**Pain Control After Total Hip Arthroplasty: A Randomized Trial Determining Efficacy of Fascia Iliaca Compartment Blocks in the Immediate Post-Operative Period**

Contact Person: Kamil Bober, MD

Contact phone #: 7738292348

Contact e-mail: kbober1@hfhs.org

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**Protocol:**

The purpose of this project is to study the effectiveness of nerve blockade to improve pain control after total hip arthroplasty. Specifically, this study seeks to identify if the fascia iliaca compartment blockade provides additional pain relief and decreased morphine consumption when used in conjunction with a multimodal pain control regimen.Patients are consented and recruited according to the inclusion and exclusion criteria of the study at their pre-operative visit 1-2 weeks prior to their scheduled surgical date. All patients recieve a total hip replacement via the posterior approach. After surgery the patients are brought to the block room where a randomization table is used to randomize patients to the placebo or block group. If in the block group a senior trained anesthesiologist then performs a fascia iliaca block, infusing the standard volume of 40 mL of bupivicaine under ultrasound guidance. If in the placebo group the anesthesiologist only places the ultrasound probe to the skin for the length of time it would take to normally perform a block. At the end, a bandaid is placed at the injection site for all paitents. Following the procedure, pain is assessed while inpatient on post operative days one and two, as well as during the first postoperative visit (3-4 weeks after surgery). There is standard daily monitoring and team rouding. Patients are assessed subjectively with visual analog scale and numeric rating scale pain scores. Patients are routinely seen 6 hours after surgery for a post op check, and in the morning of post operative days one and two for morning rounds. At these encounters, pain levels again are recorded, as well as strength of straight leg raise. Patients are also given a chart to record their pain levels every 6 hours after surgery while they are awake. Each patient is given a stop watch during the hospital stay that reminds them to record their own pain level on the chart. Patients work with physical therapy per existing protocol, who record distance walked, pain level with ambulation, and a time-to-up-and-go test. The morphine equivalents consumed per each six hour interval will be obtained from the electronic medical record (already standard protocol) and the times to discharge readiness will be calculated in hours. Data will primarily be obtained from daily progress notes, existing medical record flowsheets, and data collection sheets filled out by the patients.

**Enrollment**

Number of participants: 120

**Privacy**

Where are the names of research subjects kept? In a locked cabinet in the anesthesia department

Where are signed original consent forms kept? In a locked closet in the orthopedic department

What provisions do you have in place to ensure confidentiality of data? Secure information is kept in 2 locations: a secured electronic spreadsheet for data collection and paper records. Paper records are kept in a locked file with key access available only to the senior study personnel. Study information is stored in a password-protected spreadsheet file. Individual patients are de-identified by a unique coded identifier which corresponds to the patient MRN kept in paper format in a separate location. Only key study personnel will have access to the data.

**Conflict of Interest**

Principal Investigator: Do you or any member of your family have a compensated arrangement(s) or have you personally received any compensation (not including honorarium for reviewing federally-funded grants) or investment interest from any organization that funds your research, or has the potential to benefit from the results?

**NO**

**Personnel**

Michael Charters, MD

Trevor North, MD

Craig Silverton, MD

Kamil Bober, MD

M. Chad Mahan, MD

Mohamed-Rida, Alsaden

Christina Fidowski, MD

Nandak Choksi, MD

**Statistical Analysis Plan**

All statistics were performed using STATA software (StataCorp). Student's *t*-tests were used to compare independent continuous variables. Repeated measure of analysis of variance testing was used to compare pain scores at each time interval. Chi-squared tests were used to compare categorical variables. A power analysis was calculated to determine the sample size used in the study. At an alpha value of 0.05 and using 2-sided testing, a sample size of 60 patients per group was needed to detect a difference of 1.3 in pain scores and 9.0 in morphine equivalents consumed with 80% power. Differences of this magnitude would be considered clinically significant. Effect sizes and standard deviations were obtained from a literature review.