Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of rTMS and tDCS combined with postural exercises on balance, postural stability and level of fear of falling in patients with Multiple sclerosis: a double-blind randomized controlled trial

Protocol summary

Study aim

Comparison of the effects of rTMS and tDCS combined with postural exercises on balance, postural stability, and level of fear of falling in patients with Multiple sclerosis

Design

A randomized, double-blinded, sham-controlled clinical trial with a parallel-group design of 60 patients. Block randomization using Random allocation software is performed with Sealed envelopes.

Settings and conduct

The study is conducted in the Research Centre of Neuromuscular Rehabilitation of Semnan University of Medical Sciences (Iran). All participants are blind to the sham and active applications of the rTMS and tDCS. All outcome measures are taken before and after the intervention by a blinded physiotherapist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age > 20 and <65 years; disability between 4.5 and 6.5 on the Expanded Disability Status Scale (EDSS); walking ability according to the EDSS score; a minimal leg spasticity score ≤ 1 on the Modified Ashworth spasticity scale; exclusion criteria: Pregnant women; neurological, orthopedic, and severe cardiac comorbidities; peripheral vestibular disorders (i.e., positional paroxysmal vertigo, Meniere's disease, and acoustic neuroma); blindness in one or both eyes; exacerbation in the past 2 months or during the study.

Intervention groups

Three groups: cerebellar rTMS with postural training, cerebellar tDCS with postural training, sham rTMS, and tDCS with postural training.

Main outcome variables

The Berg Balance Score (BBS) and the stability indices at both static and dynamic levels of the Biodex Balance System are evaluated before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210905052374N1**
Registration date: **2021-11-14, 1400/08/23**
Registration timing: **prospective**

Last update: **2021-11-14, 1400/08/23**
Update count: **0**

Registration date

2021-11-14, 1400/08/23

Registrant information

Name

Mostafa Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

rahimim@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effects of rTMS and tDCS combined with postural exercises on balance, postural stability and level of fear of falling in patients with Multiple sclerosis: a double-blind randomized controlled trial

Public title
Effects of rTMS and tDCS in balance of MS patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clinically definite MS Age > 20 and <65 years Disability between 4.5 and 6.5 on the Expanded Disability Status Scale (EDSS) Walking ability according to the EDSS score A minimal leg spasticity score ≤ 1 on the Modified Ashworth spasticity scale

Exclusion criteria:
Pregnant women Neurological, orthopedic and severe cardiac comorbidities Peripheral vestibular disorders (i.e., positional paroxysmal vertigo, Meniere's disease, and acoustic neuroma) Blindness in one or both eyes Exacerbation in the past 2 months Exacerbation during the study

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
We will use the Block randomization method of the Restricted randomization method. Block randomization will be done by using Random allocation software and sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
All participants are blind to the sham and active applications of the rTMS and tDCS. All outcome measures are taken before and after the intervention by a blinded physiotherapist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
District 12, Enghelab St, Pich-e-Shemiran. Tehran University of Medical Sciences - School of Rehabilitation

City
Tehran

Province
Tehran

Postal code
11489-65111

Approval date
2021-06-30, 1400/04/09

Ethics committee reference number
IR.TUMS.FNM.REC.1400.107

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis (MS)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The stability indices at both static and dynamic levels of the Biodex Balance System

Timepoint
Before and after the intervention

Method of measurement
The Biodex Balance System (302-950 model, Biodex Medical Systems, Inc., New York, USA)

Secondary outcomes

1

Description
The Berg Balance Scale Score

Timepoint
Before and after the intervention

Method of measurement
Questionnaire

Intervention groups

1

Description

Participants in intervention group 1(cerebellar rTMS with postural training) receive 20 min of rTMS on their cerebellum during progressive postural training on the Biodex Balance System. Participants in intervention group 2 (cerebellar tDCS with postural training) receive 20 min of rTMS on their cerebellum during progressive postural training on the Biodex Balance System. In the sham rTMS and tDCS group (sham rTMS, and tDCS with postural training), participants receive only 30 s of stimulation at the beginning of a postural training session.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Neuromuscular Rehabilitation Research Centre of Semnan University of Medical Sciences

Full name of responsible person
Mostafa Rahimi

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District 12, Enghelab St, Pich-e-Shemiran. Tehran University of Medical Sciences - School of Rehabilitation

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotoohi

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Quds Street, Keshavarz Blvd, Central University Organization, sixth floor

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mostafa Rahimi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

Contact

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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

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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Starting 6 months after publication.

To whom data/document is available

Anyone interested can access the data.

Under which criteria data/document could be used

Any kind of analysis is allowed, provided that if the information is used somewhere, the source will be mentioned.

From where data/document is obtainable

Mostafa Rahimi rahimim@sina.tums.ac.ir 0098 912 2070616

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

All he/she has to do is send an email and he/she will receive the information within a month.

Comments