Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of Prostanen soft capsule with tamsulosin in the treatment of patients with benign prostatic hyperplasia (Single blind randomised Clinical Trial)

Protocol summary

Study aim

Comparing the efficacy of prostanen and tamsulosin in the treatment of symptoms of benign prostatic hyperplasia (BPH).

Design

In this randomized clinical trial with parallel control group, 128 patients older than 50 years suffering from benign prostate hyperplasia with sequential randomized allocation method by the help of sealed envelopes will be assigned to one of two groups (prostanen or tamsulosin) and will receive the related intervention for two months. Outcome processor is blinded to the treatment allocation; they only have access to the codes (A or B) without knowing which drug corresponds to each code.

Settings and conduct

Patients referring to Shahid Mofateh clinic of Yasuj suffering from benign prostatic hyperplasia who candidates for medical treatment will be assigned with sequential randomization method in one of two groups. In the first group, prostanen and in the second group, tamsulosin will be prescribed. Two months later, the patients will be re-examined, and the success of treatment measured and recorded according to symptoms and the International Prostatic Symptom Score of patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men older than 50 years old with benign prostatic hyperplasia with International Prostatic Symptom Score less than 20, signed an informed consent form Exclusion criteria: Men suffering from benign prostate hyperplasia with azotemia, active urinary tract infection, and patients with a history of herbal or medical allergy

Intervention groups

Intervention group: In the first group, every night, one soft prostanen capsule was prescribed with a glass of water for two months. Control group: every night one 0.4 mg tamsulosin oral capsule prescribed with a glass of water for two months.

Main outcome variables

Change of symptoms of benign prostatic hyperplasia according to the International Prostatic Symptom Score criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081011001323N32**
Registration date: **2025-06-08, 1404/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-08, 1404/03/18**
Update count: **0**

Registration date

2025-06-08, 1404/03/18

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-05, 1404/01/16

Expected recruitment end date

2026-04-05, 1405/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Prostanen soft capsule with tamsulosin in the treatment of patients with benign prostatic hyperplasia (Single blind randomised Clinical Trial)

Public title

Comparison of the effect of Prostanen with tamsulosin in the treatment of benign prostatic hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men older than 45 years old suffering from Benign Prostatic Hyperplasia (BPH) candidate for medical treatment with International Prostatic Symptom Score (IPSS) less than 20

Exclusion criteria:

Men with benign prostatic hyperplasia with azotemia Patients with active urinary tract infection Patients with history of herbal or medical allergy Patients suspicions for prostatic cancer

Age

From **50 years** old to **85 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Patients are allocated to one of two treatment groups (Prostanan capsule or Tamsulosin) using simple randomization. This is done through sealed, opaque envelopes containing treatment codes (A = Prostanan, B = Tamsulosin). Each patient randomly selects one sealed envelope at the time of enrollment, ensuring allocation concealment. This method corresponds to the well-established approach known as "Simple Randomization using sealed opaque envelopes" Blinding: The medication is dispensed by an independent researcher who is not involved in patient assessment and follows the randomization list. The person assessing patient symptoms is blinded to the treatment allocation; they only have access to the codes (A or B) without knowing which drug corresponds to each code. Patients and the drug dispenser may not be blinded, but the outcome assessor is. Thus, this is a single-blind design with blinded outcome assessors assessing the patients' symptoms. The assessors are unaware of the patients' allocation and only have access to the codes.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this randomised, single blind clinical trial, outcome assessors will be blinded.The medication is dispensed by an independent researcher who is not involved in patient assessment and follows the randomization list. The person assessing patient symptoms is blinded to the treatment allocation; they only have access to the codes (A or B) without knowing which drug corresponds to each code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Approval date

2025-05-10, 1404/02/20

Ethics committee reference number

IR.YUMS.REC.1404.032

Health conditions studied

1

Description of health condition studied

Benign prostatic hyperplasia

ICD-10 code

Hyperplasi

ICD-10 code description

N40

Primary outcomes

1

Description

Change of obstructive and irritative symptoms of prostatic hyperplasia

Timepoint

At the start of study and two month later

Method of measurement

Using international prostatic symptom score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Every night, one soft prostanen capsule was prescribed with a glass of water for two months.

Category

Treatment - Drugs

2

Description

Control group: every night, one 0.4 mg oral capsule of tamsulosin was prescribed with one glass of water for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh clinic

Full name of responsible person

Sadrolleh Mehrabi

Street address

Shahid Mofateh clinic, Montazeri street,Yasuj,Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591951176

Phone

+98 74 3322 1813

Email

sadrollahm@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Amir hossain dosti motlagh

Street address

Deputy of research, Yasuj University of Medical Sciences,, Motahari St

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Phone

+98 74 3334 6074

Email

amirhosseindoustimotlagh@gmail.com

Grant name

Zardband company

Grant code / Reference number

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

No

Title of funding source

Doing clinical trial of soft capsule of prostanen

Proportion provided by this source

100

Public or private sector

Private

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

Yasouj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Shahid Mofateh clinic, Montazeri street,Yasuj,Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Phone

+98 74 3322 1812

Email

sadrollahm@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Sadrollah Mehrabi

Position
Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree
Subspecialist

Other areas of specialty/work
Urology

Street address
Shahid Mofateh clinic, Montazeri street,Yasuj,Iran

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Phone
+98 74 3322 1812

Email
sadrollahm@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Sadrollah Mehrabi

Position
Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree
Subspecialist

Other areas of specialty/work
Urology

Street address
Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Phone
+98 74 3322 9297

Email
dr.mehrabi@yums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available