Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of medical treatment (Duloxetine andSsolifenacine) and Transcutaneous tibia nerve stimulation in the treatment of post- prostatectomy urinary incontinence

Protocol summary

Study aim

Comparison of the effect of duloxetine and solifenacin, with stimulation of the posterior tibial nerve in the treatment of post-prostatectomy.urinary incontinence

Design

A controlled, parallel-group, single-blind, randomized, phase 2-3 clinical trial on 60 patients. The rand function of Excel software will be used for randomization

Settings and conduct

The study will be conducted in the urology department of Shahid Beheshti Hospital in Hamedan, on patients with urinary incontinence caused by prostate surgery. After removing the Foley catheter, a group of patients underwent stimulation of the posterior tibial nerve in addition to strengthening the anterior pelvic floor muscles to control urinary incontinence. Electrical stimulation of posterior tibial nerve during 12 sessions, 3 sessions per week, each session will be 30 minutes. The other group should take 20 mg daily for 8 weeks and 10 mg solifenacin daily for 8 weeks. The person analyzing the data should be unaware of the intervention groups (blinded).

Participants/Inclusion and exclusion criteria

The participants will be patients with urinary incontinence. inclusion criteria: urinary incontinence due to prostate surgery and the patient's consent to participate in the study. The conditions for not entering the study are: urinary infection during the treatment process, prostate cancer recurrence, the presence of a pacemaker, and the inability to perform Kegel exercises.

Intervention groups

The first group: in addition to strengthening the anterior muscles of the pelvic floor to control urinary incontinence, the posterior tibial nerve stimulation method will also be used. The second group: Instead of stimulating the posterior tibial nerve, they will receive medical treatment.

Main outcome variables

Change in frequency of urinary incontinence within 24 hours, quality of life related to urinary incontinence, side effects of drug treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N41**
Registration date: **2024-10-03, 1403/07/12**
Registration timing: **prospective**

Last update: **2024-10-03, 1403/07/12**
Update count: **0**

Registration date

2024-10-03, 1403/07/12

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

2024-10-22, 1403/08/01

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of medical treatment (Duloxetine andSsolifenacine) and Transcutaneous tibia nerve stimulation in the treatment of post-prostatectomy urinary incontinence

Public title
Treatment of post -radical prostatectomy urinary incontinence, comparison of drug treatment and posterior tibial nerve stimulation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Total prostatectomy and urinary incontinence afterwards Declaration of consent to participate in the study
Exclusion criteria:
Urinary tract infection during the treatment process History of previous surgery for urinary incontinence Recurrence of prostate cancer The presence of a pacemaker Inability to do Kegel exercises
Age
No age limit
Gender
Male

Phase
2-3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The envelope method will be used for random allocation. They will be randomly assigned to intervention and control groups. 60 cards are prepared and on 30 cards the letter A means the first group and on the other 30 the letter B means the second group is written and each one is put inside an envelope with aluminum foil and the lid is glued and placed inside a box. At the time of patients' arrival, one of the letter envelopes will be randomly selected and opened. According to the chosen letter (A or B), the patient will be assigned to the nerve stimulation or drug therapy group
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the type of interventions, there is no possibility of blinding the patient and the physicians. Only, the person analyzing the data will not know about the treatment groups until the end of the analysis
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan Univercity of Medical Science
Street address
Shahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838697
Approval date
2024-09-14, 1403/06/24
Ethics committee reference number
IR.UMSHA.REC.1403.380

Health conditions studied

1

Description of health condition studied
Urinary incontinence
ICD-10 code
R32
ICD-10 code description
Unspecified urinary incontinence

Primary outcomes

1

Description
Changes in the frequency of urinary incontinence
Timepoint
Before treatment, 4th and 8th week after treatment
Method of measurement
Asking the patient

2

Description
Quality of life related to urinary incontinence
Timepoint
Before treatment, 4th and 8th week after treatment
Method of measurement
Questionnaire for evaluating the quality of life of patients with urinary incontinence

Secondary outcomes

1

Description
Side effects of treatment
Timepoint
4th and 8th week after treatment
Method of measurement
Clinical examination and taking history from the patient

Intervention groups

1

Description
Intervention group: Since the removal of the Foley catheter (about 20 days after the operation), in addition to strengthening the anterior muscles of the pelvic floor to control urinary incontinence,also the posterior tibial nerve stimulation will be used. Electrical stimulation of the posterior tibial nerve will be performed using Enraf model 438 DYNATRON device made in the Netherlands. The characteristics of the current include: intensity of 0.5-10 mA, frequency of 20 Hz, pulse length of 200 microseconds, of course, the intensity of the current increases up to the threshold of motor nerve stimulation, which is characterized by flexion of the big toe. To perform electrical stimulation, the negative electrode (cathode) is placed behind the inner ankle on the left side of the body and the positive electrode (anode) is placed 10 cm above the cathode. The number of posterior tibial nerve stimulation sessions will be 12 sessions, 3 sessions each week and the duration of each session will be 30 minutes.
Category
Rehabilitation

2

Description
Intervention group: To control urinary incontinence, duloxetine and solifenacin tablets will be prescribed. Dose of Duloxetine, take 2 tablets of 20 mg daily (one every 12 hours) for 8 weeks and Sulifnacin one tablet (10 mg) daily after breakfast for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
dr Mohsen Alemi
Street address
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
Full name of responsible person
Abbas Moradi
Position
مربی
Latest degree

Master
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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
No - There is not a plan to make this available
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data can be shared except for authors names
When the data will become available and for how long
From 2026 onwards it is permissible
To whom data/document is available
Clinical professionals and Researchers in all fields
Under which criteria data/document could be used
For treatment of patients and develop research and science
From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study
What processes are involved for a request to access data/document
Send and receive email
Comments