Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of the herbal medicine Prostatan® on lower urinary tract symptoms severity of patients with benign prostatic hyperplasia: A randomized controlled trial

Protocol summary

Study aim
Determining the efficacy of the herbal medicine Prostatan® on improvement of lower urinary tract symptoms severity in patients with benign prostatic hyperplasia

Design
A concealed, randomized, blinded controlled clinical trial with a parallel group design of 80 patients, phase 3, randomization done by random allocation software.

Settings and conduct
The study will be carried out at the urology clinics of Al-Zahra and Khorshid hospitals, in Isfahan, Iran. Patients with benign prostatic hyperplasia will be randomized into the case or control groups. Demographic and clinical data will be recorded. The Persian version of the IPSS questionnaire will be filled out before and three months after receiving intervention. PSA level will be assessed at baseline and three months after intervention.

Participants/Inclusion and exclusion criteria
Patients with urinary symptoms due to benign prostatic hyperplasia who are older than 40 years of age will be included

Intervention groups
Patients in the case group will receive Prostatan, while patients in the control group will receive a placebo.

Main outcome variables
IPSS score; PSA level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150420021869N6**
Registration date: **2023-05-14, 1402/02/24**
Registration timing: **prospective**
Last update: **2023-05-14, 1402/02/24**
Update count: **0**

Registration date
2023-05-14, 1402/02/24

Registrant information

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Farshad Gholipour

Name of organization / entity
Tehran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of the herbal medicine Prostatan® on lower urinary tract symptoms severity of patients with benign prostatic hyperplasia: A randomized controlled trial

Public title
Effect of Prostatan on symptoms of patients with benign prostatic hyperplasia

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed with benign prostatic hyperplasia based on clinical diagnosis Moderate lower urinary tract symptoms due to IPSS score Age more than 40 years old
Exclusion criteria:
Not having consent to enter the study Patients having lower urinary tract symptoms due to other causes including ureteral stricture, prostate cancer, bladder neck cancer, bladder or ureteral stone, neurogenic bladder, or urinary tract infection Patients with liver or kidney failure
Age
From **40 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients are randomly assigned to 2 control and intervention groups by random allocation software in individual units. Block randomization will be used with a block size of 6. Sealed envelopes containing a number attributed to each intervention group will be used. The patient and the practitioner are blinded to the intervention received.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is a triple blind study in which the participants and the clinical caregiver and the analyzer are blind and patient group are selected by random allocation software. Randomly assigned to the case or control group (Prostatan and placebo). Then, if he is in any group, he will receive a drug that is appropriate for the group, and both pills are similar in shape. But patients and caregivers do not know which medication or placebo they received, and outcome assessors do not know the participants and record their findings based on patient numbers.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of isfahan University of Medical Sciences
Street address
Hezar-Jarib Blvd.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-04-03, 1402/01/14
Ethics committee reference number
IR.MUI.MED.REC.1402.023

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia
ICD-10 code
D29.1
ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
IPSS score
Timepoint
At baseline and 3 months after intervention
Method of measurement
IPSS questionnaire

Secondary outcomes

1

Description
Serum PSA level
Timepoint
At baseline and 3 months after intervention
Method of measurement
Blood sampling

Intervention groups

1

Description
Intervention group: Prostatan drug (GOLDAROU company Isfahan_Iran) will be prescribed in this group. dosage will be 1 pill every 12 hours for 3 months.
Category
Treatment - Drugs

2

Description
Control group: In this group placebo will be prescribed every 12 hours for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Farshad Gholipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Farshad Gholipour
Position
Associate professor of Urology
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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
The data will be used in future studies.

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