

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation (a-tDCS) on balance, static and dynamic postural stability in older adults with a high risk for falling

Protocol summary

Summary

The purpose of the present study was to investigate the immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation (a-tDCS) on balance and postural stability in older adults with high risk for falling. This study has clinical trial design. Participants will be randomly allocated in two groups included; Group I who received 20 minutes a-tDCS over the cerebellum region and Group II who served as placebo group (mounted TDCS electrodes over the cerebellum region without any TDCS currents for 2 minutes). The participants with 60-75 years and high risk for falling will be included. Participants who have history of neurological diseases or musculoskeletal disorders, severe perceptual and memorial problems, brain diseases, visual and auditory problems, lower extremity pathology and range of motion limitation will be excluded. All participants will be asked to stand on each static and dynamic level of Byodex Balance System (BBS) platform for 30-second, before and after receiving a-tDSC treatment. Accordingly, the anterior/posterior, medial/lateral and overall stability indices will be analyzed before and after a-tDCS treatment. In addition, before, after intervention and for one-week following, the falling sensation, stability indices and balance will be assessed by fall risk assessment tool, BBS and Berg balance scale, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101021294N4**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Fatemeh Ehsani

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Semnan University of Medical Sciences

Expected recruitment start date

2016-12-31, 1395/10/11

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation (a-tDCS) on balance, static and dynamic postural stability in older adults with a high risk for falling

Public title

The immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation (a-tDCS) on balance, static and dynamic postural stability in older adults with a high risk for falling

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Participants who have 60-75 years old and older adults who are prone to falling based on fall risk assessment tool or having falling history during 6 last month will be concluded. Exclusion criteria: Adults were no high risk for falling; Adults with severe perceptual and memory problems evidenced by Mini Mental Status Examination (MMSE) scores of less than 21; having neurological disease, especially Parkinson and Alzheimer's; having visual or auditory problems; having lower extremity pathology and range of motion limitations will be excluded from the study.

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan university of medical science

Street address

5 kilometer in Damghan Road, Semnan, Iran

City

Semnan

Postal code

Approval date

2016-08-10, 1395/05/20

Ethics committee reference number

IR.Semums.REC.1395.159

Health conditions studied

1

Description of health condition studied

Immediate and long-term effect of cerebellar anodal trans-cranial direct current stimulation on balance and postural stability older adults with high risk for falling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Static stability indices

Timepoint

Before receiving TDCS intervention, immediate and one-week after intervention after

Method of measurement

Byodex Balance System

Secondary outcomes

1

Description

Dynamic postural indices

Timepoint

Before and after receiving TDCS, after one-week receiving TDCS

Method of measurement

Byodex Balance System

2

Description

Falling sensation

Timepoint

Before and after receiving TDCS, after one-week receiving TDCS

Method of measurement

Fall risk assessment tool

3

Description

Balance

Timepoint

Before and after receiving TDCS, after one-week receiving TDCS

Method of measurement

Berg balance scale

Intervention groups

1

Description

Intervention group: Before and after receiving TDCS intervention, the participants will be asked to stand on

static and dynamic levels of Byodex Balance System for 30-second. In TDCS intervention, anodal and cathodal electrodes will be positioned on cerebellum and ipsi-lateral deltoid muscle, respectively. Stimulation will be used with 2 Mili Ampere intensity for 20-minute.

Category

Rehabilitation

2

Description

Control group: Before and after receiving sham-TDCS intervention, the participants will be asked to stand on static and dynamic levels of Byodex Balance System for 30-second. In sham-TDCS intervention, anodal and cathodal electrodes will be positioned on cerebellum and ipsi-lateral deltoid muscle, respectively. Stimulation will be used with 2 Mili Ampere intensity for 2-minute.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fatemeh Ehsani

Street address

Blvd. Ghods, Mashahir Square, Semnan

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Semnan University of Medical Sciences

Full name of responsible person

Ali Rashidipoor

Street address

Vice Chancellor for research of Semnan University of Medical Sciences, Blvd. Basig

City

Semnan

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 of Semnan University of Medical Sciences

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

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fatemeh Ehsani

Position

Assistant Professor

Other areas of specialty/work

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Web page address**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