

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of tamsulosin versus pumpkin seed oil on clinical symptoms in patients with benign prostatic hyperplasia: a single-blind randomized controlled trial

Protocol summary

Study aim

To assess the effect of tamsulosin versus pumpkin seed oil on clinical symptoms in patients with benign prostatic hyperplasia

Design

This is a single-blind randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with benign prostatic hypertrophy 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. This trial will be single-blinded so that the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 50 to 90 years, Benign prostatic hypertrophy Exclusion criteria: Indication of surgery, Taking medications for the treatment of benign prostatic hypertrophy in the past 6 months

Intervention groups

Intervention group: Pumpkin seed oil 360 mg (manufactured by Tehran Daru Pharmaceutical Co.) once every night for 3 months Control group: Tamsulosin capsule 0.4 mg (manufactured by Tasnim Pharmaceutical Co.) once every night for 3 months

Main outcome variables

Primary outcome: Clinical symptoms, measuring prostate

General information

Reason for update

There has been a slight change in the intervention group that needs to be updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N340**

Registration date: **2020-02-19, 1398/11/30**

Registration timing: **retrospective**

Last update: **2021-07-25, 1400/05/03**

Update count: **1**

Registration date

2020-02-19, 1398/11/30

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

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of tamsulosin versus pumpkin seed oil on clinical

symptoms in patients with benign prostatic hyperplasia: a single-blind randomized controlled trial

Public title

Effect of tamsulosin versus pumpkin seed oil on clinical symptoms in patients with benign prostatic hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 50 to 90 years, Benign prostatic hypertrophy

Exclusion criteria:

Indication of surgery, Taking medications for treatment of benign prostatic hypertrophy in the past 6 months

Age

From **50 years** old to **90 years** old

Gender

Male

Phase

2

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

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 "tamsulosin group" on one sheet and "pumpkin group" 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)

Single blinded

Blinding description

The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single-blind.

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

2019-08-10, 1398/05/19

Ethics committee reference number

IR.UMSHA.REC.1398.429

Health conditions studied

1

Description of health condition studied

Benign prostatic hypertrophy

ICD-10 code

D29.1

ICD-10 code description

Benign neoplasm of prostate

Primary outcomes

1

Description

Clinical symptoms

Timepoint

Before the intervention and then monthly for 3 months

Method of measurement

By taking history

2

Description

Measuring prostate

Timepoint

Before the intervention and 3 months later

Method of measurement

By sonography

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Tamsulosin capsule 0.4 mg (manufactured by Tasnim Pharmaceutical Co.) once every night for 3 months

Category

Treatment - Drugs

2

Description

Control group: Tamsulosin capsule 0.4 mg (manufactured by Tasnim Pharmaceutical Co.) once every night for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamadan city

Full name of responsible person

Dr Nikan Zerafatjoo

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0283

Email

nikan_z@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

Dr Nikan Zerafatjoo

Position

Resident of Urology

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

nikan_z@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

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

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