# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Zeinab Ameli

**Position**

General Practitioner

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Web page address**

## 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*