Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effectiveness of Cerebellar Transcranial Alternating and Direct Current Stimulation on Balance in People with Cerebellar Ataxia

Protocol summary

Study aim

A comparison of cerebellar transcranial alternating and direct current stimulation effects on balance in people with cerebellar ataxia

Design

A randomized, Phase III, multi-center, double-blind, crossover, sham-controlled clinical trial with a sample size of 36 patients. Randomization will be carried out using block randomization through a web-based service.

Settings and conduct

All participants will randomly receive three single-session interventions, including anodal tDCS, tACS, and sham stimulation, at the Musculoskeletal Research Center in Isfahan and the Mobasher Kashani Rehabilitation Center in Hamadan. Both the participants and the outcome assessor are blinded to the type of intervention. A 1-week washout period will be considered between intervention sessions. Immediately before and after each intervention, balance will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals with cerebellar ataxia diagnosed by a neurologist; Individuals with standing impairment scored between 1 and 4 based on the scale for the assessment and rating of ataxia; Individuals with gait impairment scored between 3 and 8 based on the scale for the assessment and rating of ataxia. Exclusion criteria: Individuals with a history of neurological, psychiatric, or cognitive disorders; Use of medications that impair balance; Pregnancy; Persons with uncorrected visual impairments.

Intervention groups

Intervention 1: Transcranial direct current stimulation، 2 milliampere current intensity, 20 minutes of stimulation Intervention 2: Transcranial alternating current stimulation، 2 milliampere current intensity, 40 hertz frequency, 20 minutes of stimulation Intervention 3: Sham transcranial direct or alternating current stimulation, the current will be applied only for the first 30 seconds.

Main outcome variables

Static balance; Dynamic balance

General information

Reason for update

Acronym

تی دی سی اس

IRCT registration information

IRCT registration number: **IRCT20250130064571N2**
Registration date: **2026-09-15, 1405/06/24**
Registration timing: **prospective**

Last update: **2026-09-15, 1405/06/24**
Update count: **0**

Registration date

2026-09-15, 1405/06/24

Registrant information

Name

Ailin Talimkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-21, 1405/08/30

Expected recruitment end date

2027-06-20, 1406/03/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Cerebellar Transcranial Alternating and Direct Current Stimulation on Balance in People with Cerebellar Ataxia

Public title
Comparison of the Cerebellar Transcranial Alternating and Direct Current Stimulation on Balance
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with Cerebellar Ataxia Diagnosed by a Neurologist Individuals with no history of neurological diseases, epilepsy, dementia, or psychiatric disorders Individuals with Standing Impairment Scored Between 1 and 4 Based on the Scale for the Assessment and Rating of Ataxia Individuals with Gait Impairment Scored Between 3 and 8 Based on the Scale for the Assessment and Rating of Ataxia
Exclusion criteria:
Individuals with a history of neurological, psychiatric, or cognitive disorders. Individuals using medications that affect balance as a side effect. Individuals with uncorrected visual impairments. Participants who withdraw from the study for any reason.
Age
From **18 years** old to **47 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be recruited consecutively and randomly allocated to groups using block randomization via a web-based system. Allocation concealment will be ensured through the use of sequentially numbered, opaque, sealed envelopes
Blinding (investigator's opinion)
Double blinded
Blinding description
The outcome assessor and participants will be blinded to the type of intervention. To maintain participant blinding, participants will be unaware of whether the stimulator is active. To ensure assessor blinding, the stimulation protocols will be administered by the principal investigator, who will not be involved in outcome assessment
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Vice-Chancellery for Research and Technology., Hamadan University of Medical Sciences Headquarters., Pajuhesh Sq., Shahid Fahmideh Blvd
City
Hamadan
Province
Hamadan
Postal code
6516955373
Approval date
2026-08-22, 1405/05/31
Ethics committee reference number
IR.UMSHA.REC.1405.350

Health conditions studied

1

Description of health condition studied
Balance
ICD-10 code
Z50
ICD-10 code description
Care involving use of rehabilitation procedures

Primary outcomes

1

Description
Static balance
Timepoint
Assessment of static balance at the beginning of the study (before starting the intervention), immediately after completing the real or sham brain stimulation
Method of measurement
Force plate

2

Description
Dynamic balance

Timepoint
Assessment of dynamic balance at the beginning of the study (before starting the intervention), immediately after completing the real or sham brain stimulation
Method of measurement
Functional test of Timed Up and Go

Secondary outcomes

empty

Intervention groups

1

Description
First intervention: Transcranial direct current stimulation، Anode electrode placement on cerebellum, Cathode electrode placement on right shoulder, 2 milliampere current intensity, 20 minutes of stimulation
Category
Rehabilitation

2

Description
Second intervention: Transcranial alternating current stimulation، Anode electrode placement on cerebellum, Cathode electrode placement on right shoulder, 2 milliampere current intensity, 40 hertz frequency, 20 minutes of stimulation
Category
Rehabilitation

3

Description
Third intervention: Sham transcranial direct or alternating current stimulation, 2 milliampere current intensity only for the first 30 s, Turned off current for the other 20 minutes of stimulation
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mobasher Kashani Rehabilitation Center of Hamadan University of Medical Sciences
Full name of responsible person
Ailin Talimkhani
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2

Recruitment center
Name of recruitment center
Musculoskeletal Disorders Research Center of Isfahan University of Medical Sciences
Full name of responsible person
Hamzeh Baharlouei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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6517669664
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arsoltanian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Ailin Talimkhani
Position
Assistant Professor of Physiotherapy, Department of Physiotherapy, School of Rehabilitation Sciences
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only part of the static and dynamic balance data of individuals can be shared
When the data will become available and for how long
The data access period starts 6 months after the publication of the results
To whom data/document is available

For researchers at academic and scientific institutions only

Under which criteria data/document could be used

Ethical approval: Researchers must provide the necessary approval from their institutional ethics committee or the central ethics committee. Non-disclosure agreement: Signing a non-disclosure agreement and maintaining the confidentiality of the data are mandatory. Time limitation: Access to the data will be granted after approval and for 6 months after the publication of the results. Citation of source: In any report, article, or presentation prepared based on these data, the original source of the data must be accurately cited. Privacy protection: Researchers must fully adhere to the principles of protecting participant privacy and anonymizing the data.

From where data/document is obtainable

Ailin Talimkhani, Assistant Professor of Physiotherapy, Department of Physiotherapy, School of Rehabilitation Sciences, Hamadan University of Medical Sciences

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

Once approved, the anonymized dataset is prepared and quality-checked by the research team. The data is then released either through a secure data-sharing platform or after signing a Non-Disclosure Agreement. Estimated total time is 5–7 working days.

Comments