Comparison of oxygenation between nasal positive airway pressure (PAP) versus standard care during propofol-based sedation for endoscopic ultrasound in an ambulatory surgical center: a prospective randomized controlled trial.

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1. SAMPLE SIZE DETERMINATION AND DATA ANALYSIS

1.1. Sample Size Determination

Power analyses were performed for the three primary objectives, using a power level of 0.80 and an alpha level of 0.05. Based on the literature the incidence of hypoxemia (ie: oxygen saturation < 90% for > 15 seconds) in using supplemental oxygen with nasal cannula is as high 43%. (Patel et. al.) Thus we expect the complication rate of hypoxemia in the SuperNO_2VA Et™ group to be 13%, we need 62 patients per group (124 patients in total). This sample size will allow us to detect this expected difference with 80% power at 0.05 two sided level of significance. To adjust for 10% missing rate, we need approximately 124 patients in total.

1.2. Randomization

A random number generator program will be used to assign sequential qualified study cases to control group (N = 62) or SuperNO_2VA™EtCO2 group (N = 62) before collection of additional demographic information and before anesthetic and surgical care. After study group assignment, baseline data will be collected, including age, gender, height, weight, and BMI.

1.3. Planned Statistical Analysis

Although randomization into treatment groups should minimize differences between the groups, basic bivariate analyses will be performed to determine if there are any clinical or demographic differences, using the data collected in table 1. Logistic regression models will be performed to determine if there are significant differences between the groups for both incidence and severity. Student's t-tests will be performed to determine if there is a significant difference between groups for duration, with Wilcoxon non-parametric tests being performed if the data are non-linear. If significant differences in clinical or demographics characteristics were found, multivariable models will be performed to adjust for these possible confounding variables using logistic regression and ANCOVA models (with GEE models being used to model non-linear data with the appropriate exponential family distribution). All analytic assumptions will be verified and all analyses performed with SAS v9.4, SAS Institute, Cary, NC), analyzing the data as both per-protocol and intention-to-treat.

A Data Safety and Monitoring Board (DSMB) will be convened once half the necessary study population has been enrolled, to discuss the current status of primary endpoints and adverse events, all of which will be tabulated throughout the study. If effect sizes are larger than originally planned and there is a statistically significant decrease in the primary event at this halfway mark, the study will end at this time.