

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Online Transcranial DC Stimulation (tDCS) over the Dorsolateral Prefrontal Cortex and Cue Induced Craving in Methamphetamine Dependents: A double-blind, sham-controlled study

Protocol summary

Summary

The aim of this study was investigating the effects of transcranial direct current stimulation (tDCS) over the dorsolateral prefrontal cortex (DLPFC) on cue-induced craving in abstinence methamphetamine-dependent patients. Present study, is a randomized, double-blind, sham-controlled, cross-over study. 32 Subjects were selected from Methamphetamine abusers, which were referred for treatment in the Vardij Therapeutic Community Center which is a specialized center for stimulants. Initially, subjects are examined in terms of inclusion and exclusion criteria. If they were eligible, then they would be taken of demographic information and informed consent. Inclusion criteria; having a history of at least 12 months methamphetamine dependence, being abstinence from any drugs except cigarettes, at least for the last week and having cue reactivity for cue-induced craving. Also exclusion criteria that the patient should not be eligible include: history of epilepsy; brain surgery, tumor, clinically significant head trauma. This study is a crossover design and the active stimulation compared with sham stimulation. At first, the subjects were randomly assigned to an intervention block; Active-Sham stimulations or Sham-Active stimulations. If someone received sham stimulation in the first session, he would receive active stimulation in the next session and vice versa. Washout period between 2 session interventions was at least 72-h, to avoid the any potentially carryover effects due to previous stimulation. In the active stimulation (active tDCS), the anode electrode was placed on the right dorsolateral prefrontal cortex (rDLPFC), and cathode on the left supraorbital area, whereas 2 mA direct current was passed through the subject's skull for 20 minutes. For sham stimulation, the same methods of placing anode and cathode were used, however, the stimulator was ramped-up to 2mA in 30s, then gradually ramped-down to 0 mA over the

period of 1 minute, and then turned off but the electrodes were on the scalp for 20 minutes and subjects were not informed that the device is turned off. Participants and the evaluating investigators (except the technician that applied tDCS) were blinded to the intervention type. Baseline craving assessed before and after brain stimulation, in the both sessions by Desire for Drug Questionnaire (DDQ) which is adapted for methamphetamine. Furthermore, Induced craving was evaluated online with a computerized cue-induced craving assessment Task (CCIC), which run for 10 minutes and included 20 cue-induced craving pictures and 5 neutral pictures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102311234N1**

Registration date: **2012-11-28, 1391/09/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

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Name of organization / entity

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Recruitment status**Recruitment complete****Funding source**

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-10-06, 1391/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Online Transcranial DC Stimulation (tDCS) over the Dorsolateral Prefrontal Cortex and Cue Induced Craving in Methamphetamine Dependents: A double-blind, sham-controlled study

Public title

Effects of Transcranial Direct Current Stimulation (tDCS) over Craving in abstinence methamphetamine user

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria; Having a history of at least 12 months methamphetamine dependence, based on DSM-IV-TR criteria; before entering the treatment program and also being abstinence from any drugs except cigarettes, at least for the last week; We tested subjects' cue-reactivity in the recruitment process based on their subjective reports of craving feeling after exposure to 2 drug-related cues, which were not included in the main craving task; Subjects were excluded if at least their mean craving self-report was below 20 out of 100. Exclusion Criteria: Individuals with any current or past clinical significant neurologic disorder; usage of central nervous system-effective medication; history of epilepsy; brain surgery; tumor; intracranial metal implantation; clinically significant head trauma; or any clinical significant psychiatric disorder (in axis I, except substance-related disorders).

AgeFrom **20 years** old to **45 years** old**Gender**

Male

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **32****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

6th floor, Central Organization of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

City

Iran

Postal code**Approval date**

2012-05-28, 1391/03/08

Ethics committee reference number

130.218.91.3

Health conditions studied**1****Description of health condition studied**

Methamphetamine dependency

ICD-10 code

F15.2

ICD-10 code description

Dependence syndrom, Mental and behavioural disorders due to use of other stimulants, including methamphetamine

Primary outcomes**1****Description**

Methamphetamine Craving

Timepoint

before intervention, online with intervention and After intervention

Method of measurement

Computerized Cue-induced Craving Assessment Task (CCIC), Desires for Drug Questionnaire (DDQ)

Secondary outcomes**1****Description**

Mood Status

Timepoint

It is assessed before and after brain stimulation and induced craving, in both sessions.

Method of measurement

Positive and Negative Affect Scale(PANAS)

Intervention groups

1

Description

Direct current was delivered from a battery-driven, constant current stimulator (ActivaDosell. Iontophoresis Delivery Unit, P/N00148-Rev A, ActivaTek, Inc. Salt Lake City UT 84119 USA) and transferred by a pair of 5×7 (35cm²) electrodes. Electrodes were standard carbonic, covered with a normal saline soaked sponge cases. Subjects were randomized to receive sham or anodal tDCS. In this study, intervention group received real tDCS. In this case, the anode electrode was placed on right Dorsolateral prefrontal cortex (rDLPFC) and cathode electrode was placed on the forehead above the left eye (Supraorbital). 2 mA current for 20 minimums was passed from patient's brain. In our study, washout period between 2 session interventions was at least 72-h, to avoid the potential of any carry-over effects due to previous stimulation.

Category

Treatment - Other

2

Description

In this study, control group received sham transcranial direct current stimulation(tDCS). For sham stimulation, the same methods of placing anode and cathode were used, however, the stimulator was ramped-up to 2 mA in 30s, then gradually ramped-down to 0 mA over the period of 1 minute, and then turned off □ but the electrodes were on the scalp for 20 minutes and subjects were not informed that the device is turned off.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vardij Therapeutic Community Center which is a specialized center for stimulants

Full name of responsible person

Mohammad Reza Nosrati moghadam

Street address

Km 6th Vardij Village Road, Ardestani Street, end of West Hemat Highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research,Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

6th floor, Central Organization of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research,Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iranian institute for Cognitive Science Studies

Full name of responsible person

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Research Center for Molecular and Cellular Imaging
(RCMCI)

Full name of responsible person

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PHD student in Neuro Imaging

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty