Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of pomegranate peel extract oral formulation and soft capsule including Cucurbita pepo oil and vitamin E for treatment of benign prostate hyperplasia

Protocol summary

Study aim

Comparison of the effect of oral formulation prepared from extract of pomegranate with soft capsule including Cucurbita pepo oil and vitamin E for treatment of benign prostate hyperplasia

Design

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

Settings and conduct

This study will perform on 40 patients with benign prostate hyperplasia who refer to Quem Hospital or private clinic of of the executor of the project, Mashhad, Iran.They whether will received 3 capsules contain 250 mg of pomegranate peel extract daily for 4 month or prostabarij capsules once daily in control group. This study will be single blind and just analyzer will be blind. Data will be inserted in spss file as A or B code.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1-age between 50-80 y 2-clinical diagnosis of mild to moderate benign prostate hypertrophy (BPH) (IPSS lower than18) not including criteria: 1-simultaneous use of BPH medications except tamsulosin 2-use of supplements which existing in BPH such as saw palmetto and Quercetin 3-PSA above 4 mg/ml 4-Post void residue (PVR) higher or equal to 200 ml 5-history of allergy to pomegranate and its derivatives

Intervention groups

Treatment group: 3 capsules contains 250 mg of peel pomegranate extract daily for 2 month, control group: one 390mg prostabarij capsules including vitamin E and Cucurbita pepo oil capsule c 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: **IRCT20200408046990N8**
Registration date: **2021-09-23, 1400/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-23, 1400/07/01**
Update count: **0**

Registration date

2021-09-23, 1400/07/01

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

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of pomegranate peel extract oral formulation and soft capsule including Cucurbita pepo oil and vitamin E for treatment of benign prostate hyperplasia

Public title
comparison of pomegranate peel extract capsule effect with prostabarij soft capsule in patients with 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, 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 concomitant use of warfarin in both group and statins except rosuvastatin, tacrolimus, and cyclosporine in pomegranate group Patient dissatisfaction

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

Gender
Male

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization using website https://www.sealedenvelope.com With the explanation that each block has 4 members and the shape of the blocks can be as follows: [ABAB], [ABBA, [AABB],[BBAA],[BABA][BAAB] Code A belongs to the intervention group and code B belongs to the control group. the mentioned website selects 10 blocks from Quadruple blocks and finally 40 patients will enter the study. Allocation concealment method: Use of the central service, which consists of people who work in the center and have no knowledge of the researchers and will make a secret allocation for the research. In this method, based on the blocks created in the randomization method, a code is considered for each patient, which will be provided to the researcher at the time of patient admission by a person who has no knowledge of the process of studies and statistical analysis.

Blinding (investigator's opinion)
Single blinded

Blinding description
Data will be inserted in SPSS software as A and B and after analyzing data by the analyzer the codes will be defined.

Placebo
Not 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
2021-09-01, 1400/06/10

Ethics committee reference number
IR.MUMS.REC.1400.160

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
Enzyme Immuno Assay

2

Description
prostate size

Timepoint
at the beginning of the study and after 4m

Method of measurement

sonography

3

Description
post void volume
Timepoint
at the beginning of the study and after 4m
Method of measurement
sonography

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 Mashhad pharmacy school, daily for 4 month
Category
Treatment - Drugs

2

Description
Control group: Prostabarij capsule including 390 mg vitamin E and Cucurbita pepo oil once daily for 4 months, standardized based on the presence of 230-200 mg of linoleic acid and 30 mg of alpha tocopherol in each soft capsule produced by barijessence company.
Category
Treatment - Drugs

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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9137913316
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2

Recruitment center
Name of recruitment center
private office of Dr Darabi
Full name of responsible person
Mohammad Reza Darabi Mahboub
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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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17871 91886
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tafaghodim@mums.ac.ir
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
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
Mashhad University of Medical Sciences
Full name of responsible person
Sepideh Elyasi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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Faculty of Pharmacy, Ferdosi University, Vakilabad Aven.
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
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