

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 referred 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)

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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

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Isfahan

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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

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Web page address<https://research.mui.ac.ir/fa>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

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Researcher

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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