Protocol Title: Prophylactic Antibiotics After Functional Endoscopic Sinus Surgery: a Randomized, Double-blind Placebo Controlled Trial

NCT: NCT01919411

Date this document was last updated: 1/28/2020

Statistical Analysis Plan

The primary endpoint was the overall change in SNOT-22 scores from baseline to the final study visit. Secondary outcomes included the change in LK Endoscopic Score from the same time points, as well as rates of post-operative infection. Additional exploratory analyses included the effect of baseline clinical factors, including baseline sinus culture results, history of prior sinus surgery, comorbid asthma, and presence of nasal polyps.

The primary outcome and secondary outcome were analyzed using a repeated-measures analysis of variance (ANOVA) to assess for a group x time interaction on clinical scores. For the secondary analysis of the primary outcome, this model was modified to include baseline clinical covariates in a repeated-measures analysis of covariance (ANCOVA).

The achieved power for non-inferiority was calculated via the same methods as the prospective power analysis. Rather than an *a priori* estimate of standard deviation in scores, the achieved power was based on the actual number of randomized subjects and the actual pooled standard deviation of post-treatment SNOT-22 scores in the two groups. The non-inferiority margin was 9 units on the SNOT-22.