Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of percutaneous posterior tibial nerve stimulation on treatment of lower urinary tract symptom in women patient multiple sclerosis who referred to Emam Khomeini hospital

Protocol summary

Summary

In the intervention study, twenty women patients (between 18-55 years old) with various kinds of multiple sclerosis (MC Donald 2010 criteria) and have urinary symptom with detrusor sphincter dyssynergia or over active bladder refractory to drug therapy are considered in study. The exclusion criteria are urinary infection, pervious urogenital surgery, renal stone, pregnancy, severe cardiopulmonary diseases, physical inability, diabetes mellitus, other central nervous system diseases. Also, patients who don't consent do not consider. When the urinary symptoms aggravate, attack of multiple sclerosis appear or weekly treatment are not followed, are removed from the study. Patients will be treated with 12 sections of electrical posterior tibial stimulation. Each stimulation will be applied for 30 minutes, once a week for 12 weeks, by unilateral insertion of 38 monopolar needle at 60-degree angle, approximately 5cm cephalad to the medial malleolus and slightly posterior to the tibial. Stimulation will be done with .5-9mA current level , 200 microsec pulse and pulse rate of 20 Hz, based on base subjects foot planter motor and sensory response . PVR and UDS will be performed after 12 weeks. The effect of stimulation on urodynamic and PVR will be compared of paseline and after stimulation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031512820N1**
Registration date: **2013-04-17, 1392/01/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-17, 1392/01/28

Registrant information

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Payam Sarraf
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-08-06, 1392/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of percutaneous posterior tibial nerve stimulation on treatment of lower urinary tract symptom in women patient multiple sclerosis who referred to Emam Khomeini hospital

Public title

the effect of tibial nerve stimulation on urinary symptoms in multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Women with Multiple Sclerosis (between 18-55 years old) who have lower urinary symptoms such as urgency, frequency and nacturia with detrusor sphincter dyssynergia or over active bladder refractory to drug therapy (treatment of at least three months with one or two anticholinergic drugs) are included in study. The exclusion criteria are: urinary infection; previous urogenital surgery; renal stone; pregnancy; severe cardiopulmonary diseases; physical inability; diabetes mellitus; other central nervous system diseases. Also, patients who don’t consent do not consider. When the urinary symptoms aggravate, attack of multiple sclerosis appear or weekly treatment are not followed, the patients are also removed from the study.

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2013-03-09, 1391/12/19

Ethics committee reference number

78777-20284-054-04-91

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

Maximum-systometric-capacity

Timepoint

Before and after intervention

Method of measurement

Urodynamic study

2

Description

Involuntary detrusor contraction volume

Timepoint

Before and after intervention

Method of measurement

Urodynamic study

Secondary outcomes

1

Description

Frequency

Timepoint

In each refering

Method of measurement

Ask from the patients

2

Description

Nacturia

Timepoint

In each refering

Method of measurement

Ask from the patients

3

Description

PVR

Timepoint

Before and after of stimulation

Method of measurement

Nelaton Catheter

Intervention groups

1

Description
Patients will be treated with 12 sections of electrical posterior tibial stimulation. Each stimulation will be applied for 30 minutes, once a week for 12 weeks, by unilateral insertion of 38 monopolar needle at 60-degree angle, approximately 5cm cephalad to the medial malleolus and slightly posterior to the tibial. Stimulation will be done with .5-9mA current level , 200 microsec pulse and pulse rate of 20 Hz, based on base subjects foot planter motor and sensory response .The age, kind of disease , the average duration of disease, duration of urinary symptom , EDSS, frequency nacturia, PVR and UDS will be recorded. PVR and UDS will be performed after 12 weeks. The effect of stimulation on urodynamic and PVR will be compared of paseline and after stimulation.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital-Iranian Center of Neurological Research
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
tehran-ghods ave. -central organization of Tehran university of medical sciences-six floor
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Sarraf Payam
Position

Assisstant professor

Other areas of specialty/work

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Imam khomeini hospital

City

Tehran

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty