

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study the effects of stimulation of transcranial direct current in nocturnal sleep on the Glymphatic system in the mild cognitive impairment patients: A randomized controlled parallel clinical trial

Protocol summary

Study aim

Study the effects of stimulation of transcranial direct current in nocturnal sleep on the Glymphatic system in the mild cognitive impairment patients: A randomized controlled parallel clinical trial

Design

This randomized clinical trial design is a parallel design with a control group. In this single-blinded study, patients are unaware that they are assigned to the first, second, or control group. This randomized study with phase 2-3, will be performed on 24 patients with mild cognitive impairment. Random blocks are used for randomization and participants are assigned to three groups (two intervention groups and one control group).

Settings and conduct

This study, which will be conducted at Farabi Hospital of Kermanshah, is single-blinded. One week before the start of the test, patients are asked to go to bed at 23:00 at night and wake up at 7:00 to 8:00 in the morning. On the night of the experiment, participants in all three groups are asked to be present at the sleep clinic of Farabi Hospital at 21:00.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 55 years; Diagnosis of mild cognitive impairment based on Petersen 2004 clinical criteria; The score of mental state short test between 24 and 30 Exclusion criteria: History of central nerve diseases (such as stroke, tumor, and brain trauma, epilepsy and etc.); The presence of metal parts in the brain, skull, and anywhere else in the body; Alcohol and drug addiction

Intervention groups

The first intervention group will receive an active transcranial direct current stimulation (TDCS) overnight. The second intervention group will receive active TDCS stimulation for two consecutive nights. The control group is stimulated with sham (in which the electrodes of the

TDCS device are connected according to the protocol but the device is off).

Main outcome variables

The rate of activity of the glymphatic system system

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N162**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effects of stimulation of transcranial direct current in nocturnal sleep on the Glymphatic system in the mild cognitive impairment patients: A randomized controlled parallel clinical trial

Public title

The effects of stimulation of transcranial direct current in nocturnal sleep on in the mild cognitive impairment patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 55 years Diagnosis of mild cognitive impairment based on Petersen 2004 clinical criteria The score of mental state short test between 24 and 30, and CDR equal to 0.5

Exclusion criteria:

History of central nerve diseases (such as stroke, tumor and brain trauma, epilepsy, psychiatric illness, etc.) The presence of metal parts in the brain, skull and anywhere else in the body Alcohol and drug addiction Use of drugs affecting the central nervous system and sleep disorders

AgeFrom **55 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant

Sample sizeTarget sample size: **24****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, 8 blocks with random permutations and in each block, 3 samples with one of the 6 possible permutations will be assigned to three groups, which in total 24 samples with the same volume will be assigned to three groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blinded study, patients are unaware that they will be assigned to the first, second, or control group.

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

2021-01-12, 1399/10/23

Ethics committee reference number

lr.kums.rec.1399.1036

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**

The rate of activity of the glymphatic system

Timepoint

Before and after interventions (30 minutes after the start of the intervention)

Method of measurement

Using Tensor Diffusion Imaging (DTI)

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive an active transcranial direct current stimulation (TDCS) overnight. Stimulation begins anodally at a frequency of 0.75 Hz, 4 minutes after individuals enter the second phase of nonREM sleep for the first time. A total of 5 5-minute stimuli applied at 1-minute intervals are applied.

Category

Treatment - Other

2

Description

The second intervention group will receive active transcranial direct current stimulation (TDCS) for two consecutive nights. Stimulation begins anodally at a frequency of 0.75 Hz, 4 minutes after individuals enter the second phase of nonREM sleep for the first time. A total of 5 5-minute stimuli applied at 1-minute intervals are applied.

Category

Treatment - Other

3

Description

The control group is stimulated with sham (in which the electrodes of the TDCS device are connected according to the protocol but the device is off).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Fatemeh Haj Zeinolabedini

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Farabi Hospital, Dolatabad Blvd, Isar Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

Fatemeh Haj Zeinolabedini

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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Latest degree

A Level or less

Other areas of specialty/work

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable