Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparing effect of cutaneous posterior tibial nerve stimulation with medical treatment with Solifenacin in patients with overactive bladder

Protocol summary

Study aim
Comparing effect of cutaneous posterior tibial nerve stimulation with medical treatment with Solifenacin in patients with overactive bladder

Design
In a randomized controlled clinical trial, 74 patients were included over activity bladder patients are randomly assigned to two groups of drug therapy and tibial nerve stimulation.

Settings and conduct
This study was performed at the urology clinic of Shahid Beheshti Hospital in Hamadan, Iran. The study participants were randomly divided into two groups, each with 5 mg twice daily for 12 weeks during the preparation period. The other group received treatment twice a week for 12 weeks with posterior tibial nerve stimulation in the posterior region of the medial ankle. PTNS is performed by a TENS device with 20 Hz, 200 cycles / s of normal stimulation for 30 minutes per session. At each session, patients receive a motor response that includes the flexoin plantar toe. Initial results are reported as 3 days of urinary bladder questionnaire results (q-OAB), 3 months after treatment. Complications of treatment will also be reported and reported in all patients. Patients will be followed up two to one and three months after treatment to evaluate outcomes and potential complications.

Participants/Inclusion and exclusion criteria
The target groups in this study are all patients with overactive bladder referred to Beheshti Hospital of Hamedan, with a urinary recurrence complaint were diagnosed based on criteria. Minimum age of 18 years and urine culture negative are inclusion criteria and non-returning patients to follow up of intervention outcome are exclusion criteria

Intervention groups
Intervention group: Patients with overactive bladder treated by posterior tibial nerve stimulation The control group : Patients with overactive bladder treated with medical treatment with Solifenacin

Main outcome variables
Improve urinary incontinence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151123025202N4**
Registration date: **2019-11-28, 1398/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-28, 1398/09/07**
Update count: **0**

Registration date
2019-11-28, 1398/09/07

Registrant information

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Abbas Moradi

Name of organization / entity
Hamedan University of Medical Of Science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-21, 1398/08/30

Expected recruitment end date
2020-07-21, 1399/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing effect of cutaneous posterior tibial nerve stimulation with medical treatment with Solifenacin in patients with overactive bladder

Public title
treatment of overactive bladder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical Diagnosis of overactive bladder minimum age of 18 years old negative result of Urine culture
Exclusion criteria:
pregnant women People with Pacemaker Inflammatory or neurological origin History of spinal cord trauma Central nervous system lesions Metabolic disease or genetic syndromes history of abdominal surgery History of pelvic fractures Eurogenital Anomalies history of taking anticholinergic drugs for six months Psychological Disorders
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 74 sealed envelopes will be used which in 37 letter M envelope means Medical treatment and in 37 letter S envelope mean tibial nerve stimulation. All envelopes are available for physician, after mixing randomly removed and opened . Depending on whether the envelope contains the letter M or S, the individual will be assigned to the medical treatment or tibial nerve stimulation group.
Blinding (investigator's opinion)
Not 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 Hamedan University of Medical Science
Street address
Shahid Fahmideh Ave, Vice-Chancellor for Research and Technology
City
Hamedan
Province
Hamadan
Postal code
6517838697
Approval date
2019-06-14, 1398/03/24
Ethics committee reference number
IR.UMSHA.REC.1398.237

Health conditions studied

1

Description of health condition studied
Over Active Bladder
ICD-10 code
N32.81
ICD-10 code description
Overactive bladder

Primary outcomes

1

Description
Improved quality of life due to urinary incontinence three months after treatment The outcome of this study is evaluated by a standard questionnaire.
Timepoint
1 and 3 months after treatment
Method of measurement
The q-OAB questionnaire will be used to collect the frequency of urinary frequency, urgency, and urgency incontinence for 3 days. q-OAB is a quality of life questionnaire designed to assess symptoms of health-related symptoms and quality of life (HRQL) in patients with or without incontinence and OAB. q-OAB contains 4 subset include social, interaction, concern, coping and HRQL

Secondary outcomes

1

Description
Improving patients' quality of life is a secondary outcome of this study
Timepoint

1 and 3 months after treatment onset

Method of measurement

Outcoms are measured using the summary form of the Bladder Hyperactivity Questionnaire, which contains 25 questions. The questionnaire consists of two parts: 6 questions (symptoms of bladder hyperactivity) and 19 questions (quality of life associated with bladder hyperactivity).

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

2

Description

Control group: Receiving Solifenacin is given 5 mg twice daily for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti hospital

Full name of responsible person
dr Mohammadreza Niko

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Eram Blv, Ghaem Sq, Hamedan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

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Position
Coach

Latest degree
Master

Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Objectives and methods of the study can be published

When the data will become available and for how long
From 6 months after printing the results

To whom data/document is available
Medical science researchers

Under which criteria data/document could be used
It is permissible to cite the source

From where data/document is obtainable
Correspondence email

What processes are involved for a request to access data/document
Send and receive email

Comments