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)

Phone
+98 23 3345 1336

Email address
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.
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4180
Email
are20935@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Abasali Vafaie
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan.
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
sem.ums.res@gmail.com
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
Street address
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4180
Email
are20935@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Ehsani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4180
Email
are20935@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Elham Hakimzade
Position
Student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4180
Email
hakimzadeh_eli@gmil.com

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