Prospective Study of Opioid Prescribing Practices in Laparoscopic Gynecologic Surgery

NCT Number: Not Yet Assigned

Document Date: 7/25/2024

Study Protocol

Our intent is to validate the use of the Opioid Calculator, published at the University of Michigan (www.opioidcalculator.org), which takes several variables into account, including age, risk factors (history of depression, alcohol abuse, others) to determine in a more scientific way the number of pills sufficient to prescribe. Subjects will be screened for current or previous opioid use via patient interview and review of the medical record. Subjects will be provided, as standard of care, verbal and written information (approved by Regional One Hospital) and instructions regarding postoperative care, which includes monitoring for changes in postoperative pain level and signs of infection. All enrolled participants will be prescribed 5 mg oxycodone tablets for postoperative pain relief following laparoscopic gynecologic surgery. Patients in the standard practice group will receive our historical average of 16 tablets, calculated from the previous 3 months, which was derived from physician discretion without the use of a calculator.

Patients will be approached in clinic at the time they are consenting to laparoscopic hysterectomy and will be counseled about postoperative pain medication management. Randomization to either standard practice or calculator will be performed using computer-generated, permuted blocks of 4 participants. Sealed randomization envelopes will be opened for each subject on the day of surgery, after anesthesia is initiated. The study will be single-blinded to the participant. Patients will be contacted via phone call on day 2 and day 7 postoperatively to inquire where they are on the Visual Analog Scale (VAS) and how many pills they have taken. Two weeks after surgery, patients will be seen in office for VAS and requested to bring unused pills for accounting purposes. Adverse events will be monitored and collected through the Day 30 visit, to include the following categories: Death, Life-threatening, Hospitalization (initial or prolonged), Disability or Permanent Damage, Required Intervention to Prevent Permanent Impairment or Damage (Devices), Other Serious (Important Medical Events). This will be accomplished through assessment of all body systems, with specific focus on: respiratory: decreased respirations, shallow breathing, decreased SPO2; integumentary: swelling, pressure, or crackling sound skin on palpitation of skin, increased abdominal distension; neurological: uncontrolled pain.

Statistical Analysis Plan

We have estimated a necessary sample size of 6 participants per group (12 total) with an anticipated effect size of 2.6 based on estimated means of 5 doses for the experimental arm (SD 1 dose) and 16 doses for the control arm (SD 6 doses), accounting for expected loss to follow up of 10%. Patients will be randomized using 3 block groups of size 4 each.
We will provide a table of demographic and clinical characteristics by assigned group. For continuous variables, we will provide means and standard deviations per group, applying Wilcoxon rank sum for comparison of independent means. For categorical variables, we will provide counts and percentages, applying Fisher's exact test for comparison of proportions.
All statistical analyses will be performed using SAS. Data will be presented as means for continuous variables or medians for data not normally distributed. Categorical data will be presented as frequency. Group means that follow normal distributions will be compared using student's t-tests. Non-normal distributions will be compared using Wilcoxon rank-sum tests. Chi-squared analyses or Fisher's exact tests will be used to compared proportional data.

Multivariable modeling will be done using logistic regression. All outcomes will be evaluated at a 0.05 level of significance.