Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the efficacy of pumpkin seed oil and amygdalous scorparia herbal tea in treatment of benign prostate hyperplasia in patients older than 45 years old

Protocol summary

Study aim

Comparing the efficacy of amygdalous scorparia herbal tea and pumpkin seed oil in treatment of symptoms of benign prostatic hyperplasia (BPH).

Design

In this randomized clinical trial with parallel control group , eighty patients older than 45 years suffering from benign prostate hyperplasia with sequential randomized allocation method by help of sealed envelope will assigned in one of two groups (pumpkin seed , amygdalous scorparia) and will received related intervention for one month.

Settings and conduct

Patients referring to Shahid Mofateh clinic of Yasuj suffering from benign prostatic hyperplasia candidate for medical treatment with sequential randomization method allocated in one of two groups. The history and physical exam and basic serum samples will be checked. In two groups standard treatment will be done by tamsulosin .One months later, the patients will re-examined and the success of treatment measured and recorded according to improvement of symptoms and International Prostatic Symptom Score of patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men older than 45 years old with benign prostatic hyperplasia with International Prostatic Symptom Score less than 20, Exclusion criteria: Men suffering from benign prostate hyperplasia with azotemia, active urinary tract infection and patients with history of herbal or medical allergy

Intervention groups

Intervention group: every 12 hours, the herbal tea of amygdalous scorparia, along with a glass of water plus 0.4 milligram of tamsulosin capsule every night will prescribe for one month. Control group: every 12 hours 20 drops of pumpkin seeds oil produced by Zardband company, along with a glass of water plus 0.4 milligram of tamsulosin capsule will prescribed for one month.

Main outcome variables

Improvement symptoms of benign prostatic hyperplasia according to the International Prostatic Symptom Score criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081011001323N18**
Registration date: **2018-11-07, 1397/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-07, 1397/08/16**
Update count: **0**

Registration date

2018-11-07, 1397/08/16

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the efficacy of pumpkin seed oil and amygdalous scorparia herbal tea in treatment of benign prostate hyperplasia in patients older than 45 years old

Public title
Pumpkin seed oil and amygdalous scorparia in treatment of benign prostate hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men older than 45 years old suffering from Benign Prostatic Hyperplasia (BPH) candidate for medical treatment International Prostatic Symptom Score (IPSS) less than 20
Exclusion criteria:
Men with benign prostatic hyperplasia with azotemia Patients with active urinary tract infection Patients with history of herbal or medical allergy
Age
From **45 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope and receive the intervention of the same group. The unit of randomization will be the refereed patient. In every envelope, one of two codes (A=pumpkin seed oil) and or (B=amygdalous scorparia) will be taken. The sealed envelopes will be placed at the disposal of the expert. With the referral of each patient one of the envelopes will be randomly selected by the patients and will be introduced as a study group. The stratification approach is not used. Concealment will not take place in the study.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran
City
Yasuj
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Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Approval date
2018-03-03, 1396/12/12
Ethics committee reference number
IR.YUMS.REC.1396.174

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia
ICD-10 code
N40
ICD-10 code description
Hyperplasia of prostate

Primary outcomes

1

Description
Improvement of obstructive and irritative symptoms of prostatic hyperplasia
Timepoint
At the start of study and one month later
Method of measurement
Using international prostatic symptom score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The amygdalous scorparia herbal tea with definite herbarium number will used ,along with a glass of water every 12 hours with 0.4 milligram of tamsulosin capsule every night for one month.

Category
Treatment - Drugs

2

Description
Control group: Twenty drops of pumpkin seeds oil every 12 hour with one glass of water plus 0.4 milligram of tamsulosin capsule will prescribed every night for 1 month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mofateh clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Yasouj 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
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Sadrollah Mehrabi
Position
Professor Education vice chansellor, Yasuj University of Medical Sciences
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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 further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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