

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Evaluation of the effect of aerobic exercise with stationary bike in concomitant with trans cranial direct current stimulation on gait improvement in multiple sclerosis patients

Protocol summary

Study aim

evaluation the effect of aerobic exercise with stationary bike with trans cranial direct current stimulation on gait improvement in multiple sclerosis patients

Design

Clinical trial with control group, with parallel, double-blind, randomized

Settings and conduct

A study was conducted at the Neurology Research Center of Imam Khomeini Hospital.double-blind (researcher & patients)

Participants/Inclusion and exclusion criteria

inclusion criteria: definite MS, age:18-48, EDSS<6, mild to moderate spasticity or MAS scale grade less than 3 on remission period ; No recurrence of the disease in the last 30 days exclusion criteria:Dissatisfaction patients to enter the study and follow up ;Active phase of the disease; Pregnant women ;Simultaneous use of neuromuscular electrical stimulation techniques; Underlying illness ;accompanied History of using TDCS

Intervention groups

The room's temperature will be set to 21 degrees for both groups. control group: for Twenty-five patients with multiple sclerosis (relapsing remitting type) with EDSS<6 : During the 6 weeks & twice a week(12 session).In each session for the patient work with stationary bike a total of 30 minutes :10 minutes of activity And 5 minutes of rest with 20 watts per minute It will also use tdcS as the sham. A case group with similar specifications in addition to the use of a bike Also received tDCS.In the sitting position, two electrodes (anode and cathode) are placed on the desired locations.Anod is placed in the motor cortical area (3C) and the cathode in the shoulder region And will be adjusted at 1.5 mAh intensity and within 20 minutes.

Main outcome variables

initially, 6 weeks and 3 months later; Muscle weakness

by VAS; Disability rate will be measured later by EDSS ; Fatigue severity is measured (FSS); Quality of life is measured f by Multiple sclerosis quality of life questionnaire MSQOL-54

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180703040321N1**

Registration date: **2018-10-29, 1397/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-29, 1397/08/07**

Update count: **0**

Registration date

2018-10-29, 1397/08/07

Registrant information

Name

mohaddeseh Azadvari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6119 2291

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of aerobic exercise with stationary bike in concomitant with trans cranial direct current stimulation on gait improvement in multiple sclerosis patients

Public title
Evaluation the effect of aerobic exercise with stationary bike with trans cranial direct current stimulation on gait improvement in multiple sclerosis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
definite MS according to Mc Donald criteria age:18-48, EDSS<6, mild to moderate lower limbs spasticity ,MAS scale<3 on remission period No recurrence of the disease in the last 30 days

Exclusion criteria:
Dissatisfaction patients to enter the study and follow up
Active phase of the disease
Pregnant women
Simultaneous use of neuromuscular electrical stimulation techniques
Underlying illness accompanied
History of using TDCS

Age
From **18 years** old to **48 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the quadruple number block

Blinding (investigator's opinion)
Double blinded

Blinding description
After the patients entered the study according to entry and exit criteria,Initial evaluation carried out by a researcher fellow,They will then be packed with a fellow secretary in a random Which identifies the line and day of treatment Which is done by another research colleague.After the completion of the treatment, the assessment will be carried out by a colleague of another researcher

Placebo
Not 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 science

Street address

keshavarz AVE, Imam khomeini hospital

City

Tehran

Province

Tehran

Postal code

66581615

Approval date

2018-05-31, 1397/03/10

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.022

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Gait improvement

Timepoint

before intervention and after 6weeks

Method of measurement

2minute walking test,5meter walking test,timed up&go

Secondary outcomes

1

Description

Muscle force/Quality of life/severity of disability/severity of fatigue

Timepoint

before intervention and after 6weeks

Method of measurement

Muscle force>manual muscle test/ MS Quality of life questionnaire/ severity of disability:Expanded disability

status scale/ severity of fatigue:Fatigue severity scale questionnaire

Intervention groups

1

Description

Intervention group: The patients received transcranial direct current stimulation with 1/5 mA and during 20 minutes and at the same time they are cycling with stationary bike during 30 minutes with 5 minutes rest between every 10 minutes

Category

Rehabilitation

2

Description

Control group: The patients are cycling with stationary bike during 30 minutes and 5 minutes rest between every 10 minutes and used transcranial direct current stimulation as sham

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Mohaddeseh azadvari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr mohammad ali sahraian

Street address

Tehran University of Medical Sciences Office of Vice-Chancellor for Global Strategies and International Affairs, Number 21, Dameshgh St., Vali-e Asr Ave., Tehran 1416753955

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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

mohaddeseh azadvari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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inquiries

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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

Results of data analysis after the article published If required, raw data will be provided by the researcher in correspondence with the responsible author.

When the data will become available and for how long

the article will be accessible 2 months after its publication date

To whom data/document is available

all people working in academic institutions or people working in businesses

Under which criteria data/document could be used

Those who request information regarding our research should submit their request via their university vice-chancellor or official authority of their academic institution

From where data/document is obtainable

via E-mail: drazadvari@yahoo.com contact number: +982161192291

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

the requester should provide more details on the processes involved to receive these documents /data files. the description should give sufficient insight to the applicant of the amount of time needed to follow through these processes.

Comments