Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Survey the addition of tadalafil to tamsulosin in the treatment of acute urinary retention in patient with benign prostatic hyperplasia

Protocol summary

Summary

The aim of this study was to evaluate the effects of adding tadalafil to tamsulosin for the treatment of acute urinary retention in patients with benign prostatic hyperplasia. A double-blind randomized clinical trial Patients in the study, 80 patients with acute urinary retention in an emergency. After draining urine with nelaton,accidentally, Tadalafil 10 mg with a 0.4 mg Tamsulosin capsule or Tamsulosin with placebo for seven days is given.Then 24 hours and a week later with a phone call from the patient's urinary retention, he asked again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041833506N1**
Registration date: **2017-09-13, 1396/06/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-13, 1396/06/22

Registrant information

Name
zeinab ameli
Name of organization / entity
sabzevar university of medical scinence
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Iran (Islamic Republic of)
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+98 51 3859 6778
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ameliz88@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2016-09-23, 1395/07/02

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the addition of tadalafil to tamsulosin in the treatment of acute urinary retention in patient with benign prostatic hyperplasia

Public title

Evaluation of the effect of tadalafil on the treatment of acute urinary retention

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who refused to participate in the study and signed informed consent form; Age over 50 years;Symptoms of LUTS or urinary tract symptoms.Exclusion criteria: Discontent of continued cooperation with the study for any reason and at any stage of the research; Age less than 50 years; Proven history of prostate cancer; Prostatitis; Urethral obstruction caused by tumor; known tumor disease caused by lower urinary tract (bladder stones, neurogenic bladder, bladder cancer, urethral stricture); Surgery lower urinary tract (bladder, prostate and urethra); Nitrate consumption at the same time; Acute urinary retention after surgery

Age

From **45 years** old to **6 years** old

Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
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
Sabzevar University of Medical Sciences
Street address
Tohid Town, Medical Science Paradise
City
Sabzevar
Postal code
Approval date
2016-09-22, 1395/07/01
Ethics committee reference number
IR.MEDSAB.REC.1395.96

Health conditions studied

1

Description of health condition studied
acute urinary retention
ICD-10 code
N40
ICD-10 code description
Hyperplasia of prostate

Primary outcomes

1

Description
Acute Urinary Retention
Timepoint
24 hours and one week after the intervention.
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, 10 mg Tadalafil tablets plus 0.4 mg Tamsulosin capsule once a day for seven days
Category
Treatment - Drugs

2

Description
Placebo pills (in the same way, the size and color of tadalafil made from starch) with Tamsulosin capsules 0.4 milligrams per night for one week
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Vasei Hospital of Sabzevar
Full name of responsible person
Zeinab Ameli
Street address
Vasei Hospital of Sabzevar
City
Sabzevar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Hamidreza Baghani Aval
Street address
Sabzevar, Medical Science Pardis
City
Sabzevar
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Zeinab Ameli

Position

General Practitioner

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