Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The Efficacy of High Definition anodal transcranial direct current stimulation in treatment of patients with Mild Cognitive Impairment (MCI), A Randomized, double-blind, parallel-controlled clinical trial

Protocol summary

Study aim
Evaluation of the efficiency of high quality anodal transcranial direct current stimulation in the treatment of patients with mild cognitive impairment

Design
This randomized clinical trial design is a parallel design with a control group. This study is a randomized, phase 2-3 will be performed on 90 patients with mild cognitive impairment. Random blocks are used for randomization and participants are assigned to three groups.

Settings and conduct
This study, which will be performed at the Kerman Neuroscience clinic, is a double-blinded one. To send direct current to the scalp, ring-shaped electrodes of Ag / AgCl will be used. The anodic electrodes will be placed on the scalp on a pre-defined area in each patient by a special plastic clamp filled with a conductive gel on the scalp.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of mild cognitive impairment; The duration of symptoms of mild cognitive impairment is at least one year. Exclusion criteria: Epilepsy; Taking any medication that affects the central nervous system; Focal neurological defects in neurological examination Scalp diseases; Previous intracranial surgery

Intervention groups
In the first intervention group, anodic TDCS stimulation is performed on the left prefrontal dorsolateral cortex with a current of 2 mA for 20 minutes 5 days a week, for two weeks. In the second intervention group, anodic TDCS stimulation will be performed on the anterior temporal cortex with a current of 2 mA for 20 minutes, 5 days a week, for two weeks. The third group will receive Sham stimulation for only 60 seconds (5 days a week, for two weeks) but the electrodes will remain in their place for 20 minutes.

Main outcome variables
Quality of Life, Cognitive status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N163**
Registration date: **2021-03-21, 1400/01/01**
Registration timing: **prospective**

Last update: **2021-03-21, 1400/01/01**
Update count: **0**

Registration date
2021-03-21, 1400/01/01

Registrant information

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Name of organization / entity
kermanshah University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-09, 1400/01/20

Expected recruitment end date
2021-10-12, 1400/07/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of High Definition anodal transcranial direct current stimulation in treatment of patients with Mild Cognitive Impairment (MCI), A Randomized, double-blind, parallel-controlled clinical trial

Public title

The Efficacy of transcranial direct current stimulation in treatment of patients with Mild Cognitive Impairment (MCI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of mild cognitive impairment Education level 4 or more The duration of symptoms of mild cognitive impairment is at least one year

Exclusion criteria:

Epilepsy; Taking any medication that affects the central nervous system Focal neurological defects in neurological examination Scalp diseases Previous intracranial surgery, metal inside the head (outside the mouth) such as shrapnel, surgical clips History of recurrent or severe headaches

Age

From **55 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random blocks. First, the size of each block is determined by 3, then all the triple permutations (for three interventions, for example, A, B, C) are determined. In this step we will have 6 possible permutations (ABC / ACB / BAC / BCA / CBA / CAB) for each block. Finally, 30 blocks with random permutations and in each block, 3 samples with one of the 6 possible permutations will be assigned to three intervention, that in total 90 samples with the same volume will be assigned to three groups. It should be noted that random numbers will be used to assign each permutation in each block.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, patients and researchers are unaware of the coding of intervention groups and TDCS stimulation will be performed by a clinical caregiver.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

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Province

Kermanshah

Postal code

6715847141

Approval date

2021-02-11, 1399/11/23

Ethics committee reference number

Ir.kums.rec.1399.42

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

Quality of Life

Timepoint

Before the intervention and three months after the end of the intervention

Method of measurement

Using a quality of life questionnaire

2

Description

Cognitive status

Timepoint

Before stimulation, after the second week, one and three months after the end of the study

Method of measurement
Using the Montreal Cognitive Test (MoCA)

Secondary outcomes

empty

Intervention groups

1

Description
In the first intervention group, anodic TDCS stimulation is performed on the left prefrontal dorsolateral cortex with a current of 2 mA for 20 minutes 5 days a week, for two weeks.
Category
Other

2

Description
In the second intervention group, anodic TDCS stimulation will be performed on the anterior temporal cortex with a current of 2 mA for 20 minutes, 5 days a week, for two weeks.
Category
Other

3

Description
The third group will receive Sham stimulation for only 60 seconds (5 days a week, for two weeks) but the electrodes will remain in their place for 20 minutes.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kerman University of Medical Sciences, Neuroscience Research Center
Full name of responsible person
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Sponsors / Funding sources

1

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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
Kermanshah 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable