Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating long-term therapeutic effects of transcranial direct current stimulation with most efficient montage over the dorsolateral prefrontal cortex targeting craving in methamphetamine abusers; Two Consecutive Randomized Clinical Trials

Protocol summary

Summary

Addiction is a chronic and progressive disease which leads to biological, psychological, and social manifestations and is characterized by inability to consistently abstain, impairment in behavioral control, and craving, and a dysfunctional emotional response. Drug addiction is one of the most important problems in our country. Methamphetamine is an extremely potent psycho-stimulant and highly addictive drug, accompanied by cheap price, ease of synthesis and long lasting effects (Henry, Minassian, & Perry, 2005; Shoptaw et al., 2008; Weber et al., 2012). In the current decade, methamphetamine use is becoming one of the most serious social concerns in Iran. There are currently no drugs approved to treat meth addiction. The main challenge in treating drug addiction is relapse phenomena. It has been estimated that 80 percent of addicts who get off drugs in detoxification phase, go back to drugs within a year. The key component of the relapse is the phenomenon of craving, or the powerful "hunger" for drugs that can linger months or years after abstinence. Thus reducing drug craving can be a major breakthrough in the field of addiction treatment. On the one hand there are currently no effective drugs approved to control meth craving. On the other hand, the recent studies indicate that the new advances in non-invasive brain stimulation techniques, can open new horizons in the addiction treatment. Transcranial direct current stimulation (tDCS) might be considered a neuromodulatory intervention. TDCS polarizes the exposed tissue and modifies spontaneous neuronal excitability and activity by a tonic de- or hyperpolarization of resting membrane potential. The efficacy of tDCS to induce acute modifications of membrane polarity depends on current density. In addition, there are several promising studies that support from effect of this type of stimulation over the dorsolateral prefrontal cortex (DLPFC) in reducing craving of methamphetamine (Shahbabaie et al 2001), cigarette (P. Boggio, Liguori, & Sultani, 2009; Fregni, Liguori, et al., 2008), alcohol (Boggio et al., 2008), marijuana (Boggio et al., 2010) and food (Fregni, Orsati, et al., 2008; Goldman et al., 2011). However, there are two main problems in published studies on tDCS. For one, there is still no consensus on the choice of the electrodes' montage (position of anode and cathode electrodes). To our knowledge (March 2014), There are no studies comparing the effectiveness of various montages on craving. The other problem is that most published studies in this regard are single-session. Although valuable in research phase, these studies come short in clinical application. There is a need to design various multiple session clinical trials, in order to achieve clinically applicable results of this new technology. In the current study, we plan to cover these two pitfalls. This study can be a trigger to move tDCS technology towards clinical application in addiction medicine All that been said, our study will have two phases: In the first phase, 120 methamphetamine dependents will be randomly assigned to six groups with different montages in order to find the most effective electrode montage (with relevant theoretical and/or empirical literature for each). The different montages are as follows: 1) Anode on the right DLPFC, cathode on the left arm 2) Anode on the left DLPFC, cathode on the right arm 3) Anode on the left DLPFC, cathode on the right DLPFC 4) Anode on the right DLPFC, cathode on the left DLPFC 5) The first Anode electrode on the right DLPFC and the second one on the left DLPFC, cathode on the arm 6) Sham stimulation The second phase of the study will start after finding the most efficient montage. At this point, in order to evaluate cumulative effect of tDCS on craving, we will apply the chosen montage in a randomized double blinded clinical trial for 10 sessions (2 weeks). The study will include two

groups (experiment and control) of 30 methamphetamine dependents.

General information

Acronym
tDCS
IRCT registration information
IRCT registration number: **IRCT2014031611234N2**
Registration date: **2015-01-27, 1393/11/07**
Registration timing: **prospective**

Last update:
Update count: **0**
Registration date
2015-01-27, 1393/11/07

Registrant information
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Recruitment status
Recruitment complete
Funding source
Cognitive Sciences and Technology Council (CSTS)

Expected recruitment start date
2015-04-21, 1394/02/01
Expected recruitment end date
2015-12-22, 1394/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating long-term therapeutic effects of transcranial direct current stimulation with most efficient montage over the dorsolateral prefrontal cortex targeting craving in methamphetamine abusers; Two Consecutive Randomized Clinical Trials

Public title
Cumulative effects of transcranial direct current stimulation on meth craving
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria are: (1) the methamphetamine dependents being referred for treatment to Vardij Therapeutic Community Residential Center which is a specialized center for stimulants; (2) a history of at least 12 months of meth dependence (moderate or severe) based on DSM-V criteria before receiving treatment; (3) Being in the age range of 18-50; (4) being abstinence from any drugs except cigarettes, for at least a week prior to the experiment, confirmed by urine analysis inside the residential centre; (5) A history of meth using at least 6 days a week in the month before entering the treatment. (6) Being able to provide informed, written consent. Exclusion criteria include: (1) any current major psychiatric disorders (2) Moderate to severe traumatic brain injury with evidence of neurological deficits, neurological disorders, or severe or unstable medical conditions that might be compromised by participation in the study; (3) having intracranial metal implantation.
Age
From **18 years** old to **50 years** old
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
university of social welfare and rehabilitation sciences
Street address
kodakyar Ave., daneshjo Blvd.,Evin,Tehran
City
Tehran
Postal code
1985713834
Approval date
2014-09-16, 1393/06/25
Ethics committee reference number
USWR.REC.1393.160

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
Immediate meth craving
Timepoint
Pre & Post brain stimulation
Method of measurement
visual-analogue scale(VAS)

2

Description
Basic meth craving
Timepoint
Pre & Post brain stimulation
Method of measurement
Desires for Drug Questionnaire Adapted for Meth (DDQ)

3

Description
cue-induced craving
Timepoint
Pre & Post brain stimulation
Method of measurement
Computerized cue-induced craving assessment task (CICT)

Secondary outcomes

1

Description
Mood state
Timepoint
Pre and Post brain stimulation
Method of measurement
Positive and Negative Affect (PANAS) questionnaire

Intervention groups

1

Description
Direct current is 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. In the first phase, 120 participants will be randomly assigned to a control group (n = 20) or a 5-intervention groups (n = 20 per group).Each of the intervention groups will receive one specific montages of real stimulation (1. Right anode, cathode extra-cephalic 2. Left anode, cathode extra-cephalic 3. Right anode, Left cathode 4 left anode, right cathode; 5. Left and right anode, cathode extra-cephalic), and the control group will receive sham stimulation. The tDCS Protocol for all groups will be 2mA during 20 minutes. The Immediate and cue induced craving will be assessed before and after stimulation by VAS, DDQ and CCICT, respectively.
Category
Other

2

Description
In this study, control group will receive sham transcranial direct current stimulation (tDCS). For sham stimulation, the anode and cathode electrodes will have same position with the one of the intervention groups' montages. However, the stimulator is 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 will be on the scalp for 20 minutes and subjects will not be informed that the device is turned off.
Category
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
Mr. Deylamizadeh
Street address
Km 4th Vardij Village Road, Ardestani Street, Vardavard Metro Station,Tehran-Karaj Highway
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cognitive Sciences and Technology Council
Full name of responsible person
Mr. Rostami
Street address
No 35, Presidency Building, Alvand St, Argentina Sq.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Cognitive Sciences and Technology Council
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
Institute for Cognitive Sciences Studies (ICSS)
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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