

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of cerebellar transcranial direct stimulation on motor cortex versus cerebellum on balance indices in faller and non-faller older adults

Protocol summary

Study aim

to assess the effect of transcranial direct current stimulation on balance in older adults

Design

randomized clinical trial, cross over design, double blinded

Settings and conduct

The center of study is Musculoskeletal Rehabilitation Research Center. Balance will be assessed before and after intervention. Intervention will be based on a randomized cross over design and includes brain stimulation and placebo stimulation. The assessor and subjects are blinded in this study.

Participants/Inclusion and exclusion criteria

inclusion criteria: age above 60; ability to stand without assistive device exclusion criteria: deformity in lower extremity; cardiac, neurological and metabolic disease; history of neurosurgery

Intervention groups

intervention group which received the electrical stimulation and control group which receive the placebo protocol of stimulation

Main outcome variables

balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150923024151N7**

Registration date: **2018-11-13, 1397/08/22**

Registration timing: **prospective**

Last update: **2018-11-13, 1397/08/22**

Update count: **0**

Registration date

2018-11-13, 1397/08/22

Registrant information

Name

Hamzeh Baharlouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cerebellar transcranial direct stimulation on motor cortex versus cerebellum on balance indices in faller and non-faller older adults

Public title

The effect of transcranial direct stimulation on balance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age above 60 ability to stand without assistive device history of falling

Exclusion criteria:

deformity in lower extremity cardiac, neurological and metabolic disease history of neurosurgery vestibular

disorders visual problems

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization by coin

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and assessors are blinded to assignments.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Street

City

Ahvaz

Province

Khouzestan

Postal code

33133-61357

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.AJUMS.REC.1397.507

Health conditions studied

1

Description of health condition studied

balance

ICD-10 code

M99.9

ICD-10 code description

Biomechanical lesion, unspecified

Primary outcomes

1

Description

balance

Timepoint

before and after intervention

Method of measurement

force plate

Secondary outcomes

empty

Intervention groups

1

Description

The intervention is stimulation of cerebellum or primary motor cortex. The Device is ActivaDose which Manufactured by ActivaTeKTM Inc., Taiwan. The intervention includes one session with 20 minutes of duration and 2 mA of intensity

Category

Rehabilitation

2

Description

In sham stimulation the intensity will decrease to zero after 1 minute but the electrode positioning and duration are similar to real intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Rehabilitation Research Center

Full name of responsible person

Mohammad Mehravar

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Hamzeh Baharlouei

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

There is possibility to publish part of data.

When the data will become available and for how**long**

The data will publish 6 month after publishing main article.

To whom data/document is available

There is no limitation

Under which criteria data/document could be used

After getting the written informed consent from Ahvaz Jundishapur University of Medical Sciences

From where data/document is obtainable

Ahvaz Jundishapur University of Medical Sciences

What processes are involved for a request to access data/document

The researcher will be referred to Musculoskeletal Rehabilitation Research Center

Comments