Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of the Elaeagnus angustifolia stone on osteoarthritis pain severity in postmenopausal women

Protocol summary

Study aim
Determining the effect of Elaeagnus angustifolia stone on the severity of menopausal osteoarthritis pain

Design
Clinical trial with control and placebo group, with parallel, double-blind, randomized, phase 3 groups on 160 patients.

Settings and conduct
This study was performed on outpatients referred to the clinic of Sabzevar Emdad Hospital. Patients in the control group received the usual drug treatment with capsules containing medicinal starch (placebo), which was similar in shape and color to the capsules of the intervention group, twice a day for 8 weeks. Patients in the intervention group were treated with 200 mg capsules of Elaeagnus angustifolia stone powder twice a day in addition to the usual medications for at least 8 weeks. Patients' pain intensity was assessed before, 4 weeks and 8 weeks after receiving the drug or placebo. Patients and researchers do not know which patient will be in which group (intervention or placebo).

Participants/Inclusion and exclusion criteria
inclusion Criteria: Menopausal patients aged 40-80 who have osteoarthritis according to the clinical and radiological criteria of the American College of Rheumatology. In active movements of the knee, they experience pain (at least 40 mm according to the VAS standard) and have back pain. Exclusion Criteria: Diseases of the spine or factors that lead to aggravation of knee pain.

Intervention groups
Elaeagnus angustifolia stone group, Elaeagnus angustifolia fruit powder, placebo and routin drug control group

Main outcome variables
osteoarthritis pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180122038472N1**
Registration date: **2020-07-22, 1399/05/01**
Registration timing: **retrospective**

Last update: **2020-07-22, 1399/05/01**
Update count: **0**

Registration date
2020-07-22, 1399/05/01

Registrant information
Name
roya akbarzadeh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-07, 1396/06/16

Expected recruitment end date
2018-09-20, 1397/06/29

Actual recruitment start date
2017-09-07, 1396/06/16

Actual recruitment end date
2019-01-14, 1397/10/24

Trial completion date
2019-01-14, 1397/10/24

Scientific title

The effect of the Elaeagnus angustifolia stone on osteoarthritis pain severity in postmenopausal women

Public title
Sanjad's effect on osteoporotic pain in menopausal women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Menopausal patients aged 40-80 years. who have osteoarthritis according to the clinical and radiological criteria of the American College of Rheumatology. In active movements of the knee, they experience pain (40 mm from the criterion of 100 mm VAS) and have back pain. Back pain
Exclusion criteria:
Musculoskeletal disorders uncontrolled hypertension receiving steroids diabetes Body mass index greater than or equal to 30 Hysterectomy and ovarectomy class 3 and 4 heart disease hyperthyroidism
Age
From **40 years** old to **80 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **160**
Actual sample size reached: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are placed in one of the two groups by simple randomization method with the help of random number table, receive a special code and receive the intervention of the same group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and the researcher are kept blind. Coding is done. Medication and placebo are similar capsules that are in the same container.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Sabzevar University of Medical Sciences
Street address
Sabzevar University of Medical Sciences, Bolvar Šohadaye Hastehie
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Approval date
2017-03-14, 1395/12/24
Ethics committee reference number
IR.MEDSAB.REC.1395.150

Health conditions studied

1

Description of health condition studied
osteoarthritis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
severity of pain
Timepoint
Before research, after 4 and 8 weeks
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients referred to the clinic of Sabzevar Emdad Hospital with inclusion criteria were selected. In the daily intervention group, two 200 mg capsules containing Elm kernel prepared by Barij Essence Pharmaceutical Company were given at Kashan University, Kashan School of Pharmacy for 8 weeks. The patient's pain was measured before the intervention, during and at the end of the study with VAS scale (100 mm).
Category
Placebo

2

Description
Control group: two capsules containing starch (similar in

shape and color to Elaeagnus angustifolia stone capsules), prepared by Barij Essence Pharmaceutical Company at Kashan University, Kashan University of Pharmacy, were given for 8 weeks. The patient's pain was measured before the intervention, during and at the end of the study with VAS scale.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Sabzevar Emdad Hospital

Full name of responsible person
Nasin Fazel

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Sabzevar Emdad Hospital, Razi Street, Sabzevar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar 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
Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
Roya Akbarzadeh

Position
Faculty instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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