

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of *Elaeagnus angustifolia* in patients with mild to moderate Benign Prostatic Hyperplasia symptom

#### Protocol summary

##### Study aim

Determining the effect of hydroalcoholic extract of *Elaeagnus angustifolia* on mild to moderate symptoms of benign prostatic hyperplasia

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 is performed on 96 patients by limited randomization method and with the help of random allocation law.

##### Settings and conduct

This study is performed in the urology clinic of Yasuj city. In this patient, first, in a room away from the treating physician, the researcher visits, then the patient is visited by a urologist and the drug that the urologist is aware of is given to the patient and the patient's details and the type of drug given on paper Written and placed in a sealed envelope.

##### Participants/Inclusion and exclusion criteria

All men over 40 years with a definite diagnosis of benign prostatic hyperplasia with an IPSS score below 21

##### Intervention groups

In the intervention group, they receive one capsule each night, containing 600 mg of hydroalcoholic extract of *Elaeagnus angustifolia* for 30 days, and in the control group, the same amount of wheat flour is found.

##### Main outcome variables

The effect of the drug on the excitatory and obstructive symptoms of benign prostatic hyperplasia compared with placebo

#### General information

##### Reason for update

##### Acronym

BPH

##### IRCT registration information

IRCT registration number: **IRCT20150622022869N8**

Registration date: **2021-11-01, 1400/08/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-01, 1400/08/10**

Update count: **0**

##### Registration date

2021-11-01, 1400/08/10

##### Registrant information

###### Name

Moslem Sedaghattalab

###### Name of organization / entity

Yasuj University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 3322 0163

###### Email address

m.sedaghattalab@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-29, 1400/08/07

##### Expected recruitment end date

2021-11-13, 1400/08/22

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of *Elaeagnus angustifolia* in patients with mild to moderate Benign Prostatic Hyperplasia symptom

##### Public title

Evaluation of the effect of *Elaeagnus angustifolia* in patients with mild to moderate Benign Prostatic Hyperplasia symptom

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

A patient with a diagnosis of benign prostatic hyperplasia with an IPSS score below 21

### **Exclusion criteria:**

Patients with a diagnosis of BPH with an IPSS score above 21

## **Age**

From **40 years** old

## **Gender**

Male

## **Phase**

3

## **Groups that have been masked**

- Participant
- Investigator

## **Sample size**

Target sample size: **96**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Sequencing by randomization with the help of the law of random allocation in such a way that 96 samples, including 48 drugs and 48 placebo, were placed in the drug bag and randomly taken out and given to patients for concealment. Random allocation is used by the non-transparent stamped envelope method, in which the contents of the letter are written by urologist and coded to patients.

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

The researcher And charge of data collection and the patient in this study is blind and the clinical caregiver who is a urologist is aware of the drugs.

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

This is the first study of bph in humans.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Yasouj University of Medical Sciences

##### **Street address**

Blood Transfusion Street, Yasouj University of Medical Sciences Campus

##### **City**

Yasuj

## **Province**

Kohgilouyeh-va-Boyerahmad

## **Postal code**

7591739308

## **Approval date**

2019-11-23, 1398/09/02

## **Ethics committee reference number**

IR.YUMS.REC.1399.095

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Benign prostatic hyperplasia

#### **ICD-10 code**

D29.1

#### **ICD-10 code description**

Benign neoplasm of prostate

## **Primary outcomes**

### 1

#### **Description**

IPSS (International prostate symptom score)questionnaire score

#### **Timepoint**

At the beginning of the study and 30 dimensions, the IPSS (International prostate symptom score)questionnaire is filled out for patients (at the same time as the end of the capsules)

#### **Method of measurement**

IPSS (International prostate symptom score)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Capsules containing 600 mg of hydroalcoholic extract of Elm fruit, which is extracted at Yasouj University of Medical Sciences and entered into the capsule, is given to the patient every day for 30 days.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Wheat flour in the amount of 600 mg in capsules has entered the capsules in the University of Medical Sciences. For 30 days, 1 capsule is given to patients daily.

#### **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Yasuj Urology Clinic

**Full name of responsible person**

Moslem Sedaghattalab

**Street address**

No. 49, Abuzar 15, Yasuj, Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

9999999999

**Phone**

+98 74 3334 5876

**Fax**

**Email**

M.sedaghattalab@yums.ac.ir

**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Moslem Sedaghattalab

**Street address**

Yasuj University of Medical Sciences, Motahari street,

Yasuj city, Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 5876

**Email**

m.sedaghattalab@yums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yasuj 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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Moslem Sedaghattalab

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No. 49, Abuzar 15, Yasuj, Iran

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## Person responsible for scientific inquiries

### Contact

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Yasouj University of Medical Sciences

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## Person responsible for updating data

### Contact

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Yasouj University of Medical Sciences

**Full name of responsible person**

Moslem Sedaghattalab

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**Latest degree**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

The full study report will be provided to the researchers as a dissertation. Also, the data will be provided to the researchers by deleting personal information.

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

This study will be available to the researcher from the beginning of 1401 AH onwards.

**To whom data/document is available**

All people who need this data to read more.

**Under which criteria data/document could be used**

Data are available for analyzes such as meta-analysis studies as well as review studies.

**From where data/document is obtainable**

m.sedaghttalab@yums.ac.ir

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

After sending the email, the data will reach the researcher in less than a month.

**Comments**