to show each individual's role, whether the individual has financial interests as defined by the UAB CIRB, and briefly describe the individual's protocol responsibilities and qualifications to perform those responsibilities. **Insert additional rows as needed.**

FDA: For studies involving investigational drugs, list all investigators who will be listed on FDA Form 1572 and include a copy of the 1572. Send the IRB a copy of Form 1572 any time you update the form with the FDA.

a. UAB Personnel (includes UAB affiliates and Children's of Alabama personnel)

Name, Degree, and Dept.	Blazer ID	Role	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: **Promil Kukreja** Degree: **M.D., Ph.D.** Department: **Anesthesiology**	**pkukreja**	Principal Investigator	☒No ☐Yes	**Oversees all aspects of project, obtains consent**
Name: **Elie Ghanem** Degree: **MD** Department: **Orthopedic Surgery**	**eghanem**	☒Sub-Investigator ☐Other	☒No ☐Yes	**Maintains open line of communication between surgeons and anesthesiologists; monitors for adverse effects**
Name: **Lisa MacBeth** Degree: **MD** Department: **Anesthesiology**	**ldspeake**	☒Sub-Investigator ☐Other	☒No ☐Yes	**Helps with recruiting, monitoring for adverse outcomes, data analysis**
Name: **Joel Feinstein** Degree: **MD** Department: **Anesthesiology**	joelfein	☒Sub-Investigator ☐Other	☒No ☐Yes	**Helps with recruiting, supervises block placement**
Name: **Prentiss Lawson** Degree: **MD** Department: **Anesthesiology**	**pjlawson**	☒Sub-Investigator ☐Other	☒No ☐Yes	**Helps with recruiting, supervises block placement**
Name: **Dan Johns** Degree: **MD** Department: **Anesthesiology**	**danjohns**	☒Sub-Investigator ☐Other	☒No ☐Yes	**Data analysis**

b. Non-UAB Personnel Relying on UAB IRB - If you are requesting that the UAB IRB serve as the IRB of record for anyone not affiliated with UAB, list these individuals below.

Name and Degree	From Institution with or without own IRB?	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: _____ Degree: _____ Institution: _____ Email: _____	☐Has own IRB but requests that UAB IRB serve as IRB of record?***-OR-*** ☐Does not have own IRB and needs to rely on UAB IRB.	☐No ☐Yes	_____

***Financial Interest** – for each individual listed above, answer **Yes** or **No** as to whether the individual or an immediate family member has any of the following:

- An ownership interest, stock options, or other equity interest related to the investigator's institutional responsibilities of any value.
- Compensation greater than $5,000 in the previous two years when aggregated for the immediate family
- Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship, regardless of compensation.
- Any other Financial Interest as defined by the UAB CIRB.

UAB Personnel: If the individual or his/her spouse or dependent child has a Financial Interest, a disclosure has to be made to the UAB CIRB. A completed CIRB evaluation has to be available before the IRB can complete its review.

Non-UAB Personnel: If the individual has a Financial Interest, ***include a copy of the report from his/her own institution's conflict of interest review with this submission to the UAB IRB.***

c. Do the investigators listed above include any students using this research for their thesis or dissertation?

☒ No, continue with Item 3.d.
☐ Yes, complete the following

Student Name	Thesis/Dissertation Title

d. Is the principal investigator a student, fellow, or resident? ☐Yes ☒No

If Yes, complete items below and obtain signature of faculty advisor or supervisor:

Supervisor's Name: _____
Degree(s) / Job Title: _____
Additional Qualifications pertinent to the protocol: _____
Telephone: _____
E-Mail: _____
Signature: _____

e. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol: **As an attending anesthesiologist, the PI is able to devote sufficient time to conduct and provide oversight for this protocol.** _____

f. Is medical supervision required for this research? ☒Yes ☐No

If Yes, who will provide the medical supervision?

☒ PI will provide ***-OR-***
☐ Other:
Name: _____ Telephone: _____
If other than PI, obtain signature of person providing medical supervision:
Signature _____

g. Describe your process for ensuring all key personnel are adequately informed about the protocol and their research-related duties and functions: **All personnel who are involved in the design or conduct of this research study will have successfully completed and maintained UAB IRB required human subjects research training, which includes the importance of measures to protect patient confidentiality**

4. Funding

Is this protocol funded? ☐Yes ☒No

If No, specify that costs of the protocol will be covered by funds from the UAB department or other source named: **Anesthesiology**

If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-d.

a. Title of Grant, Contract, or Agreement: _____

b. UAB PI of Grant, Contract, or Agreement: _____

c. Office of Sponsored Programs (OSP) Assigned Number: _____
(If not yet available, enter "Pending" and provide upon receipt from OSP.)

d. Sponsor, Funding Route:
(Check and describe all that apply)
(If subaward, list both the funding source and the institution receiving the direct award)
☐ Gov't Agency or Agencies—Agency name(s): _____
☐ Department of Defense (DoD): Identify DoD component: _____
☐ Department of Energy (DOE)
☐ Department of Justice (DOJ)
☐ Department of Education

☐ NIH Cooperative Group Trial - Group name: _____
☐ Private Nonprofit (e.g., Foundation) - Name: _____
☐ Industry, investigator-initiated - Name: _____
Describe the funding arrangement: _____
NOTE: The UAB IRB typically only reviews industry-sponsored protocols that are investigator initiated or when the protocol qualifies for expedited review or involves gene therapy.
☐ UAB Departmental/Division Funds—Specify: _____

5. Locations Involved

a. Indicate all performance sites that will provide space, services, or facilities for the conduct of this protocol.

☒ UAB Hospital
☒ UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital
☐ The Kirklin Clinic at Acton Road
☐ UAB Callahan Eye Hospital
☐ UAB Clinical Research Unit
☐ Children's of Alabama
☐ Birmingham Veterans Affairs Medical Center
☐ Jefferson County Department of Health
☐ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol) - Describe:
NOTE: Documentation of IRB approvals from sites receiving subawards must be received by the UAB OIRB before funding will be released for that subaward.

b. Describe the space, service, or facilities available for the conduct of the research in the performance sites listed in Item 5.a (For research on UAB campus, include building names): **The patients will be recruited and consented in their private rooms in the preoperative area of UAB Highlands. After enrollment and randomization, they will move to the block area that is well-equipped for placement of regional anesthesia techniques.**

c. Is this protocol a clinical trial requiring clinical services at one of the performance sites listed in Item 5.a above? ☒Yes ☐No
If Yes, will any of the services be billed to either participants/their insurance or to the study account through the Hospital Billing Office (PFS) or the HSF Billing Office (MSO)? ☐Yes ☒No

If Yes, submit a Full Fiscal Approval Process (FAP)-designated unit submission to s complete a FAP submission and send to fap@uab.edu. For more on the UAB FAP requirements, go to FAP - SiteMinder Processes.

d. Is this a field study? ☐Yes ☒No
If Yes, describe the community and include information about how the community will be involved in the design, implementation and analysis of the research. This would include focus groups, training local facilitators/community health advisors: _____

e. Has this protocol been rejected or disapproved by another review board (another IRB, similar review board, or departmental review committee(s)) that authorizes the use of its patient populations? ☐Yes ☒No

If Yes, provide name(s) of the review board(s) and reason(s) not approved: _____
Attach copies of the disapprovals.
NOTE: If this protocol is subsequently rejected or disapproved by another review board, promptly notify UAB IRB.

f. Will the protocol be conducted at or recruit participants from the Birmingham Veterans Affairs Medical Center (BVAMC)? ☐Yes ☒No

If Yes, describe the involvement of the BVAMC: _____

Attach the VA IRB approval and VA IRB-stamped consent form(s), if applicable.

NOTE: See the BVAMC section of the IRB Guidebook for more information.

g. Will the protocol be conducted at or recruit participants from the Jefferson County Department of Health (JCDH)? ☐Yes ☒No

If Yes, describe the involvement of the JCDH and list the JCDH clinics being used: _____

Attach the JCDH Research Review Panel approval, if applicable.

NOTE: Human subjects research conducted at certain JCDH clinics requires review by the JCDH Research Review Panel. See the JCDH section of the IRB Guidebook for more information.

6. Clinical Trial

Does this protocol meet the following definition of a clinical trial? ☒Yes ☐No

**A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For more information, see the full definition of clinical trial here.*

If Yes, you will need to fulfill the following requirements (regardless of funding):

a. All key personnel must complete the Good Clinical Practices (GCP) training. For information on this requirement, visit the IRB website here.

b. This protocol must be registered on ClinicalTrials.gov. Provide the National Clinical Trial (NCT) identifier number: **NCT 03408483**

If you have any questions regarding registering a study on ClinicalTrials.gov, email the UAB Center for Clinical and Translational Science at ccts@uab.edu.

7. Multi-Site Studies

a. Is this a multi-site study with the UAB investigator as the lead investigator? ☐Yes ☒No

b. Is this a multi-site study with UAB as a coordinating site? ☐Yes ☒No

c. If Yes to a or b, describe the management of information obtained in multi-site research that might be relevant to the protection of participants. Include, at a minimum, how the following items are managed:

- IRB approvals from other sites
- Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?)
- Interim results
- Protocol modifications

_____

8. Drugs

Will any drugs or supplements be *used or studied* in this protocol? ☒Yes ☐No

If Yes, attach the completed Drug Review Sheet.

9. Devices

a. Will any devices be *studied* in this protocol? ☐Yes ☒No

b. Will any *not FDA-approved* devices be *used or studied* in this protocol? ☐Yes ☒No

If Yes to a or b, attach the completed Device Review Sheet.

10. Special Approvals

a. Does this protocol involve the use of radioisotopes? ☐Yes ☒No
If Yes, attach documentation of approval from the Radiation Safety Division.

b. Does this protocol include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)? ☐Yes ☒No
If Yes, attach documentation of approval from the Infection Control Committee of the appropriate facilities.

c. Does this protocol involve obtaining remnant biopsy or surgical material from the Department of Pathology or any other source? ☐Yes ☒No
If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Anatomic Pathology Release of Pathologic Materials).

d. Does this protocol require obtaining any remnant clinical laboratory specimens, body fluids, or microbiological isolates from the Department of Pathology or any other source? ☐Yes ☒No
If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Laboratory Medicine Release of Pathologic Materials).

e. Does this protocol use stored (existing) specimens from a repository? ☐Yes ☒No
If Yes, attach documentation of approval for use of specimens, and describe how existing specimens are labeled: _____

11. Use of Specimens

Does this protocol involve the collection of specimens? ☐Yes ☒No
If Yes, complete 11.a-11.h.
If No, skip to Item 12.

a. How will specimens be obtained, processed, distributed, and stored? _____

b. How will specimens be labeled (e.g., unique identifier, medical record number, Social Security number, name, date of birth)? _____

c. How will clinical data associated with the specimens be collected and stored? _____

d. What participant-identifying information will be collected and linked to the specimens? _____

e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called "stripped" or "anonymized" specimens). _____

f. Is genetic testing planned as part of this protocol? ☐Yes ☐No
If Yes, describe the planned genetic testing here. _____

g. Will specimens be stored for future use? ☐Yes ☐No
If Yes, indicate whether they will be used for the disease under study in this protocol or research on other diseases. _____

h. Will specimens be shared with other investigators in the future? ☐Yes ☐No
If Yes, answer i. and ii.
i. What identifiers, clinical information and demographic information will be shared; or will the specimens be stripped of identifiers (i.e., anonymized)? _____
ii. Outline your procedure for assuring IRB approval for release and use prior to release of specimens.

_____

NOTE: Investigators who receive and/or use these specimens must document approval from the appropriate IRB(s) before the specimens may be released.

12. Gene Therapy

Does this protocol involve gene therapy or administering recombinant materials to humans? ☐Yes ☒No

If Yes, submit the Gene Therapy Project Review Panel Report ***-OR-*** the Protocol Oversight Review Form For Clinical Vaccine Trials, as applicable.

13. HIPAA Privacy and Security

Will the PI or others obtain, review, or make other use of participants' "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)? ☒Yes ☐No

If Yes, complete Items 13.a-13**.f.**

If No, skip to 14.

a. Will the data/information be stored or managed electronically (on a computer)?

☒Yes ☐No

b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)? ☐Yes ☒No

If Yes, attach copies of the privacy notices from each institution/entity, and provide the name of each institution/entity: _____

c. Indicate which of the entities would provide health information for this protocol, maintain health information as it was collected for this protocol, and/or store health information after it has been collected for this protocol.

☒ UAB Hospital or UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)
☐ UAB Callahan Eye Hospital
☐ Children's of Alabama
☐ Jefferson County Department of Health
☐ School of Dentistry
☐ School of Health Professions
☐ School of Medicine
☐ School of Nursing
☐ School of Optometry
☐ University of Alabama Health Services Foundation
☐ UAB Health Centers
☐ Viva Health
☐ Ophthalmology Services Foundation
☐ Valley Foundation
☐ Medical West - UAB Health System Affiliate
☐ None - **If None, skip to Item 14.**

d. Indicate any information systems that will be the sources of information used for the protocol.

☒ A system maintained centrally by UAB Health System (these include the following: HealthQuest for registration, billing, and patient administration; PowerInsight (clinical data warehouse); Cerner IMPACT for PowerNotes for meds, Lab, Radiology, UED, Surgery

NOTE: If a researcher needs information in a specified format or a specified time, the researcher must confirm with the unit who can supply the information/service that the request can be met before writing the information/service into the research protocol. In addition, the researcher must be aware that these services may have a cost attached that should be considered in the research budget.

To request access to clinical systems for research purposes, visit https://www.oneuabmedicine.org/web/hsis/technical-support, click "Accounts Request" and complete the form indicating access for research purposed.

☐ Another system on a UAB server - Describe: _____

e. Indicate which of the listed identifiers will be accessed, associated and/or linked with the protected health information (PHI) used for this protocol.

☒ Names
☐ Geographic subdivisions smaller than a state
☒ Elements of dates (except year) related to an individual
☒ Telephone numbers
☐ Fax numbers
☐ Email addresses
☐ Social security numbers
☒ Medical record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers
☐ Device identifiers and serial numbers
☐ Biometric identifiers
☐ Web universal resource locators (URLs)
☐ Internet protocol address numbers
☐ Full-face photographic images
☐ Any other unique identifying number - Describe: _____
NOTE: Codes are not identifying as long as the researcher cannot link the data to an individual
☐ None - **If None, skip to Item 14.**

f. Choose one plan to describe your use of the personal health information:

☐ The data collected meet the specifications for a "limited data set" (LDS)
-If the LDS will leave the covered entity or will be received from another covered entity you will need a Data Use Agreement

☒ Research staff will obtain authorization from each participant to use the information
-Include the HIPAA Authorization form, complete except for participant name and IRB protocol number, as the final page of the consent form

☐ PI requests waiver of authorization to use the information
-Attach Waiver of Authorization and Informed Consent form

PROPOSED RESEARCH

- The IRB will not accept grant applications and/or sponsor's protocols in lieu of the items as outlined below.
- Do not separate responses from items. Instead, insert your response to each item below the item, keeping the information in the order of this form.

14. Purpose - in nontechnical, lay language

a. Summarize the purpose and objectives of this protocol in one short paragraph.

Peripheral nerve blocks for joint and extremity surgeries have long been proven to provide effective post-operative analgesia. Of these surgeries, total hip arthroplasty (THA) remains one of the most common orthopedic procedures in the United States with approximately 300,000 operations performed annually[1]. At our institution, post-operative analgesia in these patients is often provided through parenteral and oral opioid medications. Quadratus lumborum blocks (QLB) have been described and implemented for various surgical procedures including caesarean section[2,3] and laparoscopic ovarian

surgery[4]. Recently, there has been increasing interest in the effectiveness of pain control with the use of quadratus lumborum blocks after THA . Currently, case reports have established a precedent regarding the efficacy of the QLB for THA[5, 6,10] in providing superior analgesia and decreasing verbal numerical pain scores, but randomized trials are still lacking. The goal of this study is to compare verbal numerical pain scores, post-operative pain medication (opioid) consumption, physical therapy scores, and patient satisfaction in patients that receive QLB versus no peripheral nerve blockade in patients undergoing THA. The results of this study have the potential to change the standard of care for patients undergoing THA.

b. Describe how outcomes will be measured for this protocol.

The primary end points are as follows:

1. Pain scores (numerical) will be obtained at immediate post op, 24 hours and 48 hours after surgery
2. Pain medication (opioid) use intraoperatively, as well as at 24 hours and 48 hours postoperatively
3. Physical therapist assessment of independence in mobility and transfers
4. Distance ambulated at 24 hours and 48 hours after surgery.

15. Background - in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the design of this protocol. Include any relevant past or current research by the PI. For drug and device studies, summarize the previous results (i.e., Phase I/II or III studies).

Currently, regional anesthesia techniques for total hip arthroplasty are limited. Fascia iliaca blocks (nerve blocks between the muscles of the hips) have been employed to provide analgesia for hip surgeries with blockade of the femoral, lateral femoral cutaneous, and obturator nerves via injection of local anesthetic in the iliacus fascia. In addition, lumbar plexus blocks have also been employed for post-operative analgesia, but the complexity of the block is high, and complications including epidural anesthesia are not infrequent. The quadratus lumborum block (QLB) is an abdominal truncal block in which local anesthetic is deposited into the thoracolumbar fascia (area between the muscle) or the quadratus lumborum muscle itself with the goal of providing analgesia to the ipsilateral T6 – L1 sensory dermatomes. It has already been demonstrated to provide effective post-operative analgesia for certain abdominal and pelvic surgeries[7], but its use in total hip arthroplasty is limited to case reports.

The block is accomplished by locating the quadratus lumborum muscle, using a ultrasound probe. Local anesthetic is then injected. Cadaveric studies[8] have demonstrated dye spread to the lumbar nerve roots and nerves within the transversus abdominis plane (TAP). Carney et al[9] described a "posterior TAP" block, now known to be synonymous with QLB, that demonstrated contrast spread to the thoracic paravertebral space from T5-L1. Case reports have described analgesia in the corresponding sensory dermatomes after QLB[4], and have demonstrated efficacy in patient undergoing THA [5,6,10]. The QLB block has potential to cover lateral femoral cutaneous nerve, femoral nerve, obturator nerve and portions of lumbar plexus.

This study has been designed to investigate the efficacy of the QLB in providing post-operative pain control patients undergoing THA. Previous trials have demonstrated the effectiveness of the block for abdominal and pelvic surgeries, and case reports have shown its applicability in hip arthroplasty. In this randomized, controlled study we aim to compare QLB (block group) with control (control group) in patients undergoing THA with regard to verbal numeric pain scores (to be obtained when patient arrives to PACU & at discharge from PACU, then at 24 and 48 hours after surgery). The duration of analgesia, time to first opioid medication, physical therapy evaluations, time to discharge, and patient satisfaction scores will also be obtained.

16. Participants (Screening and Selection)

a. How many participants are to be enrolled at UAB (if other sites relying on UAB IRB, list the number for each site)? **100**
If multi-site study, total number at all sites/institutions: **N/A**

b. Describe the characteristics of anticipated or planned participants (if multiple groups, repeat list for each group).
Sex: **M,F**
Race/Ethnicity: **any**
Age: **≥18 years**
Health status: **American Society of Anesthesiologist (ASA) Physical Status Score 1, II, or III**

c. From what population(s) will the participants be derived? **All patients scheduled for total hip arthroplasty are scheduled in the preoperative assessment clinic days to weeks prior to their surgery. Study participants will be derived from this population.**

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants: **Before total hip arthroplasty, all patients report to the Highlands Preoperative assessment Clinic (HPAC) for standard of care preoperative assessment and examination and preoperative testing, tailored to patient comorbidities. This is not a service that will be billed additionally for study participants, as it is standard of care for all total hip arthroplasty patients, regardless of participation in the study. During this visit they will be given a "Patient Information Sheet," describing the study. On the day of surgery, patients scheduled for surgery will be seen in the preoperative holding area and enrolled in the study if they choose and are appropriate candidates.**

d. Describe the inclusion/exclusion criteria:
Inclusion Criteria: Patients undergoing total hip arthroplasty under spinal anesthesia. Adults, 18 years of age or older. Patients classified by the American Society of Anesthesiology (ASA) class I, II, or III.

Exclusion Criteria; Any patient not classified as an ASA I, II, or III. Those who are allergic or intolerable to local anesthetics. Patients with pre-existing neurologic or anatomic deficiency and lower extremity on the side of the surgical site, or patients with coexisting coagulopathy. Patients that are pharmacologically anticoagulated will be excluded if placement of peripheral nerve block would be contraindicated according to ASRA (American Society for Regional Anesthesia) guidelines or if spinal anesthesia would be contraindicated according to ASRA guidelines.

e. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group.
Upon enrollment in the study, participants will be randomized 1:1 to either the investigational group ("Quadratus Lumborum Block" group) or the control group ("No Block" group). Participants will be randomized using a random number generator.

f. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.
☐ Pregnant Women: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Fetuses: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Neonates/Nonviable Neonates: SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates

☐ Prisoners: Attach SPRF—Prisoners
☐ Minors (<18 years old): Attach SPRF—Minors
☒ Employees or students at institution where research conducted
☐ Persons who are temporarily decisionally impaired
☐ Persons who are permanently decisionally impaired
☐ Non-English Speakers

For each box checked, describe why the group is included **and** the additional protections provided to protect the rights and welfare of these participants who are vulnerable to coercion: **Employees and students are eligible to participate. The suggested language has been included in the informed consent document to fully disclose that this project is separate from the expectations and their relationship with UAB as an employee or student.**

g. List any persons other than those directly involved in the protocol who will be at risk. If none, enter "None": **None**

h. Describe the recruitment process (e.g., medical record review, referrals, letter of invitation, existing patients) that will be used to seek potential participants (e.g., individuals, records, specimens). Research recruitment by non-treating physicians/staff may require completion of Partial Waiver of Authorization for Recruitment/Screening. **Days to weeks prior to total hip arthroplasty, patients report to the Highlands Preoperative Assessment Clinic (HPAC) for standard of care preoperative evaluation and examination and preoperative testing, tailored to patient comorbidities. This is not a service that will be billed additionally for study participants, as it is standard of care for all total hip arthroplasty patients, regardless of participation in the study. During their HPAC visit, patients that may be eligible for the study will be given a "Patient Information Sheet," describing the study. On the day of surgery, patients will be seen in the preoperative holding area and enrolled in the study if they choose.**

All surgeons who perform total hip arthroplasty have requested for their patients to have QLB, at the discretion of the anesthesiologist.

i. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., IRB Protocol Number for approved databases) from which you will recruit participants. **N/A**

j. Describe the screening process/procedures for potential participants.
Study personnel will confirm eligibility requirements using a standardized eligibility checklist. This will be completed by the PI or another member of the research team prior to consenting and enrolling subjects in the study. This eligibility screening will occur in the preoperative holding area where each patient is in a private room. We have attached the Partial HIPAA Waiver for Recruitment and Screening.

All surgeons who perform total hip arthroplasty have requested for their patients to have QLB, at the discretion of the anesthesiologist.

17. Protocol Procedures, Methods, and Duration - in nontechnical, lay language

Describe the procedures for all aspects of your protocol. Tell us what you are doing.

A. Participants in the study will be randomly assigned to either receive the pain block ("block group") or not ("control group"). The patient will be blinded and thus unaware of the group that they have been assigned. The patients are receiving sedation, including fentanyl and midazolam, an amnestic, prior to ultrasound scanning and +/- block placement. The amnestic properties of sedation will serve as blinding for the procedure. In the postoperative survey, we

ask the patients which group they believe they were in, which will help assess the adequacy of the blinding.

a. **Block group: Subjects that are in the block group will receive the pain block while they are in pre-operative holding. The block will be administered as follows:**
   i. **The patient will be placed on their side. Standard of care noninvasive monitors will be used, and oxygen will be given by nasal cannula. Midazolam and fentanyl will be given to patient comfort. Note: midazolam and fentanyl are provided to all patients who are receiving this surgery and is not part of this research project. The timing of the delivery of this medication may differ than standard of care, but the doses and indications are the same. Skin will be prepped and draped as per standard of care.**
   ii. **Using ultrasound guidance, we will locate the appropriate space for the block. We will first inject numbing medication called lidocaine under the patient's skin (1-2 mL of 1% lidocaine; 10-20 mg). Then, we will inject another numbing medication called bupivacaine (30 mL of 0.25% bupivacaine with 1:400,000 epinephrine; 75 mg bupivacaine and 75 mcg epinephrine) between muscles using a syringe and needle.**
   iii. **After the block is placed, patients will have their surgery performed.**
b. **Control group: Patients randomized to the control group will be treated in the same manner (as described in section "i" above) as those randomized to the block group. The ultrasound probe will be used to identify the quadratus lumborum muscle, similar to patients in the block group. However, no local anesthetic will be injected.**

B. Postoperative data will be collected for both groups by a blinded study team member listed on this protocol.

a. Post-operative data that will be collected is listed in the attached Case Report Form.
b. Information obtained from the patient will be collected using the attached Patient Interview Script.

c. **Patient will be followed up until nerve block resolves.**
d. **The hours from block placement until hospital discharge will be calculated.**

b. What is the probable length of time required for the entire protocol (i.e., recruitment through data analysis to study closure)? **One year.**

c. What is the total amount of time each participant will be involved? **Each participant will be involved in the study for approximately 48 hours. Each procedure time period is listed below.**

d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "None." **None**

e. List the procedures, the length of time the procedure takes, the total # of times the procedure is performed, and indicate whether each is performed solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population.
-Insert additional table rows as needed.
-If procedure is sometimes research and sometimes routine care, include on separate lines with number of times as each.

Procedure	Length of Time Required of Participants	Frequency of Repetition	Research (Res) – OR- Routine Care
Pre-surgical Evaluation on the day of surgery	**30 minutes**	**once**	☐Res ☒Routine
Randomization on day of surgery	**5 minutes**	**Once**	☒Res ☐Routine
Placement of block	**Approximately 30 min.**	**Once**	☒Res ☐Routine
Post Anesthesia Care Unit (PACU) assessment	**10 minutes**	**Once**	☒Res ☐Routine
First postoperative assessment survey (approximately 24 hours after surgery)	**10 minutes**	**Once**	☒Res ☐Routine
Second postoperative assessment survey (approximately 48 hours after surgery)	**10 minutes**	**Once**	☒Res ☐Routine

f. Will an interview script or questionnaire be used? ☒Yes ☐No
If Yes, attach a copy.

g. Will participants incur any costs as a result of their participation? ☐Yes ☒No
If Yes, describe the reason for and amount of each foreseeable cost. _____

h. Will participants be compensated? ☐Yes ☒No
If Yes, complete i-v.
i. Type: (e.g., cash, check, gift card, merchandise): _____
ii. Amount or Value: _____
iii. Method (e.g., mail, at visit): _____
iv. Timing of Payments: (e.g., every visit, each month): _____
v. Maximum Amount of Compensation per Participant: _____

18. Benefits

Describe the potential benefits of the research. **Effective post-operative pain control with regional analgesia can reduce the amount of opioid medications needed perioperatively and therefore, may help participation in physiotherapy, leading to more effective rehabilitation and shorter times to discharge from the hospital. Additionally, greater perioperative pain control can enhance patients' perioperative satisfaction.**

19. Risks - in nontechnical, lay language

a. List the known risks for participants as a result of participation in the research. This should not include the minimal risk of loss of confidentiality. However, it should include any physical, psychological, social, economic, and/or legal risks. If there is a greater than minimal risk of loss of confidentiality describe why this is so. Do not list risks associated with the standard-of-care procedures.
NOTE: Risks included here should be included in the consent form or information sheet, as applicable.

Assessment of Level of Risk: Minimal risk. Participants in this study have the risk associated with peripheral nerve block including pain and discomfort from the procedure, excessive bleeding, infection, nerve damage and failed analgesia. THA is done at this institution currently either with or without QLB. The study would scientifically compare the two existing methods of perioperative pain control (with or without QLB) to each other.

Risks Associated with 0.25 % Bupivacaine with 1:400,000 epinephrine

Reactions to bupivacaine are similar to those associated with other amide-type local anesthetics. This risk of reactions is mitigated when injected into local tissues under ultrasound guidance to assure there is no intravascular injection. Dilute epinephrine is commonly added to bupivacaine to constrict nearby blood vessels, thereby decreasing vascular uptake of the medication and prolonging its duration of effect in local tissues. Bupivacaine with epinephrine may be safely used for infiltration during regional anesthesia in amounts up to 225 mg, with total daily doses not to exceed 400 mg. Common (occurring in ≥5% uses) reported adverse events derived from clinical studies conducted in the U.S. and other countries include low blood pressure (37%), nausea (24.8%), vomiting (11.6%), slow heart rate (9.3%), fever (9.2%), pain (8%) postoperative complications (7.1%), low blood count (6.1%), numbness or weakness in limbs (5.6%), headache (5.1%), pruritus (5.1%), and back pain (5%). A major cause of complications resulting from this group of drugs may be associated with excessive plasma levels, which may be due to over-dosage, unintentional intravascular injection or slow metabolic degradation. In the case of excessive plasma levels, abnormal heart rhythms, cessation of heart beat, loss of consciousness, and/or seizures could occur.

We will be using 0.25% of bupivacaine with 1:400,000 epinephrine (75 mg bupivacaine with 75 mcg epinephrine), which is very common in our practice of regional anesthesia. We have experienced minimal adverse effects with 0.25% bupivacaine with epinephrine used in the amount suggested in our study.

Risks Associated with Lidocaine

Lidocaine is an amino-amide local anesthetic that is commonly used for anesthetization of the skin by injecting 3 mL of 1% lidocaine into the subcutaneous tissue. The toxic dose of lidocaine is 3 mg/kg. In an 80 kg (176 lbs) adult, this is equivalent to 240 mg, or 24 mL of 1% lidocaine. The adverse effects of lidocaine are similar to bupivacaine and include: central nervous system reactions including restlessness, anxiety, blurred vision, tremors, convulsions; cardiovascular system reactions including myocardial depression, decreased cardiac output, heart block, hypotension, bradycardia, arrhythmias, and cardiac arrest; allergic reactions include uticaria, pruritus, angioedema, tachycardia, and diaphoresis. The risk is exacerbated by high volume, high concentration, or intravascular injections. Clinically, 1% lidocaine has an excellent safety profile when administered by appropriately educated and trained personnel.

b. Estimate the frequency, severity, and reversibility of each risk listed.

Quadratus lumborum blocks techniques being evaluated use the most current methods available to reduce the risks of complications. Major complications such as permanent nerve injury are rare. There is limited data on the actual rate of permanent nerve injury due to the rarity of occurrence.

c. Is this a therapeutic study or intervention? ☒Yes ☐No

If Yes, complete i.-iii.

i. Describe the standard of care in the setting where the research will be conducted: **This will be a comparison of efficacy of two different approaches of perioperative pain control for total hip arthroplasty. The current standard of care at our institution does not involve regional analgesia**

for postoperative pain control, however quadratus lumborum blocks have shown in case reports to provide analgesia for hip arthroplasty.

ii. Describe any other alternative treatments or interventions: **None**

iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using: **None**

d. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? ☐Yes ☒No

If Yes, describe the provisions that have been made to make these resources available. _____

e. Do the benefits or knowledge to be gained outweigh the risks to participants?

☒Yes ☐No

If No, provide justification for performing the research: _____

20. Precautions/Minimization of Risks

a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks.

We will use the standard precautions for placement of regional blocks which include sterile technique and ultrasound-guided placement. Patients will be monitored during regional block placement with pulse oximetry, EKG, non-invasive blood pressure and capnograph monitors. Regional block will be performed under routine sterile conditions.

A data and safety monitoring plan will be implemented by Drs. Kukreja and MacBeth to ensure that there are no changes in the risk/benefit ratio during the course of the study and that confidentiality of research data is maintained. This will be achieved by close following of study participants to screen for adverse events and interim results analysis during data collection phase. Investigators and study personnel will meet either electronically or in person, monthly (more often if needed) during active participant enrollment to discuss the study (e.g., study goals and modifications of those goals; subject recruitment and completion; progress in data coding and analysis; documentation, identification of adverse events or research subject complaints; violations of confidentiality) and address any issues or concerns at that time. A DSMB committee will review outcomes and any adverse events as they occur or every six months (if no adverse or reportable events). The DSMB consists of Dr. Dale Parks, Dr. Ayesha Bryant, Dr. Timothy Ness, Dr. Mark Powell.

If the protocol involves drugs or devices skip Items 20.b. and 20.c. and go to Item 21. Instead include this information in the Drug Review Sheet or Device Review Sheet, as applicable.

b. If hazards occur to an individual participant, describe (i) the criteria that will be used to decide whether that participant should be removed from the protocol; (ii) the procedure for removing such participants when necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants.

If the patient meets the inclusion criteria, the block will be administered. Any negative event will be evaluated and treated as per standard of care. Each patient will have immediate follow-up evaluation performed by the PI or co-investigators to look for safety concerns.

c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire protocol and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants.

Quadratus lumborum blocks are described for perioperative analgesia for abdominal procedures and hip arthroplasty. We do not anticipate additional risks for the patients who choose to participate in the study, as compared to other patients who undergo truncal blocks.

A data and safety monitoring plan will be implemented by Drs. Kukreja and MacBeth to ensure that there are no changes in the risk/benefit ratio during the course of the study and that confidentiality of research data is maintained. This will be achieved by close following of study participants to screen for adverse events and interim results analysis during data collection phase. Investigators and study personnel as well as the DSMB (consisting of clinicians and scientists: Dr. Dale Parks, Dr. Ayesha Bryant, Dr. Timothy Ness, Dr. Mark Powell) will meet either electronically or in person, to evaluate any adverse or reportable event every six months during active participant enrollment.

21. Informed Consent

a. Do you plan to obtain informed consent for this protocol? ☒Yes ☐No

If Yes, complete the items below.

If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.

b. Do you plan to document informed consent (obtain signatures) for this protocol? ☒Yes ☐No

If Yes, complete the items below.

If No, complete the items below **and** include the Waiver of Informed Consent Documentation.

c. How will consent be obtained? **The interviewing investigator will confirm eligibility and absence of any exclusionary criteria. Details of the study (including risks) will be explained to prospective participant to their satisfaction and consent forms will then be signed.**

Informed consent will be obtained electronically using REDCap, a HIPAA compliant application. The UAB IRB has approved the use of REDCap for e-consents and HIPAA Authorization in other studies in the Department of Anesthesiology. The electronic Informed Consent (e-consent or eIC) is similar to the traditional paper-based Informed Consent in that it provides the potential subject with sufficient information about the research project to allow for an informed decision about the subject's voluntary participation in the study. The workflow for the consenting process will be the same as for the traditional paper consent/authorization. The Principal Investigator or study staff trained in providing Informed Consent will be present during the entire consenting process. The study staff will verbally present the study as with the paper form and then log into REDCap using unique credentials and a secure password. The subject will be presented with a touch screen enabled tablet (or paper copy if the subject requests). The subject will be allowed to read the e-consent and then ask the study personnel questions about the material as well as address any follow-up questions. Once the subject is fully satisfied that they have an understanding of the information being presented in the Informed Consent, the patient (or legally authorized representative) will use an electronic pen to provide a "wet signature" verifying their consent to participate in the study (signed in the presence of study personnel). The computer will provide time/date stamps as the time of the signature. The prospective subject will also digitally sign the HIPAA Authorization. In the case of the involvement of a legally authorized representative, the representative will digitally sign as well as type the printed name and their relationship to the participant using the attached keyboard. All versions of the IRB approved versions of the Informed Consent will be archived and easily retrievable. There some patients who may not feel comfortable with electronic systems, or have poor eyesight or impaired motor skills, so the patient will always have the option to using paper-based informed consents. In this case, the signed paper consent form will be scanned and entered into REDCap as an attached document. If requested, study personnel will provide assistance in the navigation of the e-consent.

d. Who will conduct the consent interview? **The Principal Investigator or study staff trained in providing Informed Consent will consent the patient and be present during the entire consenting process. All study staff will be fully trained and approved by the IRB.**

e. Who are the persons who will provide consent, permission, and/or assent? **The patient or their Legally Authorized Representative (LAR)**

f. What steps will be taken to minimize the possibility of coercion or undue influence? **Participation is voluntary and the potential participant will have every opportunity to ask any questions and raise any concerns and have those issues addressed to their satisfaction prior to obtaining and documenting consent.**

g. What language will the prospective participant and the legally authorized representative understand? **English**

h. What language will be used to obtain consent? **English**

i. If any potential participants will be, or will have been, in a stressful, painful, or drugged condition before or during the consent process, describe the precautions proposed to overcome the effect of the condition on the consent process. If not, enter "None." **None**

j. If any protocol-specific instruments will be used in the consenting process, such as supplemental handouts, videos, or websites, describe these here and provide a copy of each. If not, enter "None." **None**

k. How long will participants have between the time they are told about the protocol and the time they must decide whether to enroll? If not 24 hours or more, describe the proposed time interval and why the 24-hour minimum is neither feasible nor practical.
The consent process will begin during the potential participant's pre-operative visits to UAB. Participants may not have more than 24 hours after learning of the study before documenting their consent to participate, but they will have additional days following screening and documentation of consent before implementation of any study specific procedures.

22. Procedures to Protect Privacy

Describe how you will protect the privacy interest of the participants. Include how you will make sure others cannot overhear your conversation with potential participants and that individuals will not be publicly identified or embarrassed. **Privacy will be ensured at all times. Conversations with potential participants will be conducted privately, usually in an exam room with a closed door to prevent others from overhearing the conversation. Individuals will not be publicly identified or embarrassed.**

23. Procedures to Maintain Confidentiality

a. Describe how you will store research data to maintain confidentiality (both paper records and electronic data), including how access is limited. If data will be stored electronically anywhere other than a server maintained centrally by UAB, identify the department and all computer systems used to store protocol-related data. **Participant data will be stored on a password-protected server maintained for human subject's research purposes by the UAB Department of Anesthesiology. Access to this particular system is restricted to only approved members of the research team. The list of patients participating in the study, including their medical record numbers and dates of surgery, will be kept separately in a folder with access restricted to staff approved to access patient data. Access to the data will be terminated after final data analysis. Any original paper records may be scanned and stored on the above mentioned departmental server and then shredded after they have been transferred to the password-protected computer system. Signed Informed Consents will be retained for at least 3 years after closure of this study.**

b. Will any data from this protocol be given to any person, including the subject, or any group, including coordinating centers and sponsors? ☒Yes ☐No

If Yes, complete i-iii.

i. Who will receive the data? **Information will be shared with the UAB Anesthesiology faculty and residents, and other entities within the UAB Health System for quality improvement. Information may be presented at scientific meetings, conferences or may be published.**

ii. What data will be shared? **Findings from study. Information regarding participant demographics will only be presented in aggregate form – age, sex, race, educational level, ASA (American Society of Anesthesiologists) status. . Additionally, results obtained from the study may be shared, including VAS scores for pain and need for rescue pain medication.**

iii. How will the data be identified, coded, etc.? **Information will be de-identified and will be presented in aggregate form. None of the 18 HIPAA Identifiers will be disclosed**

24. Genomic Data Sharing (GDS)

Researchers who collect genomic data as part of a NIH grant funded after January 25, 2008 may be required to submit those data to a NIH database for broad scientific sharing. See Genomic Data Sharing in the IRB Guidebook for more information.

a. Does this protocol involve the proposed submission of genetic data into genomic repositories created to share genetic information for research purposes? ☐Yes ☒No

b. Will UAB be uploading the final genomic data to the central repository (e.g., dbGaP)? ☐Yes ☒No

If Yes to both a and b, submit a Detailed Data Sharing Plan to the IRB for review. This plan should include any known data use limitations and indicate whether aggregate-level data are appropriate for general research use. For guidance see the NIH Genomic Data Sharing Policy.

c. Submit a copy of the NIH Institutional Certification Form.

To determine which certification form to include, answer i-ii.

i. Was this protocol funded prior to January 25, 2015? ☐Yes ☒No

- **If yes,** and consent will be obtained, submit the Extramural Institutional Certification - Before January 25 - With Consent.
- **If yes,** and consent will not be obtained, submit the Extramural Institutional Certification - Before January 25 - Without Consent.

ii. Was this protocol funded after January 25, 2015? ☐Yes ☒No

- **If yes,** submit the Extramural Institutional Certification - After January 25.

25. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None." **None**

References:

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2. Blanco, R., Ansari, T., & Girgis, E. (2015). Quadratus lumborum block for postoperative pain after caesarean section. *European Journal of Anaesthesiology, 32*(11), 812-818. doi:10.1097/eja.0000000000000299

3. Blanco, R., Ansari, T., Riad, W., & Shetty, N. (2016). Quadratus Lumborum Block Versus Transversus Abdominis Plane Block for Postoperative Pain After Cesarean Delivery. *Regional Anesthesia and Pain Medicine, 41*(6), 757-762. doi:10.1097/aap.0000000000000495
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6. Chin, K. J., Forero, M., & Adhikary, S. D. (2017). Single-shot Quadratus Block for Postoperative Analgesia After Minimally Invasive Hip Arthroplasty A New Alternative to Continuous Lumbar Plexus Block . *Regional Anesthesia and Pain Medicine, 42*(1), 125-126. Retrieved October 16, 2017.
7. Kadam, V. (2013). Ultrasound-guided quadratus lumborum block as a postoperative analgesic technique for laparotomy. *Journal of Anaesthesiology Clinical Pharmacology, 29*(4), 550. doi:10.4103/0970-9185.119148
8. L. Carline, G. A. McLeod, C. Lamb, and L. Colvin, "A cadaver study comparing spread of dye and nerve involvement after three different quadratus lumborum blocks," *British Journal of Anaesthesia, vol. 117*, no. 3, pp. 387–394, 2016.
9. Carney J, Finnerty O, Rauf J, Bergin D, Laffey JG, McDonnell JG. Studies on the spread of local anaesthetic solution in transversus abdominis plane blocks. *Anaesthesia 2011; 66:* 1023–30.

STATISTICAL CONSIDERATIONS

General Data Analysis Plan: All demographic and clinical variables with continuous measures will be expressed as means and standard deviations; categorical factors will be expressed as proportions. For non-normal data, the medians and inter quartile ranges will be displayed. The distribution of the continuous factors will be examined using the Kolmogorov-Smirnov test. For data that are normally distributed, the one-way ANOVA and Student's t-test will be used to compare groups of data. For data that are not normally distributed, the Kruskal-Wallis and Mann-Whitney tests will be used for comparisons. Chi-square and Fisher's exact tests will be used to analyze categorical data. For all comparisons, a value of $p < 0.05$ will be considered statistically significant.

Primary Outcome Analysis: Statistical analyses will be performed using SAS for Windows, version 9.2. Student's t-test will be used to compare post-operative pain scores for investigational and control subjects. Linear regression will be also be used to test the relationship between pain scores and regional anesthetic technique, while controlling for relevant clinical and demographic variables. Distance of first ambulation will be analyzed using Cox proportional hazards model. Student's t-test will be used to compare patient and surgeon satisfaction.

Statistical Power and Sample Size Estimates : Sample size (50 each group) was determined using a Cohen's d table assuming a mean pain VAS score of 8 (SD = 3) on a scale of 0-10 for control subjects. A difference of VAS score of 3 between two study groups will be clinically relevant. A sample of 100 participants (50 patients per group) will have approximately 95% power to detect a reduction in pain score difference of 3 with significance level alpha of 0.05. We will perform an interim analysis after 50 patients have completed the study (25 patients in each group).