PittPRO | Pitt Protocol Review Online

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View: Pitt SF: Study Design

Study Design

1. **Total number of subjects to be enrolled at this site (enter -1 for chart reviews, banking, registries):**
   150

2. **Describe and explain the study design:**
   This is a descriptive, observational study in which there will be a 3 month pre-intervention phase where participants will be placed on a standard post-operative analgesic regimen consisting of an opioid, a NSAID, and acetaminophen. Patients will record their narcotic and non-opioid analgesic usage patterns in the two weeks following outpatient hand surgery.

   During the observational phase, patients will be given a prescription for an additional 3 day supply of scopolamine (total of 6 days of use), and patients will record the same data as prior to the intervention. The patients who incorporate scopolamine into their post operative analgesia regimen will be eligible for inclusion in the study.

3. **Describe the primary and secondary study endpoints:**
   Aim 1: Determine whether the addition of transdermal scopolamine to a standard analgesic regimen reduces opioid utilization following outpatient hand surgery as reported by patients
   Objectives: We will compare opioid usage between patients who complete logs during the pre-intervention stage of the study and the intervention stage of the study to determine the effect of including scopolamine as a medication in standard post-operative analgesic regimens following outpatient hand surgery. As this is the primary objective of our study, an a priori power analysis was conducted. Based on a two-sided two-sample independent t-test with a specified significant level of 0.05, a power of 0.8, and a moderate effect size of 0.5; 64 patients will need to complete each portion of the study to provide an overall sample size of 128 patients.
   Outcome Variables and Analysis: The absolute number of logged opioid use during the two-week study period will be compared between the pre-intervention and intervention groups using a two-sided independent samples t-test.

   Aim 2: Determine patient compliance with usage of multi-modal analgesic medications and the feasibility of supplementing with an additional agent
   Objectives: During the pre-intervention stage of the trial, we will encourage patients to utilize non-opioid analgesics over opioids and have patients keep a log of their NSAID and acetaminophen usage. This aim will partially establish whether patients are being adequately counseled regarding multi-modal pain control as patients with high opioid consumption should also have high rates of use of their non-opioid analgesics. It will also establish whether it is feasible to expect patients to comply with the introduction of novel medications into analgesic regimens. It will establish baseline rates of non-narcotic pain medication use overall and stratified by procedure. It may also further support the existing evidence that non-opioid pain medications reduce opioid requirements while providing more significant pain relief than opioids alone.
   Outcome Variables and Analysis: Data analyzed will include percentage of individual non-opioid pain medications used (prescriptions will be provided so patient could take medication around the clock), patient pain scores, and percentage of opioids used. Percentages of non-opioid pain medications and opioid pain medications will be compared on a patient-by-patient basis by utilizing a paired t-test. The association between patient perceived pain levels and percentage of each medication used will be determined with multiple linear regression.

   Aim 3: Aim 3: Assess patient and operative factors that contribute to prolonged or greater than expected opioid usage.
   Objectives: The factors contributing to prolonged patient use of opioids and need for repeated refills are poorly understood. An analysis of factors contributing to prolonged opioid use and a determination of baseline opioid use rates would allow hand surgeons to have a better understanding of factors that may place a patient at

risk or to identify when patients are exceeding the typical requirements for opioids. Identification of these patients may allow for increased counseling, referral to a pain specialist, or increased surveillance. Details of the operative procedure and typical narcotic requirements will guide providers in prescribing more limited opioid prescriptions appropriate to an individual procedure with few to no refills authorized. Outcome Variables and Analysis: Patients will be separated into groups based on whether they used over 80% of their opioid prescription or if they requested a refill of their opioid prescription within the two week study period. A univariate analysis of patient demographic factors and operative details will identify factors that are potentially associated with higher rates of opioid consumption following surgery. Chi square tests will be performed for categorical variables and student's t-tests will be used for continuous variables. Binary logistic regression will then be performed using variables identified in the univariate screen in order to identify independent factors contributing to a higher number of opioids used after surgery.

4. Provide a description of the following study timelines:

Duration of an individual subject's active participation:
3 weeks
Duration anticipated to enroll all subjects:
9 months
Estimated date for the investigator to complete this study (complete primary analyses):
7/1/2020

5. List the inclusion criteria:
Patients between the ages of 18-55 undergoing outpatient hand and wrist surgery via sedation and a regional block will be eligible for participation. Procedures eligible for inclusion will be limited to those involving the wrist and the hand in order to mitigate the effect of anatomic variability on pain and subsequent utilization.

6. List the exclusion criteria:
Patients undergoing procedures under local, regional anesthesia alone, sedation alone, and general endotracheal anesthesia will be excluded to attempt to isolate procedures of similar complexity and presumed pain level.

Patients will be selected for enrollment in the study based on their need for hand surgery, and their decision to undergo sedation with the regional block.

Additional exclusion criteria are based off of FDA prescribing information for transdermal scopolamine and include patients with a history of acute angle closure or open angle glaucoma; history of drug hypersensitivity to scopolamine, other belladonna alkaloids; or any other ingredient or component in the formulation or delivery system; history of previous gastrointestinal or urinary bladder obstruction; history of seizures or psychosis; patients with hepatic or renal impairment; patients under the age of 18 or over the age of 55; and patients who are currently pregnant or nursing.

Patients currently using prescription opioids for other chronic medical conditions or who are actively using heroin will be excluded from the study.

7. Will children or any gender, racial or ethnic subgroups be explicitly excluded from participation?
○ Yes ● **No**

8. Describe the power analysis used and cite your method of statistical analysis. If a power analysis is not possible, thoroughly justify the sample size required for the study, including appropriate literature citation (alternatively provide page reference in attached protocol):
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