Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 questionnair

3

Description
Assessment and diagnosis of urinary incontinence

Timepoint
before and after of intervention

Method of measurement
ICIQ-UI SF questionnair

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 miqro 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
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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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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

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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