

# 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 Oxybutynin 5 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