Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of the effects of electroacupuncture and posterior tibial nerve electrical stimulation on urinary disorders in patients with multiple sclerosis in Tehran Imamreza hospital

Protocol summary

Study aim
To investigate the effect of acupuncture with electrical stimulation (EA) compared with electrical stimulation of the posterior tibial nerve (PTNS) in urinary disorders in patients with multiple sclerosis

Design
Phase 3 randomized, parallel-group clinical trial (using a random number table) on 38 patients

Settings and conduct
protocol for the first group: 12 sessions Electrical stimulation of the posterior tibial nerve by placing a surface electrode behind the medial malleolus and a needle electrode 5 cm cephalad and 1.5 cm behind the medial malleolus with a stimulation frequency of 20 Hz, a pulse width of 200 milliseconds, a voltage of 9 mV, /protocol for the second group: 12 sessions stimulation at specific points related to urinary incontinence with a frequency of 20 Hz

Participants/Inclusion and exclusion criteria
Inclusion: Individuals 18 years of age or older / diagnosed with MS by a neurologist who are stable in terms of disease progression (operationally without change in physical or mental symptoms in the past 4 months) / have an EDSS score of less than 6.5 / have sufficient cognitive capacity to complete the evaluation and treatment protocol Exclusion: Pregnancy, previous gynecological, urological and/or neurosurgery, cesarean section or vaginal delivery in the past 6 months, pelvic organ prolapse greater than stage I / have a urinary tract infection / increase in EDSS score of more than 0.5 from baseline

Intervention groups
The first intervention group examined the effect of electroacupuncture/the second intervention group examined the effect of PTNS.

Main outcome variables
Age/Gender/Urinary Symptoms/Quality of Life/Intervention/Level of Physical Health/Level of Mental Health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260209068810N1**
Registration date: **2026-08-31, 1405/06/09**
Registration timing: **prospective**

Last update: **2026-08-31, 1405/06/09**
Update count: **0**

Registration date
2026-08-31, 1405/06/09

Registrant information

Name
Shadi Askari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-01, 1405/07/09

Expected recruitment end date
2027-03-19, 1405/12/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effects of electroacupuncture and posterior tibial nerve electrical stimulation on urinary disorders in patients with multiple sclerosis in Tehran Imamreza hospital

Public title

effects of electroacupuncture on urinary disorders in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 years of age or older diagnosis of MS by a neurologist are stable in terms of disease progression (operationally no change in physical or mental symptoms in the past 4 months), no Exacerbation Disability Status Score (EDSS) less than 6. If taking antipsychotic medications, self-medication can be included only if the medication has been taken for at least 3 months prior to the study and has not changed during the study. have sufficient cognitive capacity to complete the assessment and treatment protocol

Exclusion criteria:

pregnancy, previous gynecological, urological, and/or neurosurgery, cesarean section or vaginal delivery in the past 6 months pelvic prolapse greater than stage I on the Pelvic Prolapse Quantification System (POP-Q) examination performed by a physical therapist urinary tract infection confirmed by laboratory tests, or self-reported perimenopause or menopause. f participants reported any worsening of their primary MS symptoms during the study, they were reassessed by a neurologist using the EDSS. They were excluded if their EDSS score increased by more than 0.5 from baseline during data collection.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Artesh University of Medical Sciences

Street address

Haft Tir Square, Ghaem Maqam Street, Mashahir Street, No.49

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Approval date

2026-02-15, 1404/11/26

Ethics committee reference number

IR.AJAUMS.REC.1404.351

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system Multiple sclerosisIncl.: Multiple sclerosis (of): NOS brain stem cord disseminated generalized

Primary outcomes

1

Description

Urinary symptoms Conceptual definition: Urinary disorders in patients with multiple sclerosis (MS) are a set of functional abnormalities in the bladder and urinary tract that occur mainly due to the involvement of the central nervous system in urinary control. These disorders often include symptoms such as urinary frequency, urgency, nocturia, and urinary incontinence. Operational definition: In this study, the presence of urinary disorders in patients with MS is determined based on the score obtained from the ICIQ-OAB questionnaire. This questionnaire is a valid and standardized tool for measuring symptoms of overactive bladder, which includes 4 main questions about urinary frequency during the day, urgency, nocturia, and urge incontinence, and each item is scored from 0 to 4 (maximum score 16).

Timepoint

Before the intervention, the end of the intervention, and

three months after the end

Method of measurement

ICIQ-OAB quastionare

2

Description

quality of life

Timepoint

Before the intervention, the end of the intervention, and three months after the end

Method of measurement

SF-12 quastionare

3

Description

Physical health level

Timepoint

Before the intervention, the end of the intervention, and three months after the end

Method of measurement

ICIQ-OAB QuestionnairePart One

4

Description

Level of mental health

Timepoint

Before the intervention, the end of the intervention, and three months after the end

Method of measurement

ICIQ-OAB QuestionnairePart Two

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment protocol for the first group: 12 sessions (two sessions per week for 6 weeks) Electrical stimulation of the posterior tibial nerve by placing a surface electrode behind the medial malleolus and a needle electrode 5 cm cephalad and 1.5 cm behind the medial malleolus with a stimulation frequency of 20 Hz, a pulse width of 200 milliseconds, a voltage of 9 mV, and the stimulation intensity is increased to the point of causing thumb flexion, and then the stimulation is reduced to the point of causing a burning sensation. The duration of each session is 20 to 30 minutes.

Category

Treatment - Devices

2

Description

Intervention group: Treatment protocol for the second group: 12 sessions (two sessions per week for 6 weeks) of acupuncture with electrical stimulation at specific points related to urinary incontinence with a frequency of 20 Hz and the intensity of stimulation is at the level of a tingling sensation felt by the patient. The duration of each session is 20 to 30 minutes. Acupuncture points include:DU 20: Midline connecting the earlobesLI4: Midline of the FDI muscle, side of He8Ren3: One chin below the navelRen4: Two chins below the navel1.5 Ren6: Two chins below the navelRen7: One chin below the navelSP6: Three chins above the medial tip of the medial malleolus of the tibiaSP9: A hole inside the tibial tuberosity, almost on the posterior anserine bursaUB23: 1.5 chins lateral to the spinous process of the L2 vertebraUB28: 1.5 chins lateral to the spinous process of the S2 vertebraUB40: In the popliteal fossa and in the middle of the popliteal fossa

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Imamreza hospital

Full name of responsible person

Shadi Askari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Artesh 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
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Full name of responsible person
Shadi Askari
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Access period begins after results are printed.

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The conditions mentioned above

From where data/document is obtainable

Shadi Askari

What processes are involved for a request to access data/document

I haven't decided yet.

Comments