Safety and Efficacy of ECT for BPSD

NCT02969499

Document Date: February 5, 2021

Study protocol

Participants recruited from study sites between 2012 and 2019. Participants recruited require a diagnosis of dementia according to DSM IV and were referred to ECT for treatment of agitation and/or aggression. They have failed non-pharmacological treatments and failed at least 2 psychotropic medications at adequate dose and duration or stopped due to adverse effects. They have to be cleared by an anesthetist as being medically stable to receive ECT. Patients are excluded from the study if their temporary substitute decision make did not consent to participation in this study or they are medically unstable to receive ECT as determined by an anesthetist.

The Neuropsychiatric Inventory (NPI)–Clinician Version and Pittsburg Agitation Scale (PAS) were used as our measure for agitation and aggression. We used the Cornell Scale for Depression in Dementia (CSDD) to assess if there was any depressive symptoms at baseline and if that changed with ECT treatment. The Cornell-Brown Scale for Quality of Life (CBS) was used to see if there were any changes in the patients' quality of life before and after treatment. We captured any significant side effects due to ECT qualitatively during the course of data collection. Finally, we assessed global cognitive functioning by using the Functional Assessment Staging of Alzheimer's Disease (FAST) scale.

All of the above stated rating scales were done at baseline and after completion of ECT course done to capture their clinical characteristic prior to treatment and after treatment. During the treatment course, we used a few scales to capture the clinical course of participants during the treatment course. We repeated the PAS, CSDD and FAST every 2 weeks during the ECT treatments. All of the scales were conducted by a member of the research team through caregiver interviews. We also gathered basic demographic information, relevant psychiatric and medical diagnoses on all patients.

The MECTA SPECTRUM 5000Q ECT was used to administer the treatment (MECTA Corporation, Tualatin, OR, USA). Seizure threshold was determined using the empirical dose titration method on the first treatment. During the course of treatment, the dosage was adjusted based on seizure quality and clinical efficacy. The initial stimulus placement was either bifrontal or bitemporal with brief pulse (0.5-1.0 ms) at 1.5 to 2.5 times the seizure threshold. Patients may be switched from bifrontal to bitemporal stimulus during the course of treatment based on seizure quality and clinical efficacy.

During the course of ECT, patients received two times per week or less frequent treatments depending on the clinical situation. Anesthetic agents used would either be methohexital, etomidate or propofal (+/- remifentanyl). Succinycholine was used as the neuromuscular blocking agent. Electroencephalographic monitoring was used to capture the duration of seizure.

Statistical Analysis

The statistical program SPSS was used to complete all data analysis. Demographic data is represented by mean calculations. The primary outcome variable measured was changes in the Neuropsychiatric Inventory scores, which was analyzed using paired t-test. Cohen's d for effect size and Levene's test for equality of variances were also performed.

Secondary outcome measures evaluated include paired t-test analysis of changes in the Pittsburgh Agitation Scale. Pearson correlation was performed to analyze the relationship of positive depression screening (Cornell Scale for Depression in Dementia score >12) on NPI scores.