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Study Protocol

The process of insufflation will be used on all laparoscopic gynecological surgical patients and for the research protocol the amount of carbon dioxide measuring 12 mmHg used for the experimental group B is less than the standard amount of 15 mmHg used for the control group A. Insufflation pressures of either 12 mmHg (group B) or 15 mmHg (group A) will be used for this research, regardless of the subject's BMI, however it is noted that for patients with extreme upper BMIs, visualization can be more challenging. BMI will be one of the data points recorded for patients, however the randomization of the subjects to 12 mmHg (group B) or 15 mmHg (group A) will not be dependent on their BMI. Our maximum BMI for inclusion of subjects will be a BMI of 55.0.
Procedures other than Treatments:
Visit 1 (Day 0)

- Give informed consent at routine doctor visit (this will take an additional 30-45 min) – for research purposes only
- Information such as your age, weight, height, and medical history such as [previous heart attacks, etc.] will be copied from you medical record. Specifically, the following items will be collected: age, race, ethnicity, insurance status (public vs. private), body mass index (BMI), additional medical health conditions, surgical history-prior abdominal surgery, history of chronic pain, history of prior chronic opioid use, pre-operative medications – opioid/analgesic, history of alcohol and tobacco use, history of depression/anxiety; (this will take an additional 30-45 min) – for standard of care and for research purposes;

Visit 2 (Day 1)

- Post-anesthesia randomization to group A or group B, (this will take an additional 5-10 min) – for research purposes only;
- Intra-operative insufflation using 15 mmHg (standard-group A) or 12 mmHg (experimental-group B), adjustment of intra-operative insufflation pressure; (this will take an additional 5 min-10 min) – insufflation for group A is done as standard of care; insufflation for group B is done for research purposes only;
- Post-operative assessment to include the procedure details: indication for procedure, length, estimated blood loss, surgical complications, estimated blood loss, pathology, visual analog scale (VAS), pain medication – prescribed and taken, length of hospital stay, (this will take an additional 30-45 min) – for standard care and for research purposes;

Visit 3 (Day 14 to Day 30)

- In person post-operative follow-up assessment; (this will take an additional 15-30 min)- for standard of care and for research purposes;
- Collection of postoperative pathology reports, post-operative opioid use; (this will take an additional 30-45 min) – for standard of care and for research purposes;

Adverse events will be monitored and collected through the Day 30 visit, to include the following categories: Death, Life-threatening, Hospitalization (initial 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.

For patients randomized to 12 mmHg, if the surgeon deems that the visualization is not adequate to safely operate, then they may elect to increase the pressure to the standard 15 mmHg to improve visualization.

Statistical Analysis Plan

We have estimated a necessary sample size of 50 participants per group (100 total) with an anticipated effect size of 0.54 based on estimated means of 17mm for the experimental arm (SD 20mm) and 29mm for the control arm (SD 24mm), accounting for expected loss to follow up of 10%. Patients were randomized using 10 block groups of size 10 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 a t-test for comparison of independent means. For categorical variables, we will provide counts and percentages, applying chi-square test for comparison of proportions.