Prospective, Multi-Center Evaluation of the Efficacy of Migraine Surgery

Statistical Analysis Plan

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Outcomes

**Outcomes modeled were: MHI, MIDAS A, MIDAS B, MIDAS Total, MSQ Sum and MWPLQ7 Total

Data Analysis

Descriptive statistics, such as frequency and percents, were displayed for sex (male or female), treatment (Botox or Surgery) and site (OSU or MGH). Descriptive statistics, such as mean, standard deviation, median, lower quartile and upper quartile, were reported for age and the patient reported outcomes with the respect to their migraine for each time point (baseline, 1 year, 2 years and 2.5 years).

Each of six outcomes were highly skewed and therefore natural logarithm was applied to each one before it was modeled. A constant of 1 was added to outcome values before applying natural log function so as to include raw values of zeros.

Linear mixed models with a random effect for patient were used to evaluate the changes in each of six outcomes between two different treatments over time with inclusion of interaction between treatment and time. These models were used given to account for correlation between repeated measurements on the same patient and to account for missing data across time points. P-values for both the main and interaction effects of time and treatment were reported for each model and Tukey's post hoc method was used to adjust for pairwise comparisons. For the ease of interpretation, raw means and SDs are presented for each time point within specific treatment.

Analyses were performed using SAS v9.4 (SAS Institute; Cary, NC; www.sas.com). Statistical significance was defined as two-sided alpha<0.05.