TMS TRENDS

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NEUROSTAR TMS THERAPY CLINICAL DEVELOPMENT PROGRAM

The FDA approval of NeuroStar TMS Therapy in October 2008 was based on a series of clinical studies. This comprehensive clinical development program, which consisted of 3 separate clinical protocols conducted at 23 sites in the United States, Australia, and Canada, established the treatment procedures and protocols that are currently followed when using the NeuroStar TMS Therapy system[1].

Three hundred twenty-three patients entered the clinical program by qualifying for the randomized clinical trial. Each met DSM-IV diagnostic criteria for unipolar, non-psychotic MDD. In all 3 studies, TMS Therapy treatment parameters were identical, and over 10,000 active treatment sessions were safely performed[1].

Study 101 was a randomized controlled clinical trial designed to examine the efficacy and safety of the NeuroStar TMS device compared to a sham TMS treatment condition. After 6 weeks of treatment in Study 101, participants who achieved at least a 25% improvement in symptoms compared to baseline were eligible to enter the open –label maintenance of effect trial (Study 103), lasting 24 weeks. Participants who did not achieve this criterion for improvement were eligible to enter the open-label acute treatment trial (Study 102), in which participants received an additional 6 weeks of TMS monotherapy. If sufficient clinical benefit was received in Study 102, participants were enrolled in Study 103 (See Figure 1) [1].

A 3-week period of treatment transition, or taper phase, was conducted at the conclusion of the acute phase of Study 101 and Study 102. The purpose of this taper phase was to determine whether the acute response to TMS could be maintained, and to allow for a clinically appropriate introduction of known active antidepressant medication[1].

[1]NeuroStar University Self-Study Program, 2008

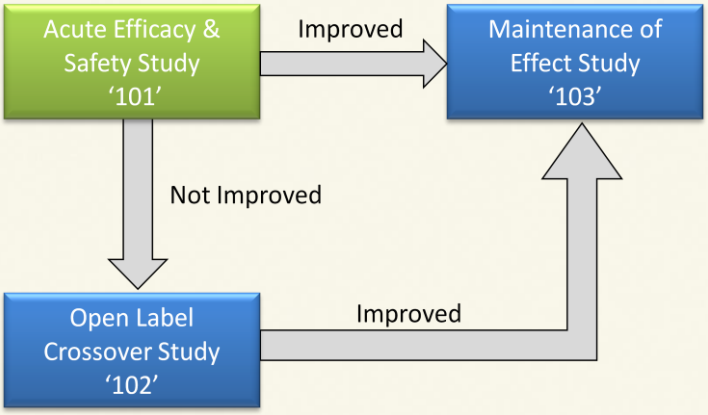

Figure 1. Overview of the comprehensive clinical development program upon which FDA clearance of TMS Therapy was based

SAFETY AND EFFICACY RESULTS

The overall discontinuation rate due to side effects was less than 5% in either active or sham-treated patients, and there were no reports of seizure or deaths. The most commonly reported side effects where mild to moderate headache and discomfort at the treatment site, both of which were transient[2].

Results from Study 101 found that patients treated with active TMS Therapy experienced an average reduction of 22% in their depression symptoms, compared to a 9% average reduction for sham-treated patients. Results from the open-label clinical trial (Study 102) showed that approximately half of the patients experienced significant improvement in depression symptoms, while about one third experienced complete symptom relief at the end of 6 weeks of treatment[2].

[2] Neuronetics.com