

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of tDCS along with postural training on static and dynamic balance on patients with diabetic neuropathy

Protocol summary

Study aim

The effect of tDCS along with postural training on static and dynamic balance on patients with diabetic neuropathy

Design

A controlled, double-blind, single-center, randomized clinical trial with 39 participants in 3 groups of 13.

Settings and conduct

Neuromuscular Rehabilitation Research Center Patients receive balance training for 4 weeks, 3 sessions per week, in 3 groups (with cerebellar tDCS stimulation, with Sham-tDCS stimulation, and alone).

Participants/Inclusion and exclusion criteria

Include criteria: Age 40-60 years; Patients who have symptoms of neuropathy such as tingling or numbness in the soles of the feet; Patients who receive a Berg scale score of less than 45; Patients who are classified as moderate or severe according to the Toronto Clinical Scoring System Exclusion criteria: Other neurological diseases (multiple sclerosis, history of stroke, Parkinson's, myelopathy, cerebellar ataxia); The patient's use of chemotherapy drugs that induced neuropathy; Mild neuropathy severity based on the Toronto Clinical Neuropathy Scale (score less than 8); Patients taking insulin

Intervention groups

Intervention group1: In this group according to the protocol, patients receive balance exercises on the device for 20 minutes simultaneously with cerebellar tDCS stimulation. Intervention group2: In this group according to the protocol, patients receive balance exercises on the device for 20 minutes simultaneously with Sham-tDCS cerebellar stimulation. Control group: In this group according to the protocol, patients receive balance exercises alone for 4 weeks, 3 sessions per week, and this is only for comparison with the intervention group.

Main outcome variables

Barge Balance Scale(BBS); Anterior-posterior stability

indices; Overall stability index; Mediolateral stability index(internal - external)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N83**

Registration date: **2025-01-17, 1403/10/28**

Registration timing: **prospective**

Last update: **2025-01-17, 1403/10/28**

Update count: **0**

Registration date

2025-01-17, 1403/10/28

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-03, 1403/11/15

Expected recruitment end date

2025-05-05, 1404/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of tDCS along with postural training on static and dynamic balance on patients with diabetic neuropathy

Public title
The effect of tDCS along with postural training on static and dynamic balance on patients with diabetic neuropathy

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Age 40-60 years Patients who have symptoms of neuropathy such as tingling or numbness in the soles of the feet Patients who receive a Berg scale score of less than 45 Patients who are classified as moderate or severe according to the Toronto Clinical Scoring System
Exclusion criteria:
Other neurological diseases (multiple sclerosis, history of stroke, Parkinson's, myelopathy, cerebellar ataxia) The patient's use of chemotherapy drugs that induced neuropathy Mild neuropathy severity based on the Toronto Clinical Neuropathy Scale (score less than 8) Patients taking insulin

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **39**

Randomization (investigator's opinion)
Randomized

Randomization description
Numbers 1 to 39 are written on paper and all of them are placed in sealed envelopes. Persons are then asked to select an envelope each. and according to the number inside the envelope, they will be placed in the relevant group. Randomization will be performed by someone other than the researcher and the evaluator.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding of the analyst, the outcome evaluator and the participant (double-blind) is done so that the groups are defined as A, B, and C for the patients and provided to the analyst and the outcome evaluator so they do not know about the grouping method. The participating person and the person who performs the statistical analysis do not know about the intervention modes.

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 Sciences
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Province
Semnan
Postal code
3514799442

Approval date
2024-10-14, 1403/07/23

Ethics committee reference number
IR.SEMUMS.REC.1403.135

Health conditions studied

1

Description of health condition studied
Movement disorder

ICD-10 code
F82

ICD-10 code description
Specific developmental disorder of motor function

Primary outcomes

1

Description
Barge Balance Scale(BBS)

Timepoint
Before the intervention, after the intervention and one month after the intervention

Method of measurement
Balance test questionnaire (Berg)

2

Description
Anterior-posterior stability indices

Timepoint
Before the intervention, after the intervention and one month after the intervention

Method of measurement

Biodex device (made in USA)

3

Description

Overall stability index

Timepoint

Before the intervention, after the intervention and one month after the intervention

Method of measurement

Biodex device (made in USA)

4

Description

Mediolateral stability index(internal - external)

Timepoint

Before the intervention, after the intervention and one month after the intervention

Method of measurement

Biodex device (made in USA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group according to the protocol, patients receive balance exercises on the device for 20 minutes simultaneously with cerebellar tDCS stimulation.

Category

Rehabilitation

2

Description

Intervention group: In this group according to the protocol, patients receive balance exercises on the device for 20 minutes simultaneously with Sham-tDCS cerebellar stimulation.

Category

Rehabilitation

3

Description

Control group: In this group according to the protocol, patients receive balance exercises alone for 4 weeks, 3 sessions per week, and this is only for comparison with the intervention group.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fatemeh Ehsani

Street address

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

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3513138111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan 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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Ehsani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Elham Hakimzade

Position

Student

Latest degree

Master

Other areas of specialty/work

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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

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available