A pilot study of cranial electrotherapy stimulation for generalized anxiety disorder

Bystritsky A, Kerwin L, Feusner J. A pilot study of cranial electrotherapy stimulation for generalized anxiety disorder. *Journal of Clinical Psychiatry*, 69:412-417.

OBJECTIVE

To evaluate the effect of a specified treatment course with Alpha-Stim CES on the anxiety and depression levels in general anxiety disorder (GAD) patients.

Design

An IRB approved 6 week open label study. Baseline measurements were done just prior to the first CES treatment and outcome variables measurements were done at endpoint of study right after the final CES treatment.

Primary Effectiveness Endpoint

The primary outcomes endpoint was the change from baseline to endpoint of the 6 week study on the Hamilton Anxiety Scale (HAM-A) and Clinical Global Impression-Improvement Scale (CGI-I).

Secondary Outcomes Measures

The secondary outcomes endpoint was the change from baseline to endpoint of the 6 week study on the Four-Dimensional Anxiety and Depression Scale – Anxiety subscale (FDADS-A), and Hamilton Depression Scale17 (HAM-D17).

Key Inclusion Criteria

Male or female outpatients age 18-64 years who had a current diagnosis of GAD were recruited. Mini-International Neuropsychiatric Interview (MINI) was conducted at screening to confirm GAD diagnosis.

Protocol Summary

Baseline measures were done, prior to start of treatment period, and outcomes measures were done at end point of study, 6 weeks. No change was made in the medical management of the patients during the study. After instruction on how to use the Alpha-Stim CES device, participants subsequently self-administered CES at home for 60 consecutive minutes each day between the hours of 3:00 PM and 7:00 PM for a total of 6 weeks.

Pre-specified Measures of Success

Response to treatment was defined as a reduction of 50% or more on the HAM-A and a CGI-I score of 1 or 2 (very much improved or much improved, respectively).

Outcome Measures

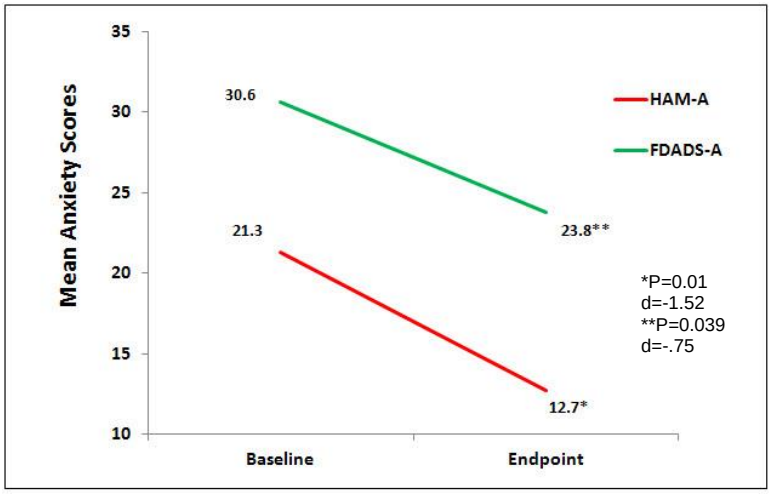
The Hamilton Anxiety Rating Scale was used to measure the severity of anxiety symptoms and the Hamilton Depression Rating Scale17 (HAM-D17) was used to measure the severity of depression symptoms. The Clinical Global Impressions Improvement Scale (CGI-I) was used to measure subjects' response to CES treatment and the Four-Dimensional Anxiety and Depression scale was also used to measure anxiety.

Subjects

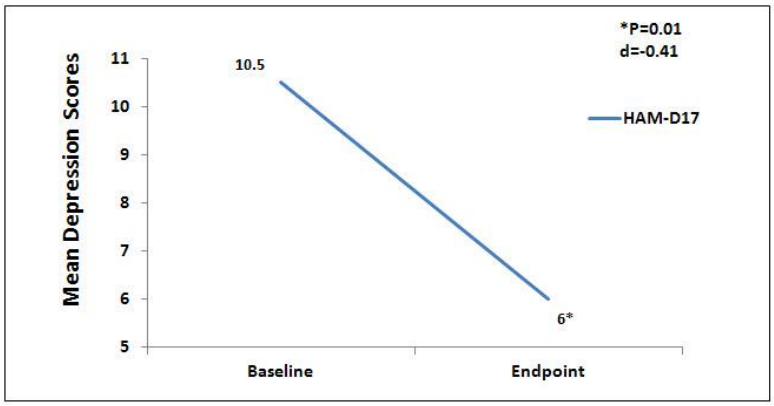
Of the 12 individuals enrolled in the study, 9 females and 3 males, 5 participants had been taking psychotropic medications (venlafaxine, N =2; prazolam, N = 2; lorazepam, N = l) for at least 3 months prior to enrollment and continued throughout the study. Two of these had failed 2 previous adequate trials of SSRIs.

Results for Anxiety and Depression

At the end point of the study, subjects had significantly lower scores from baseline to endpoint of study on both of the anxiety outcome measures, HAM-A ($p = 0.01$, $d = -1.52$) and FDADS-A ($p = 0.039$, $d = -.75$), and on the depression measure, HAM-D17 ($p = 0.01$, $d = -.41$).



Anxiety



Depression

CONCLUSION

The quality of the research of this small open label pilot study is excellent. Pre-specified criteria for success were set for outcome measures at endpoint of study. The Mini-International Neuropsychiatric Interview was conducted at screening to confirm GAD diagnosis using DSM-IV criteria. Patients were eligible for the study if they met a cut-off score of > 16 on the HAM-A and a score < I7 on HAM-D17. All subjects followed the same specific CES treatment protocol related to duration and frequency of treatments, time during the day of treatments and use of an Alpha-Stim CES device with a setting at 300 µA.

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