UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

Study Protocol

Protocol Title: Cranial electric stimulation (CES) to modify suicide risk factors in psychiatric inpatients

Study No.: HP-00065640, Date 6th February 2016
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Brief Summary

This pilot study aims to investigate whether a treatment called cranial electric stimulation or CES can decrease risk factors for suicide. The specific CES device we will use is called Alpha-Stim®. CES will be used in addition to usual treatment (medication and group therapy).

Detailed Description

Suicide is still a major issue in the United States and all around the world. There are many reasons for people attempting suicide and the major modifiable risk factors are depression, anxiety, insomnia, and agitation. The standard treatment for all suicidal patients includes medication, admission to a hospital and reducing the risk factors. Medications have potential side effects and concerns about the drug interactions. One of the biological treatment alternatives to medication is cranial electric stimulation. This technique uses a device to stimulate the brain through electrical current. Using an Alpha-Stim® device, current is applied to the brain using skin electrodes which can be easily clipped on to the earlobe. The amount of current used is very low and is 1/1000th of the current used for electroconvulsive therapy (ECT) and 1/10th to 1/20th of the 1-2 milli amperes used with transcranial direct current stimulation (tDCS). Our goal is to examine the safety and efficacy of this device when used as an add-on or adjunctive treatment to the usual treatments during the inpatient stay.

Study Type Interventional

Study Phase 4

Study Design

Allocation: Randomized Intervention Model: Parallel Assignment
Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Conditions:

- Suicide
- Depression

- Anxiety
- Insomnia
- Agitation

Intervention Device: Alpha-Stim®. Study Arms • Experimental: Adjunctive CES

CES 100μA for one hour daily, five to seven days per week. Rating scales will be administered at baseline (i.e., pre-treatment), twice a week and at the end of the study.

Intervention: Device: Alpha-Stim®.

Sham Comparator: Sham control CES

For the sham group the Alpha-Stim® will not emit electricity. All other procedures will be the same for both the sham group and the active CES group. The current intensity will be preset and locked by the manufacturer. The sham devices will appear identical to the active device.

Intervention: Device: Alpha-Stim

Primary Outcome Measures:

Change in the modifiable suicide risk factors (MSRF's)

To assess the efficacy of adjunctive cranial electric stimulation (CES), specifically Alpha-Stim®, to reduce suicide risk in psychiatric inpatients through a randomized, double-blind, sham-controlled, clinical trial. The primary efficacy outcome measure will be change in the modifiable suicide risk factors (MSRF's) as indicated by a summed global score from rating scales measuring the MSRFs that include depression (Montgomery-Åsberg Depression Rating Scale), anxiety (Hamilton Anxiety Rating Scale), insomnia (The Pittsburgh Sleep Quality Index) and agitation (Agitated Behavior Scale).

Assess adverse effects and safety

To assess safety of adjunctive cranial electric stimulation (CES), specifically Alpha-Stim®, to reduce suicide risk in psychiatric inpatients through a randomized, double-blind, sham-controlled, clinical trial. The primary safety outcome measure will be responses to an adverse effect assessment questionnaire (GASE questionnaire).

Secondary Outcome Measures:

Assess length of stay