

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

### City

Isfahan

### Province

Isfahan

### 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

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Hezar Jerib street, Isfahan, Iran

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**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

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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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Esfahan University of Medical Sciences

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**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

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**Full name of responsible person**

Meysam Amidfar

**Position**

Researcher

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Ph.D.

**Other areas of specialty/work**

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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