

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: July 30, 2023

ClinicalTrials.gov ID: NCT01876524

Study Identification

Unique Protocol ID: tRNS01072013

Brief Title: tRNS in Anterior Cingulate Cortex Reduces Craving Over Dual Pathology Patients (tRND&SUDs)

Official Title: Transcranial Random Noise Stimulation in Anterior Cingulate Cortex Reduces Craving Over Dual Pathology Patients

Secondary IDs:

Study Status

Record Verification: July 2023

Overall Status: Completed

Study Start: July 2013 []

Primary Completion: August 2014 [Actual]

Study Completion: September 2014 [Actual]

Sponsor/Collaborators

Sponsor: Spanish Foundation for Neurometrics Development

Responsible Party: Sponsor

Collaborators: Fundacion para la Formacion e Investigacion Sanitarias de la Region de Murcia

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: 07/01/2013

Board Name: Comité Etico Investigación Clínica HUVA

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Data Monitoring: Yes
FDA Regulated Intervention: No

Study Description

Brief Summary: The purpose of this study is to study the efficacy and security of noninvasive brain stimulation as a new approach for patients with Substance Use Disorders (SUDs) plus other psychiatric conditions like ADHD, Schizophrenia, Bipolar disorder, etc.

Detailed Description: Background: There is an intimate relationship between addictive behaviors and other mental disorders, proven by clinical practice and many epidemiological studies, genetic and neuroscience. This gives risk to the diagnosis of Dual Pathology: an addiction and another mental disorder.

Functional neuroimaging studies have shown that anterior cingulate cortex is associated with substance's dependence and craving. Transcranial random noise stimulation (tRNS) stimulates parts of the brain and can change its activity.

Researchers are interested in reduce cravings for substance dependence on patients with Dual Pathology using tRNS in anterior cingulate cortex.

Aims: To determine whether tRNS in anterior cingulate cortex can reduce craving over Dual Pathology patients.

Conditions

Conditions: Substance Use Disorder
Attention Deficit Disorder With Hyperactivity
Bipolar Disorder
Schizophrenia
Personality Disorder

Keywords: Substance Use Disorder
Attention Deficit Disorder With Hyperactivity
Schizophrenia
Bipolar disorder
Personality disorder

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: N/A
Interventional Study Model: Parallel Assignment
Number of Arms: 3
Masking: Double (Care Provider, Investigator)
Allocation: Randomized
Enrollment: 225 [Actual]

Arms and Interventions

Arms	Assigned Interventions
<p>Experimental: tRNS over Anterior Cingulate Dual Pathology (Substance Use Disorder plus another psychiatric trait) 75 patients with diagnosed SUDs plus another psychiatric disorder will be receive tRNS in the disease-specific Anterior Cingulate Cortex (ACC), be studied blindly to evaluate the craving reduction after 35 tRNS sessions.</p>	<p>Device: Transcranial Random Noise Stimulation Random Noise Stimulation between 100 and 500 Hz and 400-500 microAmperes are applied over head in particular areas</p> <p>Other Names:</p> <ul style="list-style-type: none"> • tRNS, tES
<p>Experimental: tRNS applied over DLPFC Dual Pathology (Substance Use Disorder plus another psychiatric trait) 75 patients with diagnosed SUDs plus another psychiatric disorder will be receive tRNS in the dorso-lateral-prefrontal-cortex (DLPFC), be studied blindly to evaluate the craving reduction after 35 tRNS sessions.</p>	<p>Device: Transcranial Random Noise Stimulation Random Noise Stimulation between 100 and 500 Hz and 400-500 microAmperes are applied over head in particular areas</p> <p>Other Names:</p> <ul style="list-style-type: none"> • tRNS, tES
<p>Sham Comparator: Sham Group 75 patients will be receive tRNS sham 35 sessions.</p>	<p>Device: Transcranial Random Noise Stimulation Random Noise Stimulation between 100 and 500 Hz and 400-500 microAmperes are applied over head in particular areas</p> <p>Other Names:</p> <ul style="list-style-type: none"> • tRNS, tES

Outcome Measures

Primary Outcome Measure:

1. AMEN Questionnaire

100 Items Questionnaire subdivided in 5 subscales: basal ganglia, cingulate cortex, temporal cortex, prefrontal cortex and limbic system

[Time Frame: Following patients during 3 months after Brain noninvasive estimation]

2. Emotional Visual Event Related Potentials

Emotional Visual Event Related Potentials responses (time courses and topographies) and ICA components related with them, identified by Mitsar 201M EEG Amplifier using EEGLab software [Time Frame: brainwaves patterns following an array of visual stimuli (human faces) during a 22 min. examination]

[Time Frame: Following patients during 3 months after Brain noninvasive estimation]

Secondary Outcome Measure:

3. CAGE Adapted to Include Drugs (CAGE-AID)

The CAGE-AID is a sensitive screen for alcohol and drug problems.

[Time Frame: Following 3 months after tRNS brain stimulation]

Eligibility

Minimum Age: 18 Years

Maximum Age: 60 Years

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- > 18 years old and less than 60 years
- Best-practice diagnosed Dual Pathology
- Diagnosed since at least two years prior to enrollment.
- Abuse more than 2 Substances

ExclusionC riteria:

- Serious visual and hearing loss
- Brain injury following cranial trauma
- Other neurological disorders like Parkinson, ME, headache, etc.
- Birth trauma
- Mental retardation
- Pregnant

Contacts/Locations

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Principal Investigator: Moises Aguilar Domingo, PhD

IPDSharing

Plan to Share IPD:

References

Citations: **[Study Results]** Soria Aledo V, Aguilar Domingo M, Garcia Cuadrado J, Carrasco Prats M, Gonzalez Martinez P. [Spontaneous rupture of the spleen: a rare form of onset of non-Hodgkin's lymphoma]. Rev Clin Esp. 1999 Aug;199(8):552-3. No abstract available. Spanish. PubMed 10522446

Links:

Available IPD/Information: