Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The assessment of effect of Tadalafil on lower urinary tract symptoms secondary to benign prostatic hyperplasia on patients treated with standard medication

Protocol summary

Summary
The purpose of this double blind, clinical trial was to evaluate the effect of Tadalafil on lower urinary tract symptoms to benign prostatic hyperplasia (BPH). A total of 132 patients with obstructive and irritation urinary symptom who referred to out-patient department of Razi hospital and two private urology clinics in Guilan province were randomly administered 10mg oral tadalafil or placebo at 10 pm every night beside standard prior regimen and medical anti-BPH treatment for 12 weeks. Severity of obstructive and irritation symptoms (according to IPSS international questionnaire), quality of life (considering urinary symptoms), and Qmax in uroflometery were measured and compared between groups.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201008094541N1**
Registration date: **2010-10-18, 1389/07/26**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2010-10-18, 1389/07/26

Registrant information
Name
Ali Roushani
Name of organization / entity
Urology Research Center
Country
Iran (Islamic Republic of)
Phone
+98 13 1552 5259
Email address
a_roshani@gums.ac.ir

Recruitment status
Recruitment complete
Funding source
Research Assistance of Guilan University of Medical Sciences

Expected recruitment start date
2009-02-05, 1387/11/17
Expected recruitment end date
2009-10-05, 1388/07/13
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The assessment of effect of Tadalafil on lower urinary tract symptoms secondary to benign prostatic hyperplasia on patients treated with standard medication

Public title
The assessment of effect of Tadalafil on lower urinary tract symptoms secondary to benign prostatic hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients with score > 8 and without any indications for prostatic surgery such as recurrent retention, persistent gross hematuria, permanent urinary infections associated with BPH, renal function failure and hydronephrosis, bladder stone due to BPH, under previous standard medical treatment with prazocine (max doze 10mg) daily with or without Finastride (5 mg,

daily, for 3 months). Response to medication should be in plateau level

Age
From **45 years** old to **80 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **132**

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
Guilan University of Medical Sciences

Street address
Guilan University of Medical Sciences

City
Rasht

Postal code
41448-95655

Approval date
2008-12-20, 1387/09/30

Ethics committee reference number
5012

Health conditions studied

1

Description of health condition studied
Benighn Prostatic Hypertrophia

ICD-10 code
N40

ICD-10 code description
Benign Prostatic Hypertrophia

Primary outcomes

1

Description
International score of prostatic signs & symptoms

Timepoint
Baseline and 3 months after the intervention

Method of measurement
IPSS: International Prostatic Symptom Score

Secondary outcomes

1

Description
Urinary satisfaction

Timepoint
Baseline and 3 months after the intervention

Method of measurement
(IPSS: International Prostatic Symptom Score)

2

Description
maximum urinary flow

Timepoint
Baseline and 3 months after the intervention

Method of measurement
Uroflometry

Intervention groups

1

Description
Placebo tablet at 10 pm every night for 12 weeks

Category
Placebo

2

Description
Tadalafil tablet 10mg at 10 pm every night for 12 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Urology clinic of Razi hospital

Full name of responsible person
Dr. Amin Afshari Moghadam (Urology resident)

Street address
Razi Hospital

City
Rasht

2

Recruitment center

Name of recruitment center
Dr. Ali Hamidi Madani's clinic
Full name of responsible person
Dr. Ali Hamidi Madani
Street address
Dr. Ali Hamidi Madani's clinic
City
Rasht

3

Recruitment center
Name of recruitment center
Dr. Ali Roushani's clinic
Full name of responsible person
Dr. Ali Roushani
Street address
Dr. Ali Roushani's clinic
City
Anzali
Full name of responsible person
Dr. Amin Afshari Moghaddam
Position
Co worker/Resident
Other areas of specialty/work
Street address
Urology Research Center, Guilan University of Medical Sciences
City
Rasht
Postal code
41448-95655
Phone
+98 13 1552 5259
Fax
+98 13 1552 5259
Email
urc@gums.ac.ir
Web page address
www.urc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr. Abdolrasoul Sobhani, Research Assistant Guilan University of Medical Sciences
Street address
Guilan University of Medical Sciences
City
Rasht
Grant name
معاونت پژوهشي دانشگاه علوم پزشكي وخدمات بهداشتي- درماني گيلان
Grant code / Reference number
10506
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan 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
Urology Research Center

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urology Research Center
Full name of responsible person
Dr. Ali Roushani
Position
Associatet Professor of Guilan University of Medical Sciences
Other areas of specialty/work
Street address
Urology Research Center, Razi Hospital
City
Rasht
Postal code
41448-95655
Phone
+98 13 1552 5259
Fax
+98 13 1552 5259
Email
urc@gums.ac.ir
Web page address
www.urc.ir

Person responsible for updating data

Contact
Name of organization / entity
Urology Research Center
Full name of responsible person
Samaneh Esmaeili
Position
Secretor of Urology Research Center/Bachelor
Other areas of specialty/work
Street address
Urology Research Center, Razi Hospital
City
Rasht

Postal code
41448-95655
Phone
+98 13 1552 5259
Fax
+98 13 1552 5259
Email
samaneh_815@yahoo.com; urc@gums.ac.ir
Web page address
www.urc.ir

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