

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of hydroalcoholic extract of *Elaeagnus angustifolia* on oxidative stress and inflammatory markers in patients with mild to moderate Benign Prostatic Hyperplasia

Protocol summary

Study aim

this study will be conducted with the aim of the effect of EA fruit on the oxidant/antioxidant status in this disease.

Design

Clinical trial with control group, with factorial groups, double-blind, randomized, phase 3 on 96 patients. The Rand function of Excel software was used for randomization

Settings and conduct

In the context of the effect of hydroalcoholic extract of Sanjad on oxidant and antioxidant factors in patients with benign prostatic hyperplasia in the urology clinic of Shahid Muftah, Yasouj, in a double-blind randomization, including the researcher and the patients.

Participants/Inclusion and exclusion criteria

. Inclusion Men over 45 years old. Presence of lower urinary tract symptoms. Grade under 20 in International Prostate Scoring System (IPSS) grading system (mild to severe symptoms). Diagnosis of Benign prostatic hyperplasia(BPH) for the first time through examination
Exclusion. Men with BPH, who were candidate surgery
Progression of signs and symptoms in the beginning of the study. Diagnosis of the cases such as prostate cancer which might have similar symptoms to BPH.

Intervention groups

The patients were divided into two groups of placebo recipient and drug recipient. A white box marked with an "A" was given to the drug recipient group and a similar white box marked with a "B" was given to the placebo recipient group.

Main outcome variables

Investigating the effect of hydroalcoholic extract of Sanjad on the amount of prostate specific antigen
Investigating the effect of Sanjad hydroalcoholic extract on the average oxidase factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150622022869N10**

Registration date: **2022-11-21, 1401/08/30**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-21, 1401/08/30**

Update count: **0**

Registration date

2022-11-21, 1401/08/30

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

2022-10-30, 1401/08/08

Expected recruitment end date

2022-11-29, 1401/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of hydroalcoholic extract of *Elaeagnus angustifolia* on oxidative stress and inflammatory markers in patients with mild to moderate Benign Prostatic Hyperplasia

Public title

Evaluation of the effect of hydroalcoholic extract of *Elaeagnus angustifolia* on oxidative stress and inflammatory markers in patients with mild to moderate Benign Prostatic Hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Men over 45 years old
- Presence of lower urinary tract symptoms, including frequent urination, feeling of incomplete emptying, intermittency, feeling of need for urgent emptying, weak and trickling urinary stream, urinary straining, and nocturia;
- Grade under 20 in IPSS grading system (mild to severe symptoms);
- Diagnosis of BPH for the first time through examination, ultrasonography and related tests.

Exclusion criteria:

- Men with BPS, who were candidate or being candidate at onset of the study; Diagnosing the symptoms of prostate cancer, prostate and gallstones, which sometimes have symptoms similar to BPH.

Age

From 45 years old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 96

Randomization (investigator's opinion)

Randomized

Randomization description

simple individual computer softwares To implement allocation concealment, sequentially numbered opaque sealed envelopes were used. Blinding for patients and researchers

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding was done in a double-blind manner for the patients and the person responsible for collecting the questionnaire, who had the task of evaluating the results.

Placebo

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

Dr. Jalil St., campus of Yasouj University of Medical Sciences., Yasuj., Iran

City

Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

7591994799

Approval date

2022-09-18, 1401/06/27

Ethics committee reference number

IR.YUMS.REC.1401.086

Health conditions studied

1

Description of health condition studied

Benign Prostatic Hyperplasia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Oxidation factors

Timepoint

At the beginning of the study and 30 days later

Method of measurement

In both groups, Oxidation factors are measured by spectrophotometric method according to the instructions of the kit after one month of consumption.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 mg of hydroalcoholic extract of senjed fruit and kernel once a day for 30 days.

Category

Treatment - Drugs

2

Description

Control group: 500 mg of white wheat flour daily for 30 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Muftah Clinic

Full name of responsible person

Moslem Sedaghattalab

Street address

Dr. Jalil St., campus of Yasouj University of Medical Sciences., Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr Sayed Amin Hosseini Motlagh

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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

Yasouj University of Medical Sciences

Full name of responsible person

Moslem Sedaghttalab

Position

Consultant

Latest degree

Medical doctor

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**Contact****Name of organization / entity**

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After the laboratory analysis, the blood samples of the patients are provided in the form of a code along with the age of the patients after distorting the names of the patients.

When the data will become available and for how long

After printing the article

To whom data/document is available

this is available for people working in academic institutions or people working in businesses can also apply to receive it.

Under which criteria data/document could be used

Any analysis on the data will be allowed

From where data/document is obtainable

m.sedaghattalab@yuma.ac.com

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

After sending the email, the required data will be available for up to 1 month

Comments