

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

**Province**

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**

Sadrolleh Mehrabi

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No.22 , Shahid Madani street, Bahonar Blvd, Yasuj, Iran

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+98 74 3322 1813

**Email**

sadrollahm@yahoo.com

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

Yasouj University of Medical Sciences

**Full name of responsible person**

Dr. Hossein Mari Oryad

**Street address**

Vice chancellor of Research, Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

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oryad.hossein@yums.ac.ir

**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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Sadrollah Mehrabi

**Position**

Professor Education vice chancellor, Yasuj University of Medical Sciences

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Sadrollah Mehrabi

**Position**

Professor, Fellowship of endourology and laparoscopy

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

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**Person responsible for updating data****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Sadrollah Mehrabi

**Position**

Professor, Fellowship of endourology and laparoscopy

**Latest degree**

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**Other areas of specialty/work**

Urology

**Street address**Vice chancellor for Education, Yasuj University of  
Medical Sciences, Mottahari Street, Yasuj, Iran**City**

Yasuj

**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