Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 locate 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 reach the maximum dose (1mA) gradually, then cut off. This help 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 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

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

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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