Study Title: Post-ERCP Pancreatitis Prophylaxis, Effectiveness of Rectal Indomethacin vs Intravenous Ketorolac in the Pediatric Population

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Statistical Analysis Plan

Descriptive analysis of the data using means ± standard deviations, medians (25^{th}-75^{th} percentiles), ranges, confidence intervals, proportions and frequencies will be performed. We will examine the distribution of all variables to identify outliers and if continuous variables are normally distributed or skewed. Additional statistical analysis of the data may include t-tests or Mann-Whitney Wilcoxon tests, Chi-square or Fischer's exact tests, ANOVA, and/or regressions to test for differences in those developing PEP between the medication groups as well as identify risk factors for developing PEP. We will control for cofounders of therapy by standardizing time of medications intra-operatively, the type and rate of IV fluids, and advancement of diet through our ERCP order set. Statistical analyses will be performed using SAS®, version 9.4 (SAS Institute, Cary, North Carolina, USA). A p-value <0.05 will be considered statistically significant.

Two-sided tests will be used for group comparisons in order to assess any differences between the medication groups. If one medication has a significantly ($p<0.05$) lower proportion of PEP and significantly decreased odds ratio of developing PEP then that medication would be deemed preferable over the other after assessing and controlling for any confounding factors.

Per internal power calculation for 80% power the study will require 96 patients in each treatment group (96 IV ketorolac and 96 rectal indomethacin) - 192 patients total. For 90% power, would need 128 patients in each treatment group (128 IV ketorolac, 128 rectal indomethacin) - 256 total patients.