# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jun 2026

## A study of the effectiveness of a tDCS session in controlling craving for cigarette smoking

### Protocol summary

**Study aim**
A study of the effectiveness of a tDCS session in controlling craving for cigarette smoking

**Design**
Control group, with parallel groups, single blind, randomized

**Settings and conduct**
This study is a clinical trial conducted in people with craving who are referred to Firoozgar Hospital. Patients are randomly divided into control and tDCS treatment groups. The excitation current is generated by a direct current generating device with a maximum voltage of 4 mA. In the intervention group, the subjects receive 2 mA for 20 minutes. Like the active excitation band, after the electrodes are inserted into the device It turns on and off after a few seconds and the ramp up is completed by the hospital and the patient receives no electrical stimulation.

**Participants/Inclusion and exclusion criteria**
Inclusion: Healthy people between the ages of 18 and 55, active smokers (at least 10 cigarettes daily) at least one yearEpilepsy, history of Cerebral Stroke, Exclusion: Stroke, Cerebral Surgery, Psychiatric Disorders, Antipsychotic Drug Use, Pregnancy, use (Alcohol; Cocaine; Amphetamine),History of cigarette withdrawal receiving treatment for withdrawal, A history of decreased consciousness for more than 15 minutes, metal objects in the body such as a cochlear implant heart rate monitor, a history of seizures.

**Intervention groups**
. All patients are electrodes placed on the left DLPFC region and on the right DLPFC catheter. The excitation current is produced by a direct current generating device with a maximum voltage of 4 mA. In the intervention group, subjects receive 2 mA for 20 minutes. In the control group, as in the active stimulation group, the electrodes are turned on after the electrodes are inserted in the device, and after a few seconds, the ramp up is euthanized by the hospital, and the patient receives no electrical stimulation.

**Main outcome variables**
Reduce craving for cigarettes

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170910036107N5**
Registration date: **2020-05-02, 1399/02/13**
Registration timing: **prospective**

Last update: **2020-05-02, 1399/02/13**
Update count: **0**

**Registration date**
2020-05-02, 1399/02/13

**Registrant information**

**Name**
Naseh Yousefi

**Name of organization / entity**
Iran university of medical science and health services

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 8896 6574

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nasehusefi@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-06-21, 1399/04/01

**Expected recruitment end date**
2020-08-22, 1399/06/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
A study of the effectiveness of a tDCS session in controlling craving for cigarette smoking

**Public title**
Effect of tDCS on smoking craving control
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Healthy people between the ages of 18 and 55 active smokers (at least 10 cigarettes daily) for at least one year
**Exclusion criteria:**
Epilepsy history of Cerebral Stroke Stroke Cerebral Surgery Psychiatric Disorders Antipsychotic Drug Use Pregnancy useing (Alcohol; Cocaine; Amphetamine) History of cigarette withdrawal or received treatment for withdrawal history of decreased consciousness over 15 minutes metal objects such as heart rate monitor, cochlear implant history of seizures
**Age**
From **18 years** old to **55 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **34**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Method of randomization: block Unit of randomization: individual Tools used in randomization such as table of random numbers.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In order to blind the patient , it is said that tDCS is effective in controlling cravings for smoking, but the control and intervention group is not mentioned.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Iran University of Medical Sciences
**Street address**
valiasr Square, Alley to Afrin, Firoozgar Hospital
**City**
Tehran
**Province**
Tehran
**Postal code**
1593747811
**Approval date**
2019-07-23, 1398/05/01
**Ethics committee reference number**
IR.IUMS.FMD.REC.1398.153

## Health conditions studied

**1**

**Description of health condition studied**
Effectiveness of a tDCS session in controlling smoking craving
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
FTND questionnaire on smoking craving
**Timepoint**
The temptation to smoke before and immediately after the intervention
**Method of measurement**
FTND questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: the intervention group, subjects receive 2 mA for 20 minutes
**Category**
Rehabilitation

**2**

**Description**
Control group: The Control group Like the active stimulation group, the electrodes are turned on after the electrodes are inserted and after 30 seconds they are switched off and receive no stimulation

**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Firoozgar Hospital
**Full name of responsible person**
Marjan Fallah
**Street address**
Valiasr Square - Afrin Alley - Firoozgar hospital
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**Email**
marjan.fallah9594@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Dr Abbas Motevaliyan
**Street address**
Department of Physical Medicine and Rehabilitation, Firoozgar Hostpital,Valiasr Square
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Tehran
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**Postal code**
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**Email**
marjan.fallah9594@gmail.com
**Grant name**
Research center of Physical Medicine and Rehabilitation
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Iran University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Marjan Fallah
**Position**
Student
**Latest degree**
A Level or less
**Other areas of specialty/work**
General Practitioner
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Iran University of Medical Sciences
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Naseh Usefi
**Position**
Associate Professor of Physical Medicine and Rehabilitation
**Latest degree**
Specialist
**Other areas of specialty/work**
Physical Medicine
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## Person responsible for updating data

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**Full name of responsible person**
Marjan Fallah

**Position**
Student

**Latest degree**
A Level or less

**Other areas of specialty/work**
General Practitioner

**Street address**
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**Province**
Tehran

**Postal code**
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**Phone**
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**Email**
marjan.fallah9594@gmail.com

## 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**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Yes - There is 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**
All the patient's data can be shared with privacy in regard to patients name

**When the data will become available and for how long**
Start accessing 6 months after publishing the results.

**To whom data/document is available**
For scholars working in academic centers.

**Under which criteria data/document could be used**
It can be analyzed and printed by other people by mentioning the source.

**From where data/document is obtainable**
Marjan fallah,98113229421,marjan.fallah9594@gmail.com

**What processes are involved for a request to access data/document**
Upon authentication,data is provided to the individual.

**Comments**
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