Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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
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Resident of Urology
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Person responsible for updating data

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Full name of responsible person
Dr. Jalal Poorolajal

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Professor of Epidemiology

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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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