

Title of Study: The Effect of Minocycline on Opioid-Induced Hyperalgesia in Opioid-Maintained Patients

NCT#: 02359006

Document: Statistical Analysis Plan

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Statistical Considerations for Minocycline in OIH

a. Statistical analysis.

The primary dependent variables will be pain sensitivity, cognitive performance, subjective drug effects, and physiological measures. Pain sensitivity will be assessed with the Cold Pressor Test (CPT). The cognitive performance will be assessed with the Digit Symbol Substitution Test (DSST) and a Go-No/Go task. Subjective drug effects will be assessed with the Drug Effects Questionnaire (DEQ). The physiological responses will include heart rate, and blood pressure. The independent variable, Treatment, will be categorical with 2 levels: minocycline or placebo. The primary analysis will be done with repeated measures of variance. In these analyses, effects for treatment (minocycline or placebo) and session and the interaction between treatment and time will be included. Adjustments will be made (e.g., Bonferroni correction) for the multiple testing of the data.

b. Sample size and power analysis:

There are no previous studies that examined minocycline's effects on OIH, as told by the CPT, in opioid-maintained patients. For power calculations, we referenced a previous study that examined the effect of gabapentin on the CPT in MM patients (Compton et al., 2010). As such, to allow for an approximate 15% drop out rate, we plan to recruit 60 participants, with 30 in each condition. This will yield over 80% power with a moderate effect size ($d=0.5$) for the between-subjects comparison of minocycline or placebo effects on opioid-induced hyperalgesia.