

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation and comparison of the effect of Tadalafil and placebo on nighttime frequency refractory to treatment with alfa-adrenergic inhibitors in males with LUTS/BPH referred to Razi Hospital

Protocol summary

Summary

Nocturnal frequency or nocturia is one of the most common and challengeable complaints related to lower urinary tract symptom (LUTS). Nocturia is to arise one or more at night to void. Nocturia affects quality of life and health of patients. This study is a pilot randomized double blind control trial that would be conducted in Razi Educational Hospital on 100 men with nocturia due to LUTS/BPH. Patients randomly based on randomized blocks with sequence 4 divided in two groups of 50; one group received tadalafil 5mg daily plus tamsulosin 0.4 mg daily as a treatment for LUTS and the other group received tamsulosin 0.4mg daily plus placebo. The patients will visit at weeks of 2, 4, 8 and 12, again. At each visit, frequency of urination during the night would be asked and recorded, IPSS questionnaire will be completed to assess symptoms of prostate and uroflowmetry will be performed. PSA test and ultrasound of the kidneys and bladder and calculate urinary residues would be done before and after treatment. Blinding for both groups (for both study subjects and study information analysis and monitoring committee) will be carried out.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208091853N9**
Registration date: **2016-05-13, 1395/02/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-13, 1395/02/24

Registrant information

Name

Siavash Falahatkar

Name of organization / entity

Urology Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 5259

Email address

urc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effect of Tadalafil and placebo on nighttime frequency refractory to treatment with alfa-adrenergic inhibitors in males with LUTS/BPH referred to Razi Hospital

Public title

The effect of Tadalafil on night time frequency refractory to treatment with alfa-adrenergic inhibitors

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: age above 50, refractory LUTS to life style change such as: quite smoking and limit consumption of liquid alcohol and caffeine before sleeping, having moderate physical activity. Exclusion criteria: BMI above 30kg/m², surgery indication for BPH, urinary residual above 200CC, chronic pelvic pain syndrome (CPPS) over active bladder (OAB) urethral or bladder stone, history of pervious neurogenic bladder ureteral or bladder stone history of urethral bladder or prostate malignancy, PSA above 4 ng/ml or PSA between 4-10 ng/ml with positive biopsy for prostate malignancy, active urinary tract infection (UTI) or active sexual transmitted disease (STD)

Age

From **50 years** old to **149 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics committee of Guilan University of Medical Sciences

Street address

Opposite Sepah Bank, Western Shahid Beheshti Blvd., Gaz Square

City

Rasht

Postal code

41938-93345

Approval date

2014-06-02, 1393/03/12

Ethics committee reference number

1930111208

Health conditions studied

1

Description of health condition studied

Nocturnal frequency or nocturia

ICD-10 code

R35

ICD-10 code description

Polyuria

Primary outcomes

1

Description

Nocturia

Timepoint

2, 4, 8 and 12 weeks after intervention

Method of measurement

Examination and evaluation by Night Time Voiding Diary, SPSS and Quality of Life score questionnaires, and uroflowmetry (Maximum Flow Rate or Qmax)

Secondary outcomes

empty

Intervention groups

1

Description

tadalafil 5mg, daily for 12 weeks Made in Iran

Category

Treatment - Drugs

2

Description

placebo, daily for 12 weeks Made in Iran

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Keivan Gholamjani Moghaddam (supervisor)

Street address

Sardar Jangal Street, Razi hospital

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Investigator

Street address

Sardar Jangal Street, Razi hospital, Urology Research Centre

City

Rasht

Grant name

10506

Grant code / Reference number

32

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, 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**

Guilan University of Medical Sciences

Full name of responsible person

Dr. Keivan Gholamjani Moghadam

Position

Co worker/General Physician

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Person responsible for scientific inquiries

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Urology Research Center

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Position

Proffesor of Guilan University of Medical Sciences

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Full name of responsible person

Samaneh Esmaeili

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Master/Research Expert

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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