

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 21 8881 6923

Email address

shadi.askari7@gmail.com

Recruitment status

Not yet 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

City

Tehran

Province

Tehran

Postal code

1589863113

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 questionnaire

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 questionnaire

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

Street address

West Fatemi Street, Aitmadzadeh Street

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6352

Email

shadi.askari7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr. Armin Zareian

Street address

Tehran - West Fatemi Street - Shahid Etemadzadeh Street

City

Tehran

Province

Tehran

Postal code

۱۴۱۱۷۱۸۵۴۱

Phone

+98 21 8609 6350

Email

ajaums@gmail.com

Web page address

https://www.ajajums.ac.ir

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**

Artesh University of Medical Sciences

Full name of responsible person

Shadi Askari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No 49,mashahir Ave,ghaem magham Blvd,haftetir SQ

City

Tehran

Province

Tehran

Postal code

1589853113

Phone

+98 21 8881 6923

Fax**Email**

shadi.askari7@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

seyed Morteza Tabatabae

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

West Fatemi Street, before reaching Shahid Chamran Highway, Etemadzadeh Street

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6350

Email

smt.1368@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Shadi Askari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No 49,mashahir Ave,ghaem magham Blvd,haftetir SQ

City

Tehran

Province

Tehran

Postal code

1589863113

Phone

+98 21 8881 6923

Fax**Email**

shadi.askari7@gmail.com

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