Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of quality of life and clinical results of posterior tibial nerve stimulation and selective anticholinergic treatment in multiple sclerosis patients with neurogenic bladder in a randomized clinical trial.

Protocol summary

Study aim
Comparison of quality of life and clinical results of Trans Tibilal Nerve Stimulation(TTNS) and drug treatment in patients with MS with neurogenic bladder

Design
A randomized clinical trial that is conducted in two groups, the first group receiving physiotherapy treatment and the second group receiving drug treatment, phase 2-3, will be conducted on each group of 27 people, a total of 54 people, and rand function of Excel software was used for randomization.

Settings and conduct
Time :1402 and 1403 in Hashminejad and Firozgar hospitals in Tehran, patients with MS will refer to the urologist with a referral letter from a neurologist based on the diagnosis of MS, and Recently, they have at least one of the symptoms of LUTS such as urgent incontinence, urgency and frequency of daily urination or nocturia, and according to the opinion of the urologist, the symptoms of LUTS need to be investigated and treated, they will be included in the study in two groups of drug treatment and TTNS. They will be assigned to each of the study groups by a simple randomization method using a table of random numbers. In one group, we will do (TTNS) method. A positive electrode is placed 10 cm above the negative electrode along the tibial nerve. The parameter settings include the frequency of 10 Hz and the pulse width of 200 milliseconds. The intensity is 1.5 times the intensity of muscle twitching. Patients will undergo 30-minute outpatient treatment sessions once a week for 12 weeks.

Participants/Inclusion and exclusion criteria
MS disease confirmed by a neurologist, which is proven by the urodynamic test of the patient's overactive bladder, and the patient is over 18 years old.

Intervention groups
TTNS treated group The group under drug treatment with anticholinergics

Main outcome variables
Quality of life include Quality Of Life(QOL) questionnaire and clinical results

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241010063320N1**
Registration date: **2024-11-25, 1403/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-25, 1403/09/05**
Update count: **0**

Registration date
2024-11-25, 1403/09/05

Registrant information

Name
Zeinab Ashoori ghazi mahaleh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-02, 1403/02/13

Expected recruitment end date
2025-05-03, 1404/02/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of quality of life and clinical results of posterior tibial nerve stimulation and selective anticholinergic treatment in multiple sclerosis patients with neurogenic bladder in a randomized clinical trial.

Public title

comparison of Effect of TTNS vs anticholinergic in OAB

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Multiple sclerosis confirmed by a neurologist Urodynamic findings based on overactive bladder

Exclusion criteria:

Sacral peripheral nerve lesions UTI Specific prostate size in digital rectal examination Bladder outlet obstruction Pregnancy Diabet melitus type 2 Severe cardio_pulmonary disease History of urinary control surgery Current bladder malignancy

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to each of the study groups using a random number table. In this way, at the time of the patient's consultation, the questionnaires, randomly half of them are in the physiotherapy group and the other half of them are in the drug treatment sub-group. The placement of the questionnaire is random and confusing, and the questionnaires and treatment method are all covered with white paper and cannot be distinguished from the content inside at the time of use. Then randomly at the time of visit, an envelope is taken by the doctor, who is unaware of the treatment method, and the method of treatment is determined from it, and the patient also fills the questionnaire inside the same envelope. The patient's name is written on this envelope and the patient fills out the questionnaire again during the next follow-up to check the changes in his condition after the treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding is that both the doctor and the patient are unaware of the content of the cards at the time of conducting this research. At the beginning of the study, questionnaire envelopes were printed for the total number of participants, which are all the same, then this questionnaire and the name of the treatment method, which is either physiotherapy or drug treatment, are placed inside each envelope containing the questionnaire separately. And all this After closing, the envelopes are randomly placed together and the doctor gives each patient an envelope, so both the doctor and the patient are unaware of the treatment method.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

No 8 mwst rashid gharbi ave, khodami blvd, vanak

City

Tehran

Province

Tehran

Postal code

1994615716

Approval date

2024-02-28, 1402/12/09

Ethics committee reference number

IR.IUMS.FMD.REC.1402.518

Health conditions studied

1

Description of health condition studied

Over active bladder

ICD-10 code

N32.8

ICD-10 code description

Other specified disorders of bladder

Primary outcomes

1

Description

Questionnaire ICIQ_OAB

Timepoint

Comparison between questionnaires in both groups, one

at the beginning of treatment and the other 12 weeks after treatment

Method of measurement

Questionnaire ICIQ_OAB & Questionnaire ICIQ_QOL

2

Description

Questionnaire ICIQ_QOL

Timepoint

Comparison between questionnaires in both groups, one at the beginning of treatment and the other 12 weeks after treatment

Method of measurement

Questionnaire ICIQ_QOL

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment with transcutaneous posterior tibial nerve stimulation

Category

Treatment - Devices

2

Description

Intervention group: Treatment with selective anticholinergics

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasheminezhad hospital

Full name of responsible person

Zeinab ashoori ghazimahaleh

Street address

Valinezhad ave, vanak

City

Tehran

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1969714713

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2

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Zeiab ashoori ghazi mahaleh

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Behafarin ave, valiasr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Hemat Highway next to Milad Tower

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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
Iran University of Medical Sciences

Full name of responsible person
Zeiab ashoori ghazi mahaleh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Maryam emami

Position
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Latest degree
Specialist

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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 the data including the initial history and all the questionnaires before and after the treatment can be published

When the data will become available and for how long
Access period starts 6 months after publication

To whom data/document is available
Only for researchers in academic and scientific institutions

Under which criteria data/document could be used
Making citations to articles and scientific and academic uses

From where data/document is obtainable
Responding to requests sent to emails

What processes are involved for a request to access data/document
After the request to zeinabashoori1373@gmail.com email will be answered within a week

Comments