

management should include good coordination of care with Family medicine, Transplant/nephrology team and social services for efficacious and successful management of patient.

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Long-Term Safety of Deutetrabenazine for the Treatment of Tardive Dyskinesia: Results From an Open-Label, Long-Term Study

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ABSTRACT: Introduction: In the 12-week ARM-TD and AIM-TD studies, deutetrabenazine showed clinically significant improvements in Abnormal Involuntary Movement Scale (AIMS) scores at Week 12 compared with placebo, and was generally well tolerated.

OBJECTIVE: To evaluate the long-term safety/tolerability and efficacy of deutetrabenazine in patients with TD. Week 54 open-label results are reported in this interim analysis.

METHODS: Patients with TD who completed ARM-TD or AIM-TD were included in this open-label, single-arm extension study, in which all patients restarted/started deutetrabenazine 12 mg/day, titrating up to a maximum total daily dose of 48 mg/day based on dyskinesia control and tolerability. The study comprised a 6-week titration period and a long-term maintenance phase. Safety measures included incidence of adverse events (AEs), serious

AEs (SAEs), drug-related AEs, and AEs leading to withdrawal, dose reduction, or dose suspension. This analysis reports results up to Week 54.

RESULTS: 304 patients enrolled in the extension study. There were 215 patient-years of exposure in this analysis, and exposure-adjusted incidence rates (EAIRs) of AEs (incidence/patient-years) were comparable to or lower than those observed with short-term deutetrabenazine treatment and placebo. The frequency of SAEs (EAIR 0.14) was similar to rates observed with short-term placebo (EAIR 0.33) and deutetrabenazine (EAIR range 0.06–0.33) treatment. AEs leading to study discontinuation (EAIR 0.08), dose reduction (EAIR 0.17), and dose suspension (EAIR 0.09) were uncommon.

CONCLUSIONS: Long-term treatment with deutetrabenazine was generally safe and well tolerated in patients with TD, and did not result in cumulative toxicity.

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Optimizing TMS Treatment for Depression - The 19 Minute Dash™ Protocol

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ABSTRACT: Title: Optimizing TMS treatment for Depression - The 19 Minute Dash™ protocol

OBJECTIVE: NeuroStar transcranial magnetic stimulation (TMS) is an effective treatment for patients with major depressive disorder. Due to the treatment session duration, a reduced treatment time would promote patients' comfort and convenience. Also, shorter treatment sessions of retained efficacy and safety would increase access to treatment. This reduction could be accomplished by decreasing the time between TMS pulse sequences, the intertrain interval (ITI).

METHODS: Meta-analysis of TMS delivered using varying treatment parameters, particularly the ratio of train

duration (“on-time”) to ITI (“off-time”). PubMed and SCOPUS databases were searched through March 30, 2015 using the terms: “transcranial magnetic stimulation”, “TMS”, “rTMS”, “inter-train interval”, “inter-stimulus interval”, and “cortical spread”. Three hundred and one articles were identified comprising a total of 3359 patients. Clinical outcomes were reported as the proportion of patients achieving response defined as 50% reduction in baseline score on the primary outcome measure in each study. Treatment risk was assessed by the frequency of adverse events reported, and specifically considering the incidence of seizures.

RESULTS: This analysis confirms prior reports that the variables which impact treatment efficacy are the number of treatment sessions, the number of pulses per session and the percent motor threshold. Varying the train duration/ITI (on-time/off-time) ratio over a broad range from 2.0 to 14 did not impact efficacy or safety.

CONCLUSIONS: Shortening the ITI to 11 seconds does not impact the safety and antidepressant effectiveness of the NeuroStar TMS and would result in shortening of each treatment session from approximately 37.5 to 19 minutes.

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The NeuroStar Outcomes Registry

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ABSTRACT: The NeuroStar Outcomes Registry

OBJECTIVE: NeuroStar transcranial magnetic stimulation (TMS) is an effective acute treatment for patients with major depressive disorder (MDD). In order to further understand use of the NeuroStar in a clinical setting, Neuronetics has established a patient treatment and outcomes registry to collect and analyze utilization information on patients receiving treatment with the NeuroStar.

METHODS: Individual NeuroStar providers are invited to participate in the registry and agree to provide their de-identified patient treatment data. The NeuroStar has an integrated electronic data management system (TrakStar) which allows for the data collection to be automated. The data collected for the registry include Demographic Elements (age, gender), Treatment Parameters, and Clinical Ratings. Clinical assessments are: Clinician Global Impression - Severity of Illness (CGI-S) and the Patient Health Questionnaire 9-item (PHQ-9). De-identified patient data is uploaded to Registry server; an independent statistical service then creates final data reports.

RESULTS: Over 500 patients have entered the NeuroStar Outcomes Registry since Sept 2016. Mean patient age: 48.0 (SD ± 16.0); 64% Female. Baseline PHQ-9, mean 18.8 (SD ± 5.0.) Response/Remission Rate, PHQ-9: 61%/33% CGI-S: 78%/59%.

CONCLUSIONS: For the initial 500 patients in the Outcomes Registry, approximately 2/3 patients achieve response and 1/3 patients achieve remission with an acute course of NeuroStar. These treatment outcomes consistent with NeuroStar open-label study data (Carpenter, 2012). The TrakStar data management system makes large scale data collection feasible. The NeuroStar Outcomes Registry is ongoing, and expected to reach 6000 outpatients from more than 47 clinical sites in 36 months.

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Add-on Filgrastim During Clozapine Rechallenge Unsuccessful in Treating Benign Ethnic Neutropenia

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ABSTRACT: Clozapine is an atypical antipsychotic approved by the Food and Drug Administration for treatment-resistant schizophrenia and also indicated for the reduction in risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder. The most serious side effect of clozapine treatment is agranulocytosis, which is defined as an absolute