

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 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

###### Name

Payam Sarraf

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2424

###### Email address

p-sarraf@tums.ac.ir

##### 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 nocturia 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 referring

#### Method of measurement

Ask from the patients

### 2

#### Description

Nocturia

#### Timepoint

In each referring

#### 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

##### Full name of responsible person

Sarraaf Payam

##### Position

Assisstant professor

##### Other areas of specialty/work

##### Street address

Imam khomeini hospital

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##### Phone

+98 21 6119 2424

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##### Email

p-sarraaf@tums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Sarraaf Payam

##### Position

Assistant professor

##### Other areas of specialty/work

##### Street address

Imam khomeini hospital

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Sarraaf Payam

##### Position

Assistant professor

**Other areas of specialty/work**

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**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*