Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 cance 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 ofYasuj University of Medical Sciences

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

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Yasuj

Province
Kohgilouyeh-va-Boyrahmad

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
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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
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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