

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

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

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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
Kermanshah
Province
Kermanshah
Postal code
6715847141

Approval date
2021-02-11, 1399/11/23

Ethics committee reference number
lr.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

Dr. Soheila Rezakhani

Street address

Kerman Neuroscience Research Center, Tahmasbabad intersection in front of Besat Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Soheila Rezakhani

Position

Faculty member of Kerman University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Person responsible for updating data

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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