

**A DOUBLE-BLIND, RANDOMIZED STUDY TO COMPARE ONOBOTULIUMTOXIN A
VERSUS KENALOG FOR INTRAVAGINAL TRIGGER POINT INJECTIONS IN THE
TREATMENT OF CHRONIC PELVIC PAIN**

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STATISTICAL ANALYSIS PLAN

December 4, 2018

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Statistical Analysis Plan

This study is an exploratory pilot study. Descriptive statistics, provided for all variables, are the main focus of the analysis because of the small sample size. Descriptive statistics are reported with count (percentages) for categorical variables, and with mean (standard deviation) or median (range) for continuous variables, as appropriate.

Exploratory data analysis is focused on comparisons between the two treatment groups. Group differences for baseline variables and clinical characteristics at the time of treatment were performed. For each subject, the difference in their scores from baseline to one month, three months and six months were calculated, respectively.

Kruskal-Wallis tests were used to compare the medians between the groups for the Visual Analog Score (VAS) pain score, pain interference and pain severity. Fisher Exact tests were used for comparisons of distribution by group of pain assessment with the GRA questionnaire. The significance level was set at 0.05 without adjustment for the testing of the primary outcomes. No tests were performed at 3 and 6 months since 23.8% of the sample was missing due to drop out.