

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 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

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code**Phone**

+98 21 8214 1229

Fax**Email**

drn94778@gmail.com, pghaboussi@yahoo.com

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

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

Full name of responsible person

Dr.Gholamreza Raissi

Position

Associate Professor

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code**Phone**

+98 21 8214 1229

Fax**Email**

graissi@gmail.com

Web page address

Person responsible for updating data

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

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code**Phone**

+98 21 8214 1229

Fax**Email**

drn94778@gmail.compghaboussi@yahoo.com

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