Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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 asistive 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

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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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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
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
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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