

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of new combined medication "Young Prostate" versus standard treatment on clinical symptoms in patients with benign prostate hypertrophy and overactive bladder: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of new combined medication "Young Prostate" versus standard treatment on clinical symptoms in patients with benign prostate hypertrophy and overactive bladder

Design

This is a randomized clinical trial, in which 64 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with benign prostate hypertrophy and overactive bladder referring to the Shahid Beheshti Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 40 to 65 years, Benign prostate hypertrophy, Overactive bladder, Exclusion criteria: History of prostate surgery

Intervention groups

Intervention group: New combined tablet "Young prostate" (containing Trazosin 2 mg, Finasteride 5 mg, and Oxybutynin 5 mg) daily for 6 months. Control group: Tablets Finasteride 5 mg and Trazosin 2 mg and oxytocin 5 mg daily for 6 months.

Main outcome variables

Sexual desire, prostate size

General information

Reason for update

The form of the medication was changed from capsule to tablet due to the ease of manufacture.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N386**

Registration date: **2021-03-07, 1399/12/17**

Registration timing: **prospective**

Last update: **2021-03-16, 1399/12/26**

Update count: **1**

Registration date

2021-03-07, 1399/12/17

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of new combined medication "Young Prostate" versus standard treatment on clinical symptoms in

patients with benign prostate hypertrophy and overactive bladder: a randomized clinical trial

Public title

Effect of new combined medication "Young Prostate" on clinical symptoms in patients with benign prostate hypertrophy and overactive bladder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 40 to 65 years Benign prostate hypertrophy
Overactive bladder

Exclusion criteria:

History of prostate surgery

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-01-19, 1399/10/30

Ethics committee reference number

IR.UMSHA.REC.1399.872

Health conditions studied**1****Description of health condition studied**

Benign prostate hypertrophy

ICD-10 code

D29.1

ICD-10 code description

Benign neoplasm of prostate

Primary outcomes**1****Description**

Sexual desire

Timepoint

Before the intervention and 3 and 6 months after that

Method of measurement

By taking history

2**Description**

Prostate size

Timepoint

Before the intervention and 3 and 6 months after that

Method of measurement

Using ultrasonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: New combined tablet "Young prostate" (containing Trazosin 2 mg, Finasteride 5 mg, and Oxybutynin5 mg) daily for 6 months

Category

Treatment - Drugs

2**Description**

Control group: Tablets Finasteride 5 mg and Trazosin 2 mg and oxytocin 5 mg daily for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamadan city

Full name of responsible person

Mohammad Hamedanian

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0283

Email

mohammad_hamedanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Mohammad Hamedanian

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

mohammad_hamedanian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Amirzargar

Position

Urologist

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

dr_amirzargar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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