

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

the effect of posterior tibial nerve superficial stimulation on frequency of urination and score of quality of life in women with overactivity of bladder

Protocol summary

Summary

overactivity of bladder(OAB) is a syndrome with symptoms in storage phase and appearance with increase of frequency of urination and with a emergency condition.in recent years introductioned use of posterior tibial nerve stimulation (PTNS) as a simple, noninvasive, without side effects method for treatment of OAB .the purpose of this study is the evaluation of the effect of PTNS on women with overactivity of bladder. the current study that is double blind, randomized controlled trial that the patients and the examiner are blind and therapist is nonblind, including 67 females participants with OAB syndrome in two groups of test and control. During the 12 sessions PTNS are performed for two groups of course The flow rate is zero for the control group. the perineometry device is used to evaluation the strength of the pelvic floor muscles and Three questionnaires of 1-assess quality of life 2- ICIQ-OAB 3- ICIQ-UI SF and voiding diary form is used to evaluate symptoms and severity of the disease, before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111030814N1**
Registration date: **2017-03-27, 1396/01/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-27, 1396/01/07

Registrant information

Name

Behnaz Ghanei

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2017-03-10, 1395/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of posterior tibial nerve superficial stimulation on frequency of urination and score of quality of life in women with overactivity of bladder

Public title

the effect of posterior tibial nerve superficial stimulation on overactivity of bladder

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criterias:Female patients with overactive bladder; age between 25 to 60 years old; having the

ability to write and complete a consent form; lack of rehabilitation and physiotherapy for the pelvic floor dysfunction and overactive bladder exclusion criterias: pregnancy; Surgery for treatment of urinary incontinency ; improvement by anticholinergic drugs; stress incontinency; three months after childbirth; urinary tract infection; diabetes; neurological disease for example Parkinson; receive physiotherapy and electrotherapy during the time of the study; don't have the ability to learn the exercises and sports that are taught to the patient; mixed incontinency; receiving the medications for treatment of bladder overactivity at the same time with this study.

Age

From **25 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **67**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences Ethic Committee

Street address

HEZAR JERIB Street

City

Isfahan

Postal code

81746-73461

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

ir.mui.rec.1395.3.317

Health conditions studied

1

Description of health condition studied

overactivity of bladder

ICD-10 code

N39.4

ICD-10 code description

Other diseases of urinary system

Primary outcomes

1

Description

strength of pelvic floor muscles

Timepoint

before and after of intervention

Method of measurement

perineometry

2

Description

Evaluate symptoms of overactive bladder and its impact on quality of life and treatment outcomes

Timepoint

before and after of intervention

Method of measurement

ICIQ-OAB questionnaire

3

Description

Assessment and diagnosis of urinary incontinence

Timepoint

before and after of intervention

Method of measurement

ICIQ-UI SF questionnaire

4

Description

quality of life in patients with lower urinary tract disorders

Timepoint

before and after of intervention

Method of measurement

Questionnaire to assess quality of life in patients with lower urinary tract disorders in Iran

5

Description

The type and severity of lower urinary tract dysfunction

Timepoint

before and after of intervention

Method of measurement

voiding diary form

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, the posterior tibial nerve superficial stimulation has the following characteristics: flow rate of 0.5 to 10 mA, frequency of 20 Hz, duration of 200 micro second. number of sessions is 12 sessions. 3 sessions per week and the duration of each session is 30 minutes

Category

Treatment - Other

2

Description

For the control group, the intensity is zero and it is used only to create a placebo effect.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pelvic Floor Dysfunction Clinic, Faculty of Rehabilitation, Isfahan University of Medical Sciences

Full name of responsible person

Behnaz Ghanei

Street address

81746-73461, Hezar jerib Street, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reseach, Isfahan University of Medical Sciences

Full name of responsible person

Dr Zahra Sadat Rezaeean

Street address

81746-73461, Hezar Jerib Street, Isfahan

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Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for reseach, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Behnaz Ghanei

Position

Student MSc in Physiotherapy

Other areas of specialty/work

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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