Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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-Boyrahmad

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

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Fax

Email
M.sedaghattalab@yums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Moslem Sedaghattalab

Street address
Yasuj University of Medical Sciences, Motahari street, Yasuj city, Iran

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+98 74 3334 5876

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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
Yasouj 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

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Person responsible for scientific inquiries

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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
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