Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation on the clinical efficacy of transcranial direct current stimulation (tDCS) combined with traditional dysphagia therapy for treatment of dysphagia in patients with Multiple Sclerosis: A randomized, double-blind, sham-controlled, clinical trial

Protocol summary

Study aim
Investigation on the clinical efficacy of transcranial direct current stimulation combined with traditional dysphagia therapy (TDT) for treatment of dysphagia in patients with Multiple Sclerosis

Design
Two arm parallel group randomized trial with blinded, sham controlled clinical trial with a parallel group design of 40 patients.Randomisation is carried out using excel software.

Settings and conduct
Study is performed on the MS patients that are refereed to kashani hospital in Isfahan city. principal researcher, the person in charge of data collecting, the person in charge of data analyzing as well as participants are blinded relative to real or sham intervention.

Participants/Inclusion and exclusion criteria
Diagnosis of multiple sclerosis based on the McDonald criteria range of age between 20 and 60 years presence of dysphagia

Intervention groups
(1) MS patients receiving real brain stimulation (2) MS patients receiving sham brain stimulation

Main outcome variables
Swallowing ability Severity of MS disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150220021150N1**
Registration date: **2022-09-19, 1401/06/28**
Registration timing: **prospective**
Last update: **2022-09-19, 1401/06/28**
Update count: **0**

Registration date
2022-09-19, 1401/06/28

Registrant information

Name
meysam amidfar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8899 1118

Email address
amidfar-m@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-01-21, 1401/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation on the clinical efficacy of transcranial direct current stimulation (tDCS) combined with traditional dysphagia therapy for treatment of dysphagia in patients with Multiple Sclerosis: A randomized, double-blind, sham-controlled, clinical trial

Public title

Effect of transcranial direct current stimulation in treatment of dysphagia in MS

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of MS based on McDonald criteria Range of age between 20 and 60 Presence of dysphagia

Exclusion criteria:
Stroke Pregnancy Substance abuse Mental Disorders Epilepsy

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization is used in this study . In this clinical trial, the size of block is 6, including 3 participants in intervention group and 3 participants in control group. The Allocation concealment is used for concealment. The Random allocation software and coded containers are used as randomization tool.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants, principal researcher, the person in charge of data collecting and persons in charge of analyzing of data are blind related to real tDCS or sham tDCS.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Hezar Jerib street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2022-07-27, 1401/05/05

Ethics committee reference number
IR.ARI.MUI.REC.1401.168

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
Swallowing ability

Timepoint
Before intervention , immediately after intervention and one month after intervention

Method of measurement
Dysphagia in Multiple Sclerosis Questionnaire

Secondary outcomes

1

Description
Severity of disease

Timepoint
Before intervention, immediately after intervention and one month after intervention

Method of measurement
Expanded Disability Status Scale

Intervention groups

1

Description
Intervention group: MS patients receiving active brain stimulation

Category
Rehabilitation

2

Description
Control group: MS patients receiving sham brain stimulation

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Fereshte Ashtari
Street address
Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3131
Fax
+98 31 3668 5149
Email
research@mui.ac.ir
Web page address
https://research.mui.ac.ir/fa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Fax
+98 31 3668 7898
Email
research@mui.ac.ir
Web page address
https://research.mui.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fereshte Ashtari
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
f_ashtari@med.mui.ac.ir
Web page address
https://med.mui.ac.ir/node/1972

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fereshte Ashtari
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone

+98 31 3792 3131

Email

f_ashtari@med.mui.ac.ir

Web page address

https://med.mui.ac.ir/node/1972

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Meysam Amidfar

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Hezar Jerib street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

81839-83434

Phone

+98 31 3233 0091

Email

amidfar.m@gmail.com

Web page address

https://inrc.mui.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available