

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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

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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

Hamadan

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

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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Hamadan

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

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

Dr Mahmood Ebrahimi

Position

Resident of Urology

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Person responsible for scientific inquiries

Contact

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Position

Urologist

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Person responsible for updating data

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Full name of responsible person

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Position

Associate Professor

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Web page address

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