

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of oral formulation prepared from extract of pomegranate for treatment of benign prostate hyperplasia: A triple blind randomized clinical trial

Protocol summary

Study aim

Evaluation of the effect of oral formulation prepared from extract of pomegranate for treatment of benign prostate hyperplasia

Design

This is a randomized triple-blind, parallel group clinical trial on 40 patients with benign prostate hyperplasia (20 patients in treatment group and 20 patients in placebo group).

Settings and conduct

This study will perform on 40 patients with benign prostate hyperplasia who refer to Quem Hospital, Mashhad, Iran. They will receive 3 capsules contain 250 mg of pomegranate peel extract daily for 4 month or placebo capsules in placebo group.

Participants/Inclusion and exclusion criteria

inclusion criteria: age between 50-80 y, clinical diagnosis of mild to moderate benign prostate hypertrophy (BPH) (IPSS<18) exclusion criteria: 1-simultaneous use of BPH medications except tamsulosin 2-use of supplements which existing in BPH such as saw palmetto, vitamin E and Quercetin 3-having prostate or bladder cancer 4-history of prostate surgery 5-PSA>4mg/ml 6-Post void residue (PVR)≥200 ml 7-history of allergy to pomegranate and its derivatives 8-use of medications with considerable metabolism through Cytochrome 3A4 9- low blood pressure during treatment 10-pomegranate use by patients during study 11- Patient dissatisfaction 12- history of severe constipation or hemorrhoids

Intervention groups

Treatment group: 3 capsules contains 250 mg of peel pomegranate extract daily for 2 month, control group: 3 capsule contains lactose as placebo daily for 4 month

Main outcome variables

PSA serum level, prostate size, post void volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046990N4**

Registration date: **2020-07-29, 1399/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-29, 1399/05/08**

Update count: **0**

Registration date

2020-07-29, 1399/05/08

Registrant information

Name

Sepideh Elyasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1588

Email address

elyasis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral formulation prepared from extract of pomegranate for treatment of benign prostate hyperplasia: A triple blind randomized clinical trial

Public title

Evaluation of the effect of oral formulation prepared from extract of pomegranate for treatment of benign prostate hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 50-80 years Mild to moderate clinical diagnosis of BPH (patient has lower urinary (based on international prostate symptom score (IPSS)<18)

Exclusion criteria:

simultaneous use of BPH medications except tamsulosin use of supplements which existing in BPH such as saw palmetto , vitamin E and Quercetin vitamins having prostate or bladder cancer history of prostate surgery PSA>4mg/ml Post void residue (PVR)≥200 ml history of allergy to pomegranate and its derivatives use of medications with considerable metabolism through Cytochrome 3A4

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

capsules contain pomegranate peel extract and placebo capsules will be packaged in identical-looking bottle and delivered to the clinician. Patients who meet the inclusion criteria are selected by clinician to be included in the study, randomly assigned to a drug or placebo group and given a bottle with A or B mark. Patients will be evaluated in the course of treatment by the physician and the pharmacy student. Data collection and analysis are performed by the pharmacy student and the clinical pharmacist. All of them will be unaware that A or B is on medication or placebo until the end of the study and data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Science

Street address

Qureshi Building, Daneshgah street

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mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.MUMS.REC.1399.132

Health conditions studied

1

Description of health condition studied

benign prostate hyperplasia

ICD-10 code

N40.0

ICD-10 code description

Enlarged prostate without lower urinary tract symptoms

Primary outcomes

1

Description

PSA serum level

Timepoint

at the beginning of the study and after 4m

Method of measurement

laboratory measurement

2

Description

prostate size and post void volume

Timepoint

at the beginning of the study and after 4m

Method of measurement

sonography

3

Description

clinical assessment

Timepoint

at the beginning of the study and after 2 and 4m

Method of measurement

review and physical examination

Secondary outcomes**1****Description**

adverse drug reaction assessment e.g. low blood pressure

Timepoint

at the beginning of the study and monthly

Method of measurement

review and physical examination

Intervention groups**1****Description**

Intervention group: 3 capsules contain 250 mg of pomegranate peel extract, prepared in pharmaceuticals laboratory of pharmacy school, daily for 4 month

Category

Treatment - Drugs

2**Description**

Control group: 3 placebo capsules with same appearance of capsules contain pomegranate peel extract, including lactose, daily for 4 month.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Quem hospital

Full name of responsible person

Sepideh Elyasi

Street address

Quem Hospital, Ahmadabad Ave., Mashhad, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Faculty of Pharmacy, Ferdowsi University, Vakilabad Boulevard

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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

Mashhad University of Medical Sciences

Proportion provided by this source

80

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

2**Sponsor****Name of organization / entity**

Rezvan Danesh Danial company

Full name of responsible person

Ali Akhundi

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Salon 1, Growth and technology center, Ghuzhd, Gonbad, Khorasan Razavi

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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

Rezvan Danesh Danial company

Proportion provided by this source

20

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Hossein Hasheminezhad

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The findings will be published in an article. Study
protocol and statistical analysis will be used for article
publication.

**When the data will become available and for how
long**

One year after the end of the study it will be published

and available in databases.

To whom data/document is available

If the funding sponsor allowed, the findings will be available for researchers, clinicians, and scientific centers.

Under which criteria data/document could be used

The other researchers can use our findings in their review articles and meta analysis.

From where data/document is obtainable

For this purpose, you can contact with Sepideh Elyasi, at

Clinical Pharmacy Department, School of Pharmacy, Vakil Abad Aven., Mashhad, Iran. Email: elyasis@mums.ac.ir

What processes are involved for a request to access data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments