Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative effect of Dorso lateral prefrontal cortex Transcranial Direct Current Stimulation and Primary Motor Cortex Transcranial Direct Current Stimulation on fatigue in the patients with multiple sclerosis

Protocol summary

Study aim
A Comparative Study of the Effect of Brain Electric Stimulation on Two area motor and DLPFC Fields on Fatigue and Quality of Life in Multiple Sclerosis Patients

Design
Randomized double blind clinical trial parallel group

Settings and conduct
By referring to the Neurological Rehabilitation Research Center and with the completion of satisfaction and fatigue and quality of life and disability questionnaires divided to motor , dorso lateral pre frontal and sham groups, and patients and therapists are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria
inclusion criteria" 1- Age between 18 to 40 years 2- According to Mc Donald 2010 Revision criteria, their multiple sclerosis detected 3-Have received steady medical therapies since the last 6 months. 4-Have experienced fatigue for at least 6 months and have Fatigue Severity Scale more than 5 5-Their extended disability Status Scale is less than 4 exclusion criteria: 1- Multiple sclerosis that has had relaps during the last two months 2 are based on a BECK DEPRESSION INVENTORY scale have depression of more than 19 4. daily sleep rate of EPWORTH of more than 11 5. severe vision defects ,Severe weakness in limb movemen ,Other neurological and neurological diseases

Intervention groups
Transcranial Direct Current Stimulation applied to the DLPFC Transcranial Direct Current Stimulation applied on the motor area Sham group by applying Transcranial Direct Current Stimulation Unreal

Main outcome variables
Fatigue, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150302021294N7**
Registration date: **2018-03-22, 1397/01/02**
Registration timing: **prospective**

Last update: **2018-03-22, 1397/01/02**
Update count: **0**

Registration date
2018-03-22, 1397/01/02

Registrant information

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Fatemeh Ehsani

Name of organization / entity
Semnan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 23 3365 4180

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-07-23, 1397/05/01

Actual recruitment start date
2018-05-22, 1397/03/01

Actual recruitment end date
2018-07-23, 1397/05/01

Trial completion date

empty

Scientific title
Comparative effect of Dorso lateral prefrontal cortex Transcranial Direct Current Stimulation and Primary Motor Cortex Transcranial Direct Current Stimulation on fatigue in the patients with multiple sclerosis

Public title
effect of Transcranial Direct current Stimulation on fatigue and quality of life in multiple sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
age between 18-40 FSS>5 at least for 6 month ago EDSS<4 constant drug therapy at least 6 month ago diagnosis of multiple sclerosis according to M C DONALD CRITERIA revision 2010

Exclusion criteria:
MULTIPLE SCLEROSIS with relaps period at least 2 month ago According to BDI have depression>19 according to EPWORTH have sleepness >11 deficit in visual view deficit in muscle power according to Medical research council score for muscle Power 12/20

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **45**
Actual sample size reached: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization,individual,random number table,randomized permutation blocks(block3), using excel software to generate random number tables

Blinding (investigator's opinion)
Double blinded

Blinding description
All of participants are blind to type of intervention and assessors are blind to type of intervention and experimental conditions

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Semnan Medical University

Street address
Deputy of Research and Technology of Semnan University of Medical Sciences.,After Amir kabir Bridge

City
Semnan

Province
Semnan

Postal code
3519899951

Approval date
2018-03-16, 1396/12/25

Ethics committee reference number
ir.semums.rec.1396.219

Health conditions studied

1

Description of health condition studied
multiple sclerosis

ICD-10 code
G37.8

ICD-10 code description
Other specified demyelinating diseases of central nervous system

Primary outcomes

1

Description
scale of fatigue in FSS

Timepoint
BEFORE OF INTERVENTION,immediate after ,on month after intervention

Method of measurement
questionaree of FSS

2

Description
QUALITY OF LIFE IN MSQOL SCALE

Timepoint
Before of intervention,immediate after,one month after intervention

Method of measurement
QUESTIONAREEOF MSQOL

Secondary outcomes

1

Description

QUALITY OF LIFE MSQOL

Timepoint

Before intervention,immediate after, one month after

Method of measurement

questionaree of MSQOL

Intervention groups

1

Description

Intervention group:First intervention group: transcranial direct current stimulation on dorsolateral prefrontal group with 20 min Exposure duration 1.5 mA

Category

Rehabilitation

2

Description

Intervention group:Direct electrical stimulation of motor area for 20 minutes with an intensity of 1.5 mA

Category

Rehabilitation

3

Description

Control group: The sham group was placed by placing the electrode on the motor or perforontal region by randomly actuating 30 seconds at the beginning of the treatment and being off until the end of the 20 minute treatment

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fatemeh Ehsani

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Next to Nemat Ice Cream., Blvd Ghods., Mashahir Square.,Neuromuscular Rehabilitation Research Center,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Sponsor: country of origin

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

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available