Title:

A randomized, placebo-controlled trial of minocycline added to serotonin reuptake inhibitors in pediatric OCD: Examining the effects on clinical symptoms and on brain glutamate levels using MRS imaging

NCT Number:

NCT01695291

Document Date:

Updated 01/07/2019

Baseline characteristics were compared between groups using two-sample t-test for continuous variables and chi-squared tests for categorical variables. Pre-specified primary (CYBOCS) outcome and secondary outcomes (CGI-IE Severity, CGI-IE Improvement, HAM-D, ADIS OCD CSR, COIS-C, COIS-P) at baseline and end of treatment (week 12) were summarized by mean, standard deviation, and frequencies. Pre-specified brain measures (glutamate and glutathione at striatum) were collected and summarized by mean and standard deviation.

All analyses were performed under intention-to-treat (ITT) principle. Linear mixed effects models with subject-specific random intercepts and covariates (race and history of CBT) were fitted to primary and secondary clinical measures and brain measures separately to assess treatment effects. Each model contained the main effect of treatment group (Minocycline + SRI versus PBO + SRI) and time (categorical for clinical measures and continuous for brain measures), and their interaction to examine within treatment group change over time and between-group treatment effects. Pre-planned moderation analysis tested interaction effect between baseline brain measures and treatment on clinical outcomes. Sensitivity analyses of comparing post-treatment dichotomized CYBOCS (week 12 CYBOCS change from baseline >25% or >35%) and CGI improvement (with improvement defined as either at least minimally improved) between groups were conducted by fisher exact tests. Exploratory analyses were performed for other brain measures. All analyses were performed using SAS version 9.4 (SAS Institute) and all tests were two-sided with a significance level of 0.05.