

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 refers 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 session 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 month afterward. Incontinence - Quality Of Life Questionnaire (I- QOL) is also filled before and after the treatment and also 6 month 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

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Email address

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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	Name of ethics committee Ethics Committee of Iran University Of Medical Sciences
Scientific title Comparative effect of Percutaneous Tibial Nerve Stimulation versus Transcutaneous Posterior Tibial Nerve Stimulation efficacy in the treatment of Overactive Bladder Syndrome	Street address Iran University of Medical Sciences, Shahid Hemmat Highway. Tehran, Iran
Public title Comparative effect of Percutaneous Tibial Nerve Stimulation versus Transcutaneous Posterior Tibial Nerve Stimulation efficacy in the treatment of Overactive Bladder Syndrome	City Tehran
Purpose Treatment	Postal code 1449614535
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 urination for more than 1 time; Incontinence: Sudden Involuntary Urine Leakage; Minimum of 18 years for age; Irrisponsiveness to Medical Therapy or Behavioral Change Therapies like Lifestyle Modification and Exercise Therapy; No Use 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	Approval date 2016-10-02, 1395/07/11
Age From 18 years old	Ethics committee reference number IR.IUMS.REC1395.9411524008
Gender Both	Health conditions studied
Phase N/A	1
Groups that have been masked No information	Description of health condition studied Overactive Bladder Syndrome
Sample size Target sample size: 48	ICD-10 code N32.8
Randomization (investigator's opinion) Randomized	ICD-10 code description Other specified disorders of bladder Incl.: calcified, contracted or overactive Bladder
Randomization description	Primary outcomes
Blinding (investigator's opinion) Single blinded	1
Blinding description	Description Overactive Bladder Symptom
Placebo Not used	Timepoint 0, 1 and 6 months after treatment
Assignment Parallel	Method of measurement Overactive Bladder Symptom Score
Other design features	2
Secondary Ids empty	Description Quality Of Life due to Incontinence
Ethics committees	Timepoint 0, 1 and 6 months after treatment
1	Method of measurement Incontinence - Quality Of Life Questionnaire Items
Ethics committee	Secondary outcomes empty
	Intervention groups
	1
	Description On the second group, Posterior Tibial Nerve Stimulation method is done with a surface pad electrode 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

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 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

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

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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

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Iran University of Medical Sciences, Shahid Hemmat
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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

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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