

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative effect of Percutaneous Tibial Nerve Stimulation versus Transcutaneous Posterior Tibial Nerve Stimulation efficacy in the treatment of Overactive Bladder Syndrome

#### Protocol summary

##### Summary

This interventional study is designed as a clinical trial in the form of a randomized, single blind, single centered method. Patients are selected from the outpatient referrals from Physical Medicine and Rehabilitation Clinics of Iran University of Medical Sciences. They are allocated by inclusion criteria to 2 groups of 24 for each by random number table. They are informed by the research therapeutic aims and each of them fill the consent form beforehand. Posterior Tibial Nerve Stimulation method is done with a single gauge 34 filliform needle inserted on the 5 cm to superior side of the medial Malleolus and posterior to tibia. The null electrode is located on the arch of the same foot by the surface Pad. The electrical stimulation is done by the 0.5 to 0.9 mAmp and 20 Hz current by the voltage which can induce plantar flexion on the toe or other toes. Each time stimulation is done for 30 mins for a single session, 3 sessions a week and total sessions of 12. On the second group this stimulation is done with the same parameters but with the surface pad electrode instead of the needle. Patients are asked to fill the questionnaire with items for urination episodes during wakefulness, sleep, Urgency and urinary incontinence during the last 7 days. The patients are asked to fill the Overactive Bladder Symptom Score (OABSS) form before and after the treatment also weekly during the treatment. They also asked to do the same monthly for the 6 months afterward. Incontinence - Quality Of Life Questionnaire (I-QOL) is also filled before and after the treatment and also 6 months later. Before the initiation of the study patients are asked for Fast Blood Sugar (FBS), those which are higher than 100 are excluded from the study. They also do the Urine Culture Test, only negative cases are included.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016101730339N1**  
Registration date: **2016-12-04, 1395/09/14**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-04, 1395/09/14

##### Registrant information

##### Name

Esmail Nouri

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8214 1229

##### Email address

drn94778@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Governmental - Iran University of Medical Sciences

##### Expected recruitment start date

2016-10-06, 1395/07/15

##### Expected recruitment end date

2017-06-21, 1396/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparative effect of Percutaneous Tibial Nerve Stimulation versus Transcutaneous Posterior Tibial Nerve Stimulation efficacy in the treatment of Overactive Bladder Syndrome

### Public title

Comparative effect of Percutaneous Tibial Nerve Stimulation versus Transcutaneous Posterior Tibial Nerve Stimulation efficacy in the treatment of Overactive Bladder Syndrome

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion Criteria: Criteria for Overactive Bladder by American Urological Association 2014 Guideline: Each of these Items: Urgency: Sudden feeling of voiding that is irressitable; Frequency: Urination for more than 7 times during wakefulness; Nocturia: Waking for uriantion for more than 1 time; Incontinence: Sudden Involuntary Urine Leakage; Minimun of 18 years for age; Irrisponsiveness to Medical Therapy or Behavioral Change Therapies like Lifestyle Modification and Exercise Therapy; No Usge of Anticholinergic Medications  
Exclusion Criteria: Diabetes Mellitus; Pregnancy or Intention for that; Urinary Tract Infection or Recurrent Urinary Tract Infection (For more than 4 times a year); Pacemaker Device; Neurological Diseases; Lack of Cooperation or Follow Up

### Age

From 18 years old

### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 48

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single 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 Iran University Of Medical Sciences

### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway. Tehran, Iran

### City

Tehran

### Postal code

1449614535

### Approval date

2016-10-02, 1395/07/11

### Ethics committee reference number

IR.IUMS.REC1395.9411524008

## Health conditions studied

### 1

#### Description of health condition studied

Overactive Bladder Syndrome

#### ICD-10 code

N32.8

#### ICD-10 code description

Other specified disorders of bladder Incl.: calcified, contracted or overactive Bladder

## Primary outcomes

### 1

#### Description

Overactive Bladder Symptom

#### Timepoint

0, 1 and 6 months after treatment

#### Method of measurement

Overactive Bladder Symtom Score

### 2

#### Description

Quality Of Life due to Incontinence

#### Timepoint

0, 1 and 6 months after treatment

#### Method of measurement

Incontinence - Quality Of Life Questionnaire Items

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

On the second group, Posterior Tibial Nerve Stimulation method is done with a surface pad electrod on the 5 cm to superior side of the medial Malleolus and posterior to tibia. The null electrod is located on the arch of the same foot by the surface Pad.The electrical stimulation is done by the 0.5 to 0.9 mAmp and 20 Hz current by the voltage

which can induce plantar flexion on the toe or other toes. Each time stimulation is done for 30 mins for a single session , 3 session a week and total sessions of 12.

**Category**

Treatment - Devices

**2****Description**

In the first group, Posterior Tibial Nerve Stimulation method is done with a single gauge 34 filliform needle inserted on the 5 cm to superior side of the medial Malleolus and posterior to tibia. The null electrode is located on the arch of the same foot by the surface Pad. The electrical stimulation is done by the 0.5 to 0.9 mAmp and 20 Hz current by the voltage which can induce plantar flexion on the toe or other toes. Each time stimulation is done for 30 mins for a single session , 3 session a week and total sessions of 12.

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Firouzgar Hospital

**Full name of responsible person**

Dr. Esmail Nouri

**Street address**

Department of Physical Medicine and Rehabilitation, Behafarin St., Karim Khan Zand Ave., Tehran , Iran

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Cancellor for Research , Iran University of Medical Sciences

**Full name of responsible person**

Dr. Javad Ali Musavi

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran , Iran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Cancellor for Research , Iran 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**

Iran University of Medical Sciences (IUMS), Faculty of Medicine

**Full name of responsible person**

Dr.Esmail Nouri

**Position**

Resident of Physical Medicine and Rehabilitation

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Associate Professor

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

Resident of Physical Medicine and Rehabilitation

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## 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*