Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Cumulative and Booster Effects of tDCS Sessions on Drug Craving, lapse and Cognitive Impairments in Methamphetamine Users, A Randomized Double Blind Clinical Trial study

Protocol summary

Study aim

This study is designed to investigate the effect of tDCS (Transcranial Direct Current Stimulation) on reducing the craving, dependency and long-term relapse in methamphetamine-dependent patients.

Design

This is a double blinded clinical trial with a sample size of 60 people, which is randomly divided into two groups of 30 patients in intervention and control groups.

Settings and conduct

Clinical trials are conducted at the Institute of Peyrovanhemat. The intervention takes place for two weeks, 5 sessions weekly, and participants in both groups are followed up for 6 months after the first intervention. In this research, only the operator of the device is aware of the members of the intervention and control groups, and the participants, campus staff and even the researcher are unaware of the identity of the participants in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Using methamphetamine for at least 6 months as the main drug based on DSM-V2, Usage history at least 3 times a week during the last 6 months, Male gender and Age range of 21-50 years. Exclusion criteria: Female gender and History of brain damage, epilepsy, brain surgery and tumor

Intervention groups

The test group will receive 10 sessions (2-weeks, 5-sessions every week) of 2-mA electric brain stimulation for 20 minutes, while the control group will experience sham, in the same condition in the same sessions.

Main outcome variables

The sustain effect of tDCS on methamphetamine craving; the effect of tDCS on changing the cognitive function of methamphetamine users; Does prescribing tDCS for ten consecutive sessions lead to a permanent decline of methamphetamine craving?

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170822035838N2**
Registration date: **2018-03-21, 1397/01/01**
Registration timing: **prospective**

Last update: **2018-03-21, 1397/01/01**
Update count: **0**

Registration date

2018-03-21, 1397/01/01

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-09-05, 1397/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cumulative and Booster Effects of tDCS Sessions on Drug Craving, lapse and Cognitive Impairments in Methamphetamine Users, A Randomized Double Blind Clinical Trial study

Public title

Studying he long-term Effects of Brain Electrical stimulation on the Rate of Craving and Return to Methamphetamine Consumption

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1. Using methamphetamine for at least 6 months as the main drug based on DSM-V2 2. Usage history at least 3 times a week during the last 6 months 3. Male gender 4. Age range of 21-50 years

Exclusion criteria:

1. History of brain damage, epilepsy, brain surgery and tumor

Age

From **21 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population of this study is methamphetamine users. Due to lack of access to all subjects in the population studied, we will sample from consumers who go to Peyrovanehemat Institute for disconnecting the drug. After applying the criteria for entry into the study and basic craving assessment tests, 71 qualified participants are identified. Obviously, at this stage, no choice has taken place, and only 71 first will be selected. The sample size was calculated using the Cochran sampling formula, according to which the maximum sample size for this study was 60. Therefore, 11 of these 71 people should be randomly excluded from the study. In this phase of randomization, the Random allocation rule is used. People are divided into three groups: The first 30 people will enter the intervention group and the second 30 people will go to the control group. The third group containing 11 people are going to be excluded. For this purpose, 71 red and green balls will be placed in a packed dish, and one of the Campus personnel will pick up a ball for each person. The 11 green balls are people who will be excluded. Red balls are numbered from 1 to 60. Couple numbers enter the intervention group and the single numbers will be entered into the control group. In this way, the balls are randomly and without substitution selected for each subject and then the No. and color is registered for the operator. In order to accurately execute the random allocation process and prevent any bias in this study, each stage of the test was conducted by a different person. The researcher tracks 71 entries to the study according to the criteria in the research. Briefly, One of the camp personnel perform the randomization phase (selecting of the balls). Next the operator will execute the test protocol based on the assigned No. to the subjects. Thus, the subjects under study, the camp's personnel and researcher are not aware of the control or intervention groups of subjects, and only the operator knows which subject is in which groups. Inevitably, the researcher is aware of the process of research, but the procedure will be such that the researcher leaves the Camp after the selection of 71 and is not included in the performance of conducting the investigation, Therefore, his data will not ruin the randomization process of the research.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double blind because in this research only the operator of the device is aware of the members of the intervention and control groups and the participants, the camp's employees, and even the self-researcher are unaware of the identity of the participants in each group. Information from volunteers is also entered by another person in a table and analyzed that has no information about the course of the illness

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

No 23, Before Poursina Street, Azar 16th street, Keshavarz Boulevard, Tehran, Iran

City

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Province

Tehran

Postal code

147863181

Approval date

2016-12-31, 1395/10/11

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1346

Health conditions studied

1

Description of health condition studied

Methamphetamine dependency

ICD-10 code

F15.2

ICD-10 code description

Other stimulant dependence

Primary outcomes

1

Description

Basic Met Craving

Timepoint

Before the intervention, 72 hours after the intervention sessions, up to 6 months after the end of the intervention

Method of measurement

Drug Desire Questionnaire (DDQ)

Secondary outcomes

1

Description

Cue-induced craving

Timepoint

Before the intervention, 72 hours after the intervention sessions, up to 6 months after the end of the intervention

Method of measurement

Drug Desire Questionnaire (DDQ)

Intervention groups

1

Description

Intervention group: Direct and constant current is generated by a battery and transferred by a pair of 4.5×5 cm (22.5 cm square) electrodes. Electrodes are standard carbonic, covered with a normal saline socked sponge cases. The intervention group receive tDCS for 10 sessions. The anode electrode is placed on right Dorsolateral prefrontal cortex (rDLPFC) and cathode on the forehead above the left eye (Supraorbital) and 2 mA current is passed through patient's brain for 20 min. At the end of the sessions, whenever participants have methamphetamine craving, they will receive one session of tDCS.

Category

Rehabilitation

2

Description

Control group: This group will not receive brain stimulation (tDCS). But to create placebo effect, we place the anode and cathode electrodes on the same position as we have done for intervention group. Here there is no brain electric stimulation and the electric current generator is only ramping up to 2 mA in 30 seconds, then gradually ramping down to 0 mA over the period of 1 minute, and then turned off but the electrodes will remain on the scalp for 20 minutes. Of course, subjects will not be informed that the device is turned off. At the end of the sessions, whenever a participant have methamphetamine craving, he will receive this placebo again.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Peyrovanehemat Ins

Full name of responsible person

Mr Jajuee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

پژوهشکده علوم شناختی

Full name of responsible person

Dr Peyman Hasani Abharian

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
پژوهشکده علوم شناختی
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

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Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The documentations of this study include reliable questionnaires for assessing the degree of patient craving, useful tests of cognitive assessments, the protocol of working with the device and our proposed methods for following up patients' rehab. All of these, of course will be published after following steps.

When the data will become available and for how long

The study is to be published as soon as the analyzes are completed and the results are published in one of the prestigious academic journals. The primary article will include how to sample patients, the correct method of randomization and the implementation of a two-way blind trial, regardless of the results and initial variables. Naturally, there is no possibility of publishing the initial data at this stage, since we want to extracted more results by various analyzes and publish other titles of articles. The remaining data will be publicly available for up to 6 months after the publication of the second article, because the target group of this study is physicians and psychologists working in the field of addiction, and if we want to win their trust, we should provide sufficient documentation for them.

To whom data/document is available

There are no restrictions for applicants

Under which criteria data/document could be used

Raw data would be relatively large since we will have a six-month follow-up a large number of patients with a variety of questionnaires and cognitive tests. Possibly, re-analyzing this information with other statistical methods would be useful. Since the purpose of this study is to extend the use of this device in rehab of the patients, who are trying to discontinue using Met, there is no limit to the review of the method of work and re-analyzing of information and documentation, and the researcher wants to be aware of such meaningful results.

From where data/document is obtainable

Contacting the researcher or Dr Abharian by e-mail is my suggested method for researchers and enthusiasts, and of course doctors and psychologists who want to learn more about this.

What processes are involved for a request to access data/document

Sending a college email is sufficient for the researcher, if not, sending a resume and phone and address to the workplace is necessary for my research team to be able to review the application.

Comments