

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Name

Fatemeh Ehsani

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

f.ehsani@semums.ac.ir

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

questionnaire 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

Street address

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

City

Semnan

Province

Semnan

Postal code

35196-98375

Phone

+98 23 3332 8502

Fax

Email

f.ehsani59@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Asgari

Street address

Semnan Headquarters., Medical Semnan University., After Amir Kabir Bridge,

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3344 1021

Email

Aasgari5000@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

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

Street address

Damghan Sreet ., Semnan Medical Uneversity,

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3344 1021

Email

fatemehehsani59@yahoo.com

Person responsible for scientific 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

Rehabilitation management

Street address

Damghan Street., Semnan Medical University,

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3344 1021

Email

fatemehehsani59@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Marzieh Mortezaejad

Position

Stuff

Latest degree

Bachelor

Other areas of specialty/work

Rehabilitation management

Street address

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

City

Semnan

Province

Semnan

Postal code

35196-98375

Phone

+98 23 3322 8502

Email

mmortezaejad98@yahoo.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

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