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 blinde, single centered method. Patients are selected from the outpatient refers from Physical Medicine and Rehabilitaion 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 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 flextion 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 electrod 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 Suger (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 Commitee 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 flextion 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 flextion 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