Introduction: Cranial Electrical Stimulation (CES) is a non-invasive brain stimulation technology that has been FDA cleared for the treatment of depression, anxiety and insomnia. However, there have not been any clinical trials evaluating its efficacy in treating the depressive phase of bipolar II disorder. This single blind, randomized, sham controlled study examines the safety and efficacy in this particular group of patients. Preliminary results of the study are discussed.

Methods: Eight patients diagnosed with bipolar II disorder currently experiencing depression symptoms by SCID-P were recruited from the Family Center for Bipolar in New York City. Subjects were randomly assigned to two groups in phase I: an active treatment group (n=4) and a sham to active treatment crossover group (control group) (n=4), for the first two weeks of daily 20 minute treatment sessions. Following this, both groups received an open label active treatment for an additional two weeks in phase II. Depression symptoms were rated using the Hamilton Depression Rating Scale (HAM-D), the Beck Depression Inventory (BDI) and the quality of life was assessed using the Quality of Life Satisfaction and Enjoyment Questionnaire (Q-LES-Q). The assessments were completed at the study intake, at the end of the 2nd week (after a period of active or sham treatment) and at the end of the 4th week (after an additional two weeks of open-label active treatment for both groups).

Results: Patients were 62.5% male and 62.5% white, with a mean age of 50.10. The treatment group had a 32% decrease on the HAM-D mean score (baseline M=20.25, 4th week M=13.67), also a 32% decrease on the BDI mean score (baseline M=36.25, 4th week M=24.50) and a minimal change on the Q-LES-Q (baseline M=30.40, 4th week M=31.50). The control group after a period of sham treatment had 18% decrease on the HAM-D mean score (baseline M=19.50, 2nd week M=16.00), a 7% decrease on the BDI mean score (baseline M=34.00, the 2nd week M=31.50) and a 14% increase on the Q-LES-Q (M=42.00). Compared with the scores at the end of the 2nd week, the scores at the end of the 4th week of active treatment were significantly lower than those of the sham treatment group.

Discussion: CES therapy had a positive treatment effect reducing the level of depression in the experimental group from severe to mild. In the control group the depression level decreased mildly on the clinician administered scale and the self-report scale after the period of sham treatment. After an additional two weeks of open-label active treatment the control group also had a substantial reduction in depression symptoms levels and marked increase in the level of life satisfaction.

Methods

Non-inclusion criteria for both groups:

- Pregnancy
- Previous history of seizures or epilepsy
- Skull fracture, deep brain stimulation, subject has a pacemaker or is pregnant
- Active suicidal plan
- History of seizures or epilepsy, active suicidal plan, pregnancy, and others.

Methods

- Inclusion criteria: diagnosis of bipolar II disorder currently in the depressive phase by SCID-P.
- Exclusion criteria: non bipolar II psychiatric diagnosis, significant current autoimmune or endocrine disorder affecting the brain, unstable cardiac disease, current active suicidal plan, history of seizures or epilepsy, skull fractures, deep brain stimulation, subject has a pacemaker or is pregnant.
- Sixty eight people were phone screened, however, the majority failed to meet the inclusion criteria for various reasons (such as, a mixed episode, history of seizures or epilepsy, active suicidal plan, pregnancy, and others.) From the pre-qualified set, eleven were invited for the initial assessment and eight candidates were enrolled in the study.
- Active treatment group received an active treatment during the first two weeks under the blinded conditions following by an open-label active treatment for the next two weeks.
- Sham to active treatment crossover group received sham treatment during the first two weeks under the blinded conditions following by an open-label active treatment for the next two weeks.
- Outcome measures:
  - Hamilton Depression Rating Scale (HAM-D)
  - Beck Depression Inventory (BDI)
  - Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q)

Discussion

- CES therapy had a positive treatment effect reducing the level of depression in the experimental group from severe to mild and was associated with an increase in quality of life during the treatment period.
- In the sham to active treatment crossover group the depression level decreased slightly after the sham treatment period.
- After an additional two weeks of open-label active treatment the sham to active treatment crossover group also had a marked reduction in depression symptoms levels and a significant increase in the level of life enjoyment and satisfaction.

References