Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Effect of pumpkin seed oil versus tamsulosin on relieving clinical symptom in patients with benign prostatic hypertrophy: a single blinded randomized controlled trial

Protocol summary

Summary

Objectives: To assess the effect of pumpkin seed oil versus tamsulosin on relieving clinical symptom in patients with benign prostatic hypertrophy. Design: .a single blind randomized clinical trial. Setting and conduct: The eligible patients with benign prostatic hypertrophy who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: Benign prostatic hypertrophy; age of 50 to 80 years. Exclusion criteria: Indication of surgery; no response to medical treatment. Intervention group: Pumpkin seed oil 20 drop twice a day for 3 months. Control group: Tamsulosin casual 0.4 mg per day for 3 months Primary outcome: (a) clinical symptoms before, and 1, 2, and 3 months after intervention through history taking; (b) maximum urine flow rate before and 3 months after intervention using uroflowmetry. Secondary outcome: Quality of life before and 3 months after intervention using standard quality of life questionnaire. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The observer how will examine the patients will not be aware of the intervention. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611019014N128**
Registration date: **2016-11-09, 1395/08/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-11-09, 1395/08/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pumpkin seed oil versus tamsulosin on relieving clinical symptom in patients with benign prostatic hypertrophy: a single blinded randomized controlled trial

Public title

Effect of pumpkin seed oil versus tamsulosin on relieving clinical symptom in patients with benign prostatic hypertrophy

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Benign prostatic hypertrophy; age of 50 to 80 years. Exclusion criteria: Indication of surgery; no response to medical treatment.

Age
From **50 years** old to **80 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The observer how will examine the patients will not be aware of the intervention. Therefore, the trial will be run as single blind.

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 the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2016-04-09, 1395/01/21

Ethics committee reference number
IR.UMSHA.REC.1395.5

Health conditions studied

1

Description of health condition studied
benign prostatic hypertrophy

ICD-10 code
N40

ICD-10 code description
Hyperplasia of prostate

Primary outcomes

1

Description
clinical symptoms

Timepoint
before, and 1, 2, and 3 months after intervention

Method of measurement
through history taking

2

Description
maximum urine flow rate

Timepoint
before and 3 months after intervention

Method of measurement
using uroflowmetry

Secondary outcomes

1

Description
Quality of life

Timepoint
before and 3 months after intervention

Method of measurement
using standard quality of life questionnaire

Intervention groups

1

Description
Intervention group: Pumpkin seed oil 20 drop twice a day for 3 months.

Category
Treatment - Drugs

2

Description
Control group: Tamsulosin casual 0.4 mg per day for 3 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr Mahmood Ebrahimi
Street address
Shahid Beheshti Hospital, Eram Ave.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan 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
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty