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 whether will received 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 , vitamine E and Quercetin vitamines 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 diagnisis 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

City
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 pharmaceutics 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
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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
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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
Street address
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 updating data

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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