Study: AN OPEN-LABEL PILOT STUDY OF PREGABALIN AS TREATMENT FOR ALCOHOL USE DISORDE

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IRB: 7491

NCT#: NCT03256253

Data Analysis Plan created 6-28-2017

Statistical Analyses

Summary statistics of baseline demographics of the sample will be computed using frequencies, means and standard deviations. For skewed distributions, medians and interquartile ranges (IQR) will be computed. Study retention will be summarized using proportions and by computing the mean number of weeks in the trial completed.

For the primary outcome measure, the maximum maintained dose will be reported with mean and standard deviation. For measures of drinking and abstinence for each participant it will be computed during the participant's last week of study participation: proportion of heavy drinking days, proportion of abstinent days, number of drinks per week, and number of drinks per drinking day. The same measures will be computed at baseline using the weekly average over the past 28 days. Wilcoxon signed rank tests will be used to analyze the change from baseline to the last week of study participation. Side effects will be summarized by creating indicators of whether subjects reported: any side effects during the trial, any dose reductions due to side effects, and any discontinuation of medication due to side effects. All analyses will be conducted in SAS® (version 9.4) and all statistical tests were 2-tailed at a significance level of 5%.