

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of anodal transcranial Direct Current Stimulation on working memory performance in individuals with Mild Cognitive Impairment

Protocol summary

Summary

Transcranial Direct Current Stimulation (tDCS) is a non-invasive brain stimulation tool which may play a potential role in treating some cortical abnormalities. It has been shown that anodal tDCS-based stimulating Dorsolateral Prefrontal Cortex (DLPFC) area of the brain can improve Working Memory. In this Crossover, triple blinded controlled randomized trial we aimed to examine if tDCS can improve working memory in people with Mild Cognitive Impairment (MCI). Twenty right handed, non-pregnant people with MCI were recruited. They have not to suffer from any neurological, physical, or other life threatening disease. For each participant two brain stimulation sessions assumed, receiving current in one session and being in sham group in the other session. The wash out period of 7 days assumed between two sessions. Session's order has been concealed and participants allocated to the orders according to stratified block randomization. Considering "10-20 international system for EEG electrode placement" the anode and cathode will be placed on F3 (left DLPFC) and contralateral (right) supraorbital region, respectively. Subjects receive 1 milliAmpere (mA) current for 20 minutes in their active tDCS session; but the current reach the maximum dose (1mA) gradually, then cut off for the rest 20 minutes in sham arm. This help participants feel the initial tingling in their sham arm, so remain blind. During mentioned 20 minutes subjects have to do Cambridge Neuropsychological Test Automated Battery (CANTAB) spatial working memory test, and as a final step we compare acquired score means in two series of sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071310267N1**

Registration date: **2012-09-16, 1391/06/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

Name

Faeze Gohari

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 4464 8321

Email address

m-mehrpour@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of anodal transcranial Direct

Current Stimulation on working memory performance in individuals with Mild Cognitive Impairment

Public title

Evaluating Direct Current Stimulation effect on memory performance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Twenty volunteers with diagnosed MCI according to Peterson's criteria will be recruited. None of them must have any neurological, physical, or other life threatening disease. All the subjects are right-handed and non-pregnant. Exclusion criteria: Lost to follow up

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features

Randomization: Subjects assigned to different strata according to their education level. In each stratum, we use blocks with different size in order to prevent selection bias and the allocation ratio is 1:1. (Stratified block randomization) Blinding: The person who implements the randomization and enrolls participants is blinded during allocation. All participants are also blinded about their final group. All data will be analyzed by a blind analyzer, who does not know which participant allocated to which group. Trial design: Because in cross over trials, the therapeutic effects of two different modes of intervention (active tDCS versus sham tDCS) will be compared in each person with same characteristics, which is better than this comparison in two different persons with different characteristics, in this Randomized Controlled Clinical Trial, cross over design is chosen. Therefore, effects of confounding variables will be minimized and fewer biases will threaten study results.

Secondary Ids

empty

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

Tehran University of Medical Science Ethic Committee

Street address

Medical Ethic Resaerch Center, Tehran University of Medical Science, 16th Azar Street, Keshavarz Blvd., Tehran

City

Tehran

Postal code**Approval date**

2012-07-02, 1391/04/12

Ethics committee reference number

91-01-54-17146-57613

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

Mild cognitive disorder

ICD-10 code

F06.7

ICD-10 code description

Mild cognitive disorder

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

Spatial Working Memory Score

Timepoint

at the beginning before the intervention, immediately after the first intervention session, immediately after the second intervention session

Method of measurement

CANTAB, executive function package, spatial working memory test

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

Mental State

Timepoint

at the beginning before the intervention

Method of measurement

Mini Mental State Examination (MMSE)

2**Description**

Dementia rating

Timepoint

at the beginning before the intervention

Method of measurement

Clinical Dementia Rating (CDR) score

Intervention groups

1

Description

Intervention Group: Transcranial Direct Current Stimulation is a non-invasive and non-convulsive technique with high safety rate and low side-effect incidence. It can modulate cortical excitability in target region of the brain, so that anodal and cathodal tDCS would increase and decrease cortical excitability, respectively. According to "10-20 international system for EEG electrode placement" the anode will be placed on F3 (left DLPFC), while the cathode would be located on contralateral (right) supraorbital region. Electrodes (35cm²) will be inserted in saline soaked sponges. These sponges will be washed from participant to participant, to avoid further saline concentrating. Each person in case group receives 1 mA current for 20 minutes.

Category

Treatment - Devices

2

Description

Control Group: Electrodes will be fixed on subject's head for 20 minutes. In sham group, the current reaches the maximum dose (1mA) gradually, then cut off. This helps participants feel the initial tingling and so remain blind during previously mentioned 20 minutes.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar General Hospital

Full name of responsible person

Dr. Masoud Mehrpour

Street address

Firoozgar General Hospital, Beh Afarin Street, Karimkhan zand Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Science

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Science, Central department, the crossing of Qods Street and Keshavarz Blvd., Tehran

City

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 Science

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

Firoozgar Hospital, Tehran University of Medical Science

Full name of responsible person

Dr. Masoud Mehrpour

Position

Assistant professor, Department of Neurology, Head of stroke unit, Firoozgar Hospital

Other areas of specialty/work

Street address

Firoozgar Hospital, Beh Afarin Street, Karimkhan zand Street, Tehran

City

Tehran

Postal code

Phone

+98 21 8214 1600

Fax

Email

m-mehrpour@tums.ac.ir; fgowhari@gmail.com

Web page address

<http://medicine.tums.ac.ir/fa/ShowHospital.aspx?It=1&li=1332>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Firoozgar Clinical Research Development Center, Tehran University of Medical Science

Full name of responsible person

Dr. Masoud Mehrpour

Position

Assistant professor, Department of Neurology, Head of stroke unit, Firoozgar Hospital

Other areas of specialty/work

Street address

Firoozgar Hospital, Beh Afarin Street, Karimkhan zand Street, Tehran

City

Tehran

Postal code**Phone**

+98 21 8214 1600

Fax**Email**

m-mehrpour@tums.ac.ir; fgowhari@gmail.com

Web page address

<http://medicine.tums.ac.ir/fa/ShowHospital.aspx?lt=1&li=1332>

City

Tehran

Postal code**Phone**

+98 21 8214 1600

Fax**Email**

fgowhari@gmail.com; f.gowhari@yahoo.com; m-mehrpour@tums.ac.ir

Web page address

<http://medicine.tums.ac.ir/fa/ShowHospital.aspx?lt=1&li=1332>

Person responsible for updating data**Contact****Name of organization / entity**

Firoozgar Hospital, Tehran University of Medical Science

Full name of responsible person

Faeze Gohari

Position

Medical Student, Stager

Other areas of specialty/work**Street address**

Firoozgar Hospital, Beh Afarin Street, Karimkhan zand Street, Tehran

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