Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effectiveness of tamsulosin and ginseng drug combination with tamsulosin and licorice on clinical symptoms of patients with benign prostate hyperplasia

Protocol summary

Study aim

Comparing the effectiveness of the pharmaceutical combination of tamsulosin and ginseng with tamsulosin and licorice on clinical symptoms of patients with benign prostatic hyperplasia

Design

A controlled clinical trial with parallel groups, without blinding, will be conducted in Phase 3 on 72 people. The rand function of Excel software will be used for randomization.

Settings and conduct

This study will be conducted at Shahid Beheshti Hospital in Hamedan on patients with benign prostatic hyperplasia. In this study, patients will be randomly assigned to two treatment groups: ginseng capsules plus tamsulosin capsules and the second group will receive licorice tablets and tamsulosin. Both groups will be followed up for three months in terms of clinical symptoms.

Participants/Inclusion and exclusion criteria

Participants will be patients with benign prostatic hyperplasia. Inclusion criteria for the study were age 50 to 70 years, IPSS equal to or greater than 8, PSA less than 4, residual urine volume less than 150 cc, and prostate volume greater than 30 cc. Exclusion criteria included history of treatment with anticholinergic drugs in the past month, history of prostate surgery, and recurrent or recurrent urinary tract infections.

Intervention groups

Group 1: Ginseng capsules from Gol Daru Pharmaceutical Company (one every 12 hours) and Tamsulosin 0.4 mg capsules from Razak Pharmaceutical Company (one daily before bedtime) will be received. Group 2: Licorice tablets from Iran Daruk Pharmaceutical Company (one every 12 hours) and Tamsulosin 0.4 mg from Razak Pharmaceutical Company (one daily before bedtime).

Main outcome variables

The main outcomes are urinary symptoms, sexual function, and medication side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N44**
Registration date: **2025-03-01, 1403/12/11**
Registration timing: **prospective**

Last update: **2025-03-01, 1403/12/11**
Update count: **0**

Registration date

2025-03-01, 1403/12/11

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-04, 1404/01/15

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of tamsulosin and ginseng drug combination with tamsulosin and licorice on clinical symptoms of patients with benign prostate hyperplasia

Public title
Comparing the effects of amsulosin and ginseng with tamsulosin and licorice on clinical symptoms of benign prostatic hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
IPSS ≥ 8 PSA<4 Residual urine volume<150 cc Prostate volume > 30 cc
Exclusion criteria:
History of treatment with anticholinergic drugs in the past month Having a urinary tract infection History of prostate surgery Having neurological disorders such as Parkinson's or stroke
Age
From **50 years** old to **70 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization and sealed envelope methods will be used for randomization.
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
Ethics committee of Hamadan Univercity of Medical Science
Street address
Śhahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838697
Approval date
2025-02-15, 1403/11/27
Ethics committee reference number
IR.UMSHA.REC.1403.838

Health conditions studied

1

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

Primary outcomes

1

Description
Changes in urinary symptoms
Timepoint
Before treatment and 3 months after treatment
Method of measurement
IPSS Urinary Function Questionnaire

2

Description
Changes in patients' sexual function
Timepoint
Before treatment and 3 months after treatment
Method of measurement
With the IIEF sexual function questionnaire

Secondary outcomes

1

Description
Occurrence of drug side effects
Timepoint
From the start of treatment to the end of treatment
Method of measurement
Clinical examination and questioning of patients

Intervention groups

1

Description
Intervention group: They will take one ginseng capsule every 12 hours and one tamsulosin capsule 0.4 mg daily

before bedtime.

Category
Treatment - Drugs

2

Description
Intervention group: They will take one licorice tablet every 12 hours and one tamsulosin 0.4 mg daily before bedtime for 3 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti hospital

Full name of responsible person
Behzad Mohammad Souri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Abbas Moradi

Position
MSc in epidemiology/ Comunity Medicine MS

Latest degree
Master

Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
No more information's
When the data will become available and for how long
From Feb 2026 onwards it is permissible
To whom data/document is available
Clinical professionals and Researchers in all fields
Under which criteria data/document could be used
For treatment of patients and develop research and science
From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study
What processes are involved for a request to access data/document
Send and receive email
Comments