

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effects of Short-Term and Long-Term Anodal tDCS over M1 Cortex Concurrent with Pelvic Floor Muscle Training (PFMT) on Pelvic Floor Muscle Function and Incontinency in Patients with Multiple Sclerosis (MS)

Protocol summary

Study aim

The effects of short-term and long-term anodal tDCS over M1 cortex concurrent with pelvic floor muscle training on pelvic floor muscle function and incontinency in patients with multiple sclerosis

Design

A randomized clinical trial study with parallel groups, Double-blinded on 30 patients, Randomization will be done simply by random numbers table.

Settings and conduct

This study is performed with the voluntary participations with multiple sclerosis at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences. Both groups of study are taught progressive pelvic floor muscle exercises. The intervention group is also received anodal tDCS on M1 region but the other group will receive sham tDCS on this region. In both groups, treatment sessions include 18 treatment sessions 3 sessions per week for 6 consecutive weeks. To evaluate the short-term and long-term effects of tDCS, participants in both groups were evaluated before, 4 and 6 weeks after the start of the intervention and also one month after the end of the intervention. Patients and evaluator are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with definitive diagnosis of MS with stable disease over the previous 4 months; Age is between 18 and 45 Years; Having symptoms of urinary incontinence; Patient's EDSS score should be less than 6.5. Exclusion criteria: History of MS relapse during treatment; Being pregnant or in the first 6 months post-partum; Urinary tract infection

Intervention groups

The first group will receive anodal tDCS with progressive pelvic floor muscle exercises during 18 sessions of rehabilitation treatment. The second intervention group will receive sham tDCS with progressive pelvic floor

muscle exercises during 18 sessions of rehabilitation treatment.

Main outcome variables

Pelvic floor muscle function; Urinary incontinency

General information

Reason for update

Acronym

tDCS

IRCT registration information

IRCT registration number: **IRCT20201102049234N1**

Registration date: **2020-11-14, 1399/08/24**

Registration timing: **prospective**

Last update: **2020-11-14, 1399/08/24**

Update count: **0**

Registration date

2020-11-14, 1399/08/24

Registrant information

Name

Mona Ramezani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 23 3332 8502

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Short-Term and Long-Term Anodal tDCS over M1 Cortex Concurrent with Pelvic Floor Muscle Training (PFMT) on Pelvic Floor Muscle Function and Incontinency in Patients with Multiple Sclerosis (MS)

Public title

The Effects of Anodal tDCS on Incontinency in Patients with Multiple Sclerosis (MS)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with Definitive Diagnosis of MS with Stable Disease over the Previous 4 Months Definite MS Diagnosis According to the 2010 Revised McDonald Criteria Age Is Between 18 and 45 Years Having Symptoms of Urinary Incontinence Patients Have Received Stable Pharmacological Therapies for the Past 6 Months Patient's Expanded disability status scale (EDSS) Score Should Be Less than 6.5 Patients Have the Cognitive Capacity to Complete the Assessment and Treatment Protocol Minimal Ability to Contract the Pelvic Floor Muscles To Be Willing to Participate in the Study

Exclusion criteria:

History of MS Relapse during Treatment Being Pregnant or in the First 6 Months Post-Partum Cesarean Section or Vaginal Delivery within 6 Months Previously to Time of Enrolment Pelvic Organ Prolapse at Vaginal Examination Urinary Tract Infection Having Undergone Surgical Treatment for Urinary Incontinence Having Undergone Prior Physiotherapy for Urinary Incontinence The Presence of Any Other Neurological or Kidney Disease Contraindications of Electrical Stimulation Declining to Participate in the Study Inability to Understand and Comply with the Study Procedures

AgeFrom **18 years** old to **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization with a random number table such that each person is given a code and they are written in a table. We select one place from the table in a blinded manner. Then we select 12 numbers smaller than the

selected number in the same row. The same would be true for the treatment and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher will be blind to the intervention using the research assistant and he/she is absent in the treatment room. The outcome evaluator will vary with the researcher and research data be given him with code and is unaware of the participants intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

Street address

Headquarters of Semnan University of Medical Sciences, Basij Blvd., Semnan

City

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Province

Semnan

Postal code

3514799442

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.SEMUMS.REC.1399.214

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**

Level of urinary incontinence

Timepoint

Before the intervention, 4 and 6 weeks after the start of intervention and one month after the end of intervention

Method of measurement

International Consultation on Incontinence
Questionnaire-Urinary Incontinence Short Form

2

Description

Pelvic floor muscle function

Timepoint

Before the intervention, 4 and 6 weeks after the start of intervention and one month after the end of intervention

Method of measurement

ultrasonographic device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Anodal tDCS over M1 cortex
concurrent group with progressive exercises of pelvic floor muscles

Category

Treatment - Devices

2

Description

Intervention group: Anodal sham tDCS over M1 cortex
concurrent group with progressive exercises of pelvic floor muscles

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan university of medical science,
Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fariba Ramezani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

empty

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

Fariba Ramezani

Position

Master Student of Physiotherapy

Latest degree

Bachelor

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