Statistical analysis plan

Efficacy and safety data will be obtained from the modified intention-to-treat (mITT) dataset, consisting of patients randomized to treatment and receiving at least one rTMS session. Statistical analyses: Groups of responders and non-responders will be created based on changes in Y-BOCS scores from baseline to post-treatment. A response to treatment is defined as a reduction of total Y-BOCS score ≥ 35% after six weeks of treatment, and remission as the Y-BOCS score equal to or less than 8 points.

Basic statistical comparisons of responders and non-responders will be carried out using a two-group Student t-test. Multiple linear regression analyses will be carried out using Y-BOCS scores as a dependent measure and structural or functional brain parameters as predictors, e.g., grey matter (GM) volumes in multiple brain regions or absolute EEG band power in multiple frequency bands. The estimated sample size for multiple regression analysis involving 5 regressors, a statistical confidence level of 95%, and an estimated maximum r2 of 0.19 is 57. To analyze the predictive value of each brain imaging parameter in one modality (e.g., GM volumes in multiple brain regions), the Support Vector Machine (SVM) approach will be used. SVM is a supervised machine learning algorithm for group classification or regression using a set of features representing a multidimensional data space. The main objective of SVM is to find an optimal hyperplane that separates different classes of data points in the feature space. SVM is comparatively immune to the presence of non-linearity in data space and works well with limited training samples.