

## LB-OR28

### **Transcranial Magnetic Stimulation (TMS) Using a Portable Device is Effective for the Acute Treatment of Migraine with Aura: Results of a DoubleBlind, Sham Controlled, Randomized Study.**

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**Objective:** To test the hypothesis that early treatment of migraine with aura with single pulse TMS is associated with improved headache pain outcomes.

**Background:** Initial studies in migraineurs suggest that treatment with TMS, in the clinic, using a large, table-top TMS device reduces headache pain. To facilitate treatment at home, a novel portable hand held device was developed and tested in comparison with sham stimulation.

**Methods:** This was a randomized, double-blind, parallel-group, sham-controlled study of 201 outpatients, 18-68 years of age, with ICHD-2 defined migraine with aura. Patients had visual aura with at least 30% of migraine episodes followed by moderate or severe headache  $\geq 90\%$  of the time. Patients applied the device twice per migraine episode within one hour of aura onset while still experiencing aura. Patients treated up to 3 attacks over 3 months. Patients recorded pain intensity and associated symptoms using an electronic diary at the time of treatment and at 30 minutes, 1 hour, 2 hours, 24 hours and 48 hours post-treatment. The primary endpoint of the study was no-pain at 2 hours for the first treated attack.

**Results:** The ITT analysis included 164 patients; mean age was 39 and 79% were female. Patients treated while pain free (31%), or with pain that was mild (40%), moderate (23%) or severe (6%). The 2 hour pain free rates were higher with TMS (39%) than with sham (22%,  $p= 0.018$ ) yielding an absolute risk reduction (ARR) of 17.1% (95% CI: 3.2%, 30.9%). TMS rates of associated symptoms (nausea, photophobia and phonophobia) at 2 hours were equal to or lower than sham treatment rates. The number of adverse events (AEs) and number of patients experiencing AEs were similar between TMS and sham groups. There were no device related serious AEs. Patients receiving TMS and sham stimulation were equally likely to believe that they received TMS, indicating that blinding was successful.

**Conclusion:** These data demonstrate that early treatment of migraine with aura with TMS is associated with increased rates of freedom from pain at 2 hours in comparison with sham treatment. Given the established safety of TMS and the lack of adverse events in the trial, TMS may be a promising treatment for migraine with aura. Studies in migraine without aura should also be conducted.