Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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 khomeoini 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
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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
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Position
Associate professor
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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