Defining Targets for Tic Detection and Suppression in Tourette Syndrome Deep Brain Stimulation

NCT05371041

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Statistical Analysis Plan:

STATISTICAL DESIGN AND POWER: This early feasibility study will examine safety and feasibility of closed-loop deep brain stimulation for the treatment on Tourette syndrome in two targets. The study cohort size is small. The main intention of the study is to ensure that closed-loop stimulation can be delivered to CM or aGPi safely and with acceptable tolerability. Outcome measures will include initial efficacy testing, but this is not a pivotal trial, limiting statistical comparisons. Results will be described using standard summary statistics, including evaluating outcomes at each visit and assessing changes. The analysis will be primarily performed on a per patient basis. Data will be collected on a laptop encrypted for use and data will be backed up by UF and UU encrypted networks. This study will be used to inform future power calculations for a formal evaluation of safety and efficacy, but the primary intention here is feasibility.

IN THIS MANUSCRIPT: Group level changes between baseline and primary endpoint (Month 9) visits were assessed using the Wilcoxon signed-rank test, a non-parametric test. This method was chosen because of paired data and small sample sizes. Median changes were computed for each outcome. Associations between changes in YGTSS and secondary outcomes were evaluated using Spearman's rank correlation coefficient (ρ). This method was chosen because of the sample size and the potential for non-normality of the data. A false discovery rate (FDR) correction was applied to p-values that were employed for correlation.