Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of the effect of direct current transcranial electrical stimulation and tibial nerve stimulation on the symptoms of women with overactive bladder syndrome

Protocol summary

Study aim
Comparison of the effect of peripheral tibial nerve stimulation with exercise with "direct current trans-cranial electrical stimulation" combined with exercise on clinical symptoms of patients with overactive bladder syndrome

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 38 patients. Sealed envelopes will be used for randomization

Settings and conduct
This study will be performed in Tehran, Firoozgar Hospital and in the pelvic floor clinic. The study will be conducted in two-way blind and the assessor and participants will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women over the age of 18, women with overactive bladder syndrome, self-report urgency incontinence Exclusion criteria: Have urinary infection, pregnancy during the period, cancer, the presence of metal implants in the skull, pacemakers, frequent unexplained headaches

Intervention groups
In the intervention group, patients will receive "direct current trans-cranial electrical stimulation" in addition to pelvic floor muscle training, and in the control group, patients will receive standard treatment including tibial nerve surface stimulation in addition to pelvic floor muscle training.

Main outcome variables
Number of urinary incontinence; Pelvic floor muscle strength; Symptoms of overactive bladder

General information

Reason for update

Acronym
tDCS

IRCT registration information
IRCT registration number: **IRCT20090301001722N26**
Registration date: **2023-03-31, 1402/01/11**
Registration timing: **prospective**

Last update: **2023-03-31, 1402/01/11**
Update count: **0**

Registration date
2023-03-31, 1402/01/11

Registrant information

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Samira Karimpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-20, 1402/01/31

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of direct current

transcranial electrical stimulation and tibial nerve stimulation on the symptoms of women with overactive bladder syndrome

Public title
Evaluation the effect of transcranial stimulation in overactive bladder syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with overactive bladder syndrome between the ages of 18 and 65 Absence of neurological and mental diseases No history of pelvic surgeries Absence of diabetes Absence of cardiac pacemaker Absence of pregnancy Lack of pelvic floor physiotherapy in the last 3 months Absence of lower urinary tract infection Absence of brain tumor No brain surgery No history of epilepsy and convulsions in the last 2 months Absence of metal implants in the skull Not taking drugs that increase the excitability of the brain, such as Ritalin and..
Exclusion criteria:
Pregnancy Urinary tract infection Cancer Presence of metal implants in the skull Heartbeats Unexplained recurrent headaches
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method in this study is simple randomization. A randomization unit is an individual that will be done through a sealed envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients are blind to treatment because they are unaware of the allocation of study groups. Also, the person evaluating the outcome is blind.
Placebo
Not used
Assignment
Parallel
Other design features
No

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Qods corner., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2023-03-12, 1401/12/21
Ethics committee reference number
IR.TUMS.FNM.REC.1401.210

Health conditions studied

1

Description of health condition studied
Overactive bladder syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Symptoms of frequency, urgency and urinary incontinence. These symptoms all indicate overactive bladder syndrome. Urinary frequency means the number of times a person goes to the toilet to urinate during the day. Urgency means urgency to urinate, and urinary incontinence is the involuntary leakage of urine that usually occurs before a person reaches the bathroom.
Timepoint
At the beginning of the study, after 4 weeks in the last session and after a month
Method of measurement
International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life Module

Secondary outcomes

1

Description
Pelvic floor muscle strength
Timepoint
At the beginning of the study, after 4 weeks in the last session
Method of measurement
Perineometer instrument

2

Description
Symptoms of frequency and urinary incontinence
Timepoint
At the beginning of the study, after 4 weeks in the last session and after a month
Method of measurement
International Consultation on Incontinence Questionnaire Overactive Bladder Module

Intervention groups

1

Description
Intervention group: In this group, patients will receive pelvic floor muscle training in addition to direct current trans-cranial stimulation. In the intervention group, all patients will be treated for 12 sessions and each session will last 30 minutes. 20 minutes will be dedicated to brain electrical stimulation and 10 minutes to pelvic floor muscle training. Brain electrical stimulation will be applied to the medial prefrontal cortex area for 4 weeks and 3 sessions every week. Pelvic floor muscle training will be taught for 4 weeks and one session per week.
Category
Rehabilitation

2

Description
Control group: In this group, patients will receive pelvic floor muscle training plus transcutaneous stimulation of the tibial nerve. The duration of each session will be 30 minutes, of which 20 minutes will be devoted to stimulating the tibial nerve and 10 minutes to training the pelvic floor muscles. Tibial nerve stimulation will be applied for 4 weeks and 3 sessions every week. Pelvic floor muscle training will be taught for 4 weeks and one session every week.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Firouzgar hospital
Full name of responsible person
Zahra Gorji
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Zahra Gorji
Position
PhD student
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Master
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