

Effects of Adrenaline Infiltration on Surgical Field of View in Endoscopic Sinus Surgery

NCT05867342

February 1, 2020

1. STATISTICAL METHODS

A prestudy power analysis was completed with Monte Carlo simulations to estimate the necessary sample size. A sample size of 38 patients in total would give the power of 82% with type I error of 0.05 to detect the difference in Wormald scale between the 2 groups. Patient-level demographics and baseline clinical factors were summarized with mean (standard deviation) for continuous variables and with n (%) for categorical variables. The comparisons of clinical variables (all continuous) between both sides of the nose were performed using paired t test. To estimate the effect of 1% lidocaine with 1:100,000 epinephrine, we constructed a mixed effect models with random slope by accounting for within-subject correlation. All the models were adjusted for age, gender, preoperative Lund-Mackay score, preoperative Lund-Kennedy score, and medication use. Surgery time was found to be right-skewed; therefore, it was log-transformed in the model, and the regression coefficient was exponentiated to represent the percentage difference. We performed reliability testing for the Wormald scale graded by 2 graders, by calculating the intraclass correlation coefficient (ICC) as well as its 95% confidence interval (CI).