Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target 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
Semnan
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 unuversity of medical science, Neuromuscular Rehabilitation Research Center
Full name of responsible person
Fariba Ramezani
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Sponsors / Funding sources

1

Sponsor
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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
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Fariba Ramezani
Position
Master Student of Physiotherapy
Latest degree
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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