

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 6778

Email address

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
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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