Efficacy of cranial electrotherapy stimulation for neuropathic pain following spinal cord injury: a multi-site randomized controlled trial with a secondary 6-month open-label phase

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OBJECTIVE

The objective of this study was to assess the effectiveness of Alpha-Stim CES in the treatment of neuropathic pain in persons with spinal cord injuries.

Design

The initial study was an IRB approved 21 day pilot study that used a randomized, sham controlled, double blind design. The treatment and the sham groups participated in 60 minutes treatments of Alpha-Stim CES using either active or sham devices for 21 consecutive days. The sham device was identical to the active CES device, except it did not conduct an electrical current. The active CES device was set to 100 µA, a subsensory level. The subjects, investigators, physicians and staff were all masked as to the identity of the device. This was followed by a 3 and 6 month open-label to assess the long term benefit of Alpha-Stim CES to chronic pain.

Primary Effectiveness Endpoint

The primary effectiveness endpoint was change in pain from baseline after a 60 minute Alpha-Stim CES treatment session.

Key Inclusion Criteria

Adult patients within the Veterans Administration Medical Center with spinal cord injuries (SCI) and chronic neuropathic pain at or below the level of injury.

Protocol Summary

Subjects were randomly assigned to an active or sham CES group by the investigator who randomly selected a device from a box which contained both active and sham units. Each subject received 60 minutes active or sham CES treatments for 21 days. Subjects were asked pain levels before and after each treatment.

As a follow up to the pilot study a long term open-label multi-site study was carried out. The follow up study contained 3 and 6 month arms in which patients received daily treatments. Pain levels were measured at baseline, 3 weeks, 3 months and 6 months.

Outcome Measures

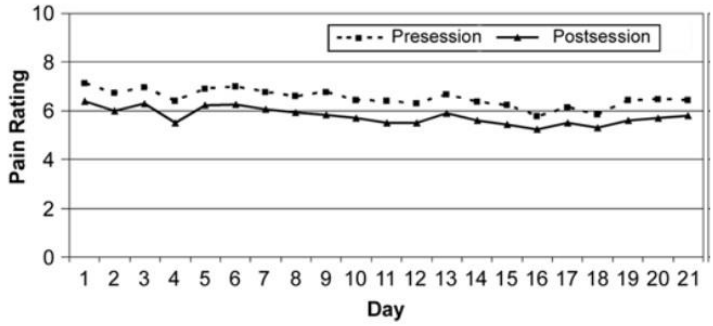
Change in pre- to post-session pain ratings.

Subjects

One hundred (100) subjects completed the pilot study; 45 in the active CES group and 55 in the sham CES group. Sixty-three (63) patients completed the long term follow up with 39 patients completing the 3 month arm and 24 patients completing the 6 month arm.

Pilot Study

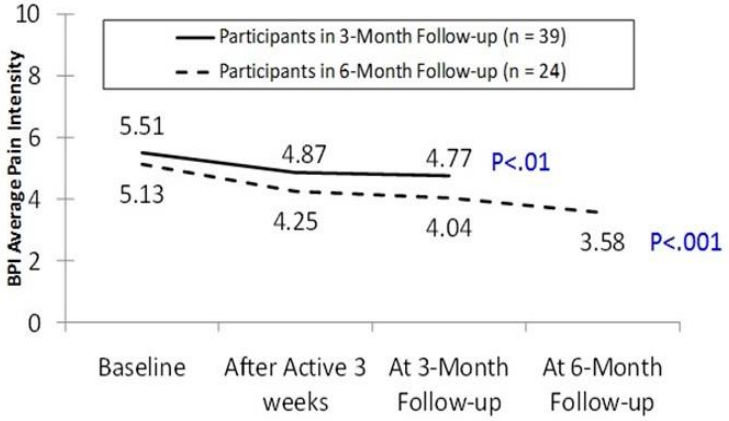
In the 21 day randomized controlled pilot study, subjects received daily 60 minute active or sham CES treatments. Patients who received active CES treatments reported less average pain than patients in the sham group.



3 and 6 Month Follow Up

At the end of month 3 in the long-term open label phase the average pain intensity decreased from baseline ($P<0.01$, $d=0.48$) and there was also a significant downward linear trend ($P<0.01$).

At the end of the 6 month long-term open-label phase the decrease in average pain intensity continued to be maintained. The effect of time across the four data points was significant ($P<0.001$, $d=1.31$) and there was also a significant downward linear trend ($P<0.01$).



CONCLUSION

On average, CES provided a statistically significant improvement in pain intensity and pain interference with few troublesome side effects. Individual results varied from no pain relief to a great deal of relief. At 6 months 54% of the respondents reported at least moderate pain relief and 68% said they would continue to use the Alpha-Stim.

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