Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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).
Age
From **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.د

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 methamphethamine

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 (ActivaDoseII. 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 socked 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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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

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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