Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effects of Alternate-Day Tadalafil and Tamsulosin Use with Daily Tamsulosin Use on Lower Urinary Tract Symptoms and Sexual Dysfunction in Men with Benign Prostatic Hyperplasia

Protocol summary

Study aim

To compare the effectiveness of alternating daily tadalafil 5 mg plus tamsulosin 0.4 mg versus daily tamsulosin 0.4 mg in improving lower urinary tract symptoms and sexual dysfunction in men with symptomatic benign prostatic hyperplasia (BPH).

Design

A randomized, parallel-group, controlled clinical trial with two study arms. A total of 62 participants will be randomly allocated (1:1) using block randomization with a block size of four.

Settings and conduct

The study will be conducted among men with symptomatic benign prostatic hyperplasia referred to the Urology Clinic of Modares Hospital, Tehran. 62 eligible participants will be randomly allocated to two intervention groups. One group will receive daily tamsulosin, while the other will receive alternating daily tadalafil and tamsulosin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men aged ≥50 years with symptomatic benign prostatic hyperplasia (BPH), IPSS >10, prostate volume >20 mL, able to complete the 12-week follow-up, and providing written informed consent. Criteria for non-entry: Suspected or confirmed prostate cancer, previous prostate or lower urinary tract surgery, significant urinary tract disorders, severe renal or hepatic impairment, recent myocardial infarction or stroke, unstable cardiovascular disease or uncontrolled diabetes, current use of nitrates or medications contraindicated with tadalafil, and known contraindications or hypersensitivity to tamsulosin or tadalafil.

Intervention groups

Intervention group 1: Participants will receive tamsulosin 0.4 mg once daily for 12 weeks. Intervention group 2: Participants will receive an alternating regimen of tadalafil 5 mg and tamsulosin 0.4 mg on alternate days for 12 weeks, such that one medication (either tadalafil or tamsulosin) is taken each day.

Main outcome variables

ower urinary tract symptoms (LUTS) Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251121068066N14**
Registration date: **2026-08-15, 1405/05/24**
Registration timing: **prospective**

Last update: **2026-08-15, 1405/05/24**
Update count: **0**

Registration date

2026-08-15, 1405/05/24

Registrant information

Name

Atiyeh Hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-11, 1405/06/20

Expected recruitment end date

2026-11-06, 1405/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Alternate-Day Tadalafil and Tamsulosin Use with Daily Tamsulosin Use on Lower Urinary Tract Symptoms and Sexual Dysfunction in Men with Benign Prostatic Hyperplasia

Public title

Evaluation of the Effect of Alternating Tadalafil and Tamsulosin Compared with Tamsulosin Alone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men aged ≥50 years. Clinical diagnosis of symptomatic benign prostatic hyperplasia (BPH). International Prostate Symptom Score (IPSS) >10. Prostate volume >20 mL. Ability to complete study questionnaires and participate in the 12-week follow-up. No use of BPH medications within the previous 2 months or completion of an appropriate washout period. Provision of written informed consent.

Exclusion criteria:

PSA ≥4 ng/mL without prior evaluation and exclusion of prostate malignancy. History or clinical suspicion of prostate cancer. Previous prostate or lower urinary tract surgery. Acute urinary retention or current need for indwelling catheterization. Active urinary tract infection, urethral stricture, bladder stones, or neurogenic bladder. Severe renal impairment (eGFR <30 mL/min/1.73 m^2) or severe hepatic impairment. Myocardial infarction or stroke within the previous 3 months. Symptomatic hypotension, unstable cardiovascular disease, or uncontrolled diabetes. Symptomatic hypotension or unstable cardiovascular disease. Uncontrolled diabetes mellitus. Current use of nitrates or medications with clinically significant interactions with tadalafil. Known hypersensitivity or contraindication to tamsulosin or tadalafil.

Age

From **50 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were recruited using convenience sampling. Treatment codes were prepared and placed in blinded packages before the start of the study. After eligibility screening and obtaining written informed consent, participants were sequentially entered into the predetermined randomization sequence according to their order of enrollment. Participants were randomly allocated in a 1:1 ratio to the intervention or control group using block randomization with a block size of four. The corresponding treatment assignment was placed in a sequentially numbered, opaque, sealed envelope and will be performed by an independent urologist who is not involved in the research team.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of School of Medicine - Shahid Beheshti University of Medical Sciences

Street address

School of Medicine, Shahid Beheshti University of Medical Sciences, Koodak-Yar Street, Daneshjoo Boulevard, Velenjak,Tehran.

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Approval date

2026-07-28, 1405/05/06

Ethics committee reference number

IR.SBMU.MSP.REC.1405.319

Health conditions studied

1

Description of health condition studied

Benign Prostatic Hyperplasia; BPH

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

Lower urinary tract symptoms (LUTS)

Timepoint

Lower urinary tract symptoms will be evaluated at baseline (prior to treatment) and at 12 weeks following treatment.

Method of measurement

Lower urinary tract symptoms will be assessed using the International Prostate Symptom Score (IPSS) questionnaire. This validated instrument evaluates the severity of urinary obstructive and irritative symptoms, with higher scores indicating greater symptom severity.

2

Description

Sexual function

Timepoint

Sexual function will be assessed at baseline and 12 weeks after treatment.

Method of measurement

Sexual function will be evaluated using the International Index of Erectile Function (IIEF) questionnaire. This 15-item instrument assesses erectile function and sexual satisfaction.

Secondary outcomes

1

Description

Peak urinary flow rate (Qmax)

Timepoint

Peak urinary flow rate will be assessed at baseline and at 12 weeks following treatment.

Method of measurement

Peak urinary flow rate will be measured by uroflowmetry. The outcome will be reported as milliliters per second (mL/s).

2

Description

Post-void residual urine volume

Timepoint

Postvoid residual urine volume will be assessed at baseline and at 12 weeks after treatment.

Method of measurement

Postvoid residual urine volume will be measured using a urinary catheter.

Intervention groups

1

Description

Intervention group 1:Participants will receive 0.4 mg of tamsulosin from Actover brand daily for 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Participants will receive an alternating regimen of tadalafil 5 mg (Mofid) and tamsulosin 0.4 mg (Actover) on alternate days for 12 weeks, such that one medication (tadalafil or tamsulosin) is taken each day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology Clinic, Modares Hospital

Full name of responsible person

Dr. Bahram Bandeh Yazdani

Street address

Saadat Abad Intersection, Yadegar-e Imam Highway, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Third Floor, School of Medicine, beside Taleghani Hospital, Evin, Shahid Chamran Highway, Tehran.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mohammad Soleimani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Assistant student

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Medical doctor

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available