

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 uroflometry 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 prazosin (max doze 10mg) daily with or without Finasteride (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

Benign Prostatic Hypertrophy

ICD-10 code

N40

ICD-10 code description

Benign Prostatic Hypertrophy

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 پژوهشی دانشگاه علوم پزشکی و خدمات بهداشتی-درمانی گیلان

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

Associate 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

Secretary 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*