Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Elaeagnus angustifolia as a Drug-Food on Osteoporosis: A Triple-Blind Randomized Clinical Trial

Protocol summary

Study aim
Determining the Effect of Elaeagnus angustifolia on Osteoporosis

Design
A controlled clinical trial with parallel groups, triple-blind, randomized, conducted on 3 groups of 50 patients each. Randomization is performed using the sealedenvelope website.

Settings and conduct
Patients diagnosed with osteoporosis who visit Shariati Hospital in Tehran during the study will be enrolled in the study if eligible, and will be randomly assigned to intervention and control groups using the block randomization method. This study is conducted in a triple-blind manner, such that the patients, the physician, and the data analyst will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: osteoporosis Patients aged 50 to 70 years of both sexes; Exclusion Criteria: Smoking, alcohol, and substance abuse; Chronic diseases such as cancer, renal failure, autoimmune diseases; Family history of estrogen-related cancers; Malabsorption syndrome caused by gastrointestinal diseases; Use of medications affecting bone metabolism within the past three months; Pregnancy and breastfeeding; bone fracture

Intervention groups
Intervention group 1: oleaster powder with seeds, Intervention group 2: oleaster powder without seeds, Control group (placebo): roasted wheat flour, Group 1 receives 20 g of oleaster fruit powder with seeds and 10 g of milk powder every day, group 2 receives 20 g of oleaster powder without seeds and 10 g of milk powder every day, and group 3 receives 20 g of placebo powder (roasted wheat flour) and 10 g of milk powder daily. This regimen will continue for 3 months, to be consumed as an afternoon snack. Drugs are produced in the laboratory of the School of Persian Medicine, Tehran University of Medical Sciences.

Main outcome variables
Bone formation; bone resorption

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260715070198N1**
Registration date: **2026-09-18, 1405/06/27**
Registration timing: **prospective**

Last update: **2026-09-18, 1405/06/27**
Update count: **0**
Registration date
2026-09-18, 1405/06/27

Registrant information
Name
Hannan Hajimahmoodi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8899 3656
Email address
h-hajimahmoodi@razi.tums.ac.ir

Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-09-23, 1405/07/01
Expected recruitment end date
2027-04-21, 1406/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Elaeagnus angustifolia as a Drug-Food on Osteoporosis: A Triple-Blind Randomized Clinical Trial

Public title
Effect of Oleaster in Osteoporosis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
osteoporosis Patients aged 50 to 70 years of both sexes
Exclusion criteria:
Smoking, alcohol, and substance abuse Chronic diseases such as cancer, renal failure, autoimmune diseases Malabsorption syndrome caused by gastrointestinal diseases Use of medications affecting bone metabolism within the past three months Family history of estrogen-related cancers Pregnancy and breastfeeding bone fracture

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into three groups using permuted block randomization. We will use the website https://www.sealedenvelope.com to generate the random sequence for the block randomization approach. In this process, the blocks will be of size three. Opaque sealed envelopes will be used for allocation concealment. Cards indicating the type of intervention, labeled with the letters A, B, and C, will be prepared. These cards will then be placed inside opaque envelopes, which will be sealed. Each envelope will be assigned a number according to the generated random sequence, marked on the envelope, and given to the physician. Patients will receive a numbered envelope in the order they present to the physician and will then be referred to the secretary to receive the corresponding medication. For each national ID code, the medication code will be recorded by the secretary. The patient list will be provided to the researcher at the end of the study, once the sample size has been completed.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The patient, physician, assistant, secretary, and the data analyst will all be blinded to the type of treatment received by the patients. The medications will be prepared in the form of identical sachets across the three groups, and only the person who prepared the medications will be aware of the content of each group of sachets.

Placebo
Used

Assignment
Parallel

Other design features
Oleaster (Russian olive) is considered a nutraceutical (medicinal food).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of The institute of Pharmaceutical Sciences - TUMS

Street address
Faculty of Medicine, Tehran University of Medical Sciences, 16 Azar Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417614411

Approval date
2026-06-05, 1405/03/15

Ethics committee reference number
IR.TUMS.TIPS.REC.1405.052

Health conditions studied

1

Description of health condition studied
osteoporosis

ICD-10 code
M81

ICD-10 code description
Osteoporosis without current pathological fracture

Primary outcomes

1

Description
bone resorption

Timepoint
Before the start of the intervention and 12 weeks after the start of the intervention

Method of measurement
C-terminal telopeptide (CTX) measurement by electro chemiluminescence immunoassay in a fasting morning blood sample

2

Description
bone formation
Timepoint
Before the start of the intervention and 12 weeks after the start of the intervention
Method of measurement
N-terminal propeptide (P1NP) measurement by electro chemiluminescence immunoassay in a fasting morning blood sample

Secondary outcomes

1

Description
quality of life
Timepoint
Before the start of the intervention and 12 weeks after the start of the intervention
Method of measurement
Quality of Life Questionnaire of the European Foundation for Osteoporosis (ECOS-16)

2

Description
bone and joint pain
Timepoint
Before the start of the intervention and 12 weeks after the start of the intervention
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group 1 (oleaster powder with seeds): Intervention group 1 dissolved one sachet containing 20 g of oleaster fruit powder with seeds and 10 g of milk powder in water daily for three months and consumed it as a snack. The drug is produced in the laboratory of the School of Persian Medicine, Tehran University of Medical Sciences
Category
Treatment - Drugs

2

Description
Intervention group 2 (oleaster powder without seeds): Intervention group 2 dissolved one sachet containing 20 g of oleaster fruit powder without seeds and 10 g of milk powder in water daily for three months and consumed it as a snack. The drug is produced in the laboratory of the School of Persian Medicine, Tehran University of Medical Sciences
Category
Treatment - Drugs

3

Description
Control group: The control (placebo) group dissolved one sachet containing 20 g of roasted wheat flour powder and 10 g of milk powder in water daily for three months and consumed it as a snack. The drug is produced in the laboratory of the School of Persian Medicine, Tehran University of Medical Sciences
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Hannan Hajimahmoodi
Street address
Dr. Shariati Educational, Research and Treatment Center, Jalal Al-e-Ahmad Three-Way Intersection, North Kargar Street, Tehran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Fax
+98 21 8863 3039
Email
hhajimahmoodi@gmail.com
Web page address
https://shariati.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Ramin Kordi
Street address
Central Organization of the University, 6th floor, Vice-Chancellor for Research and Technology, Kargar Street corner of Qods Street, Tehran
City
Tehran
Province

Tehran

Postal code
141765383761

Phone
+98 21 8163 3698

Fax
+98 21 8898 9664

Email
vcr@tums.ac.ir

Web page address
https://vcr.tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr Fatemeh Nejatbakhsh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
No. 27, North Sarparast Street, West Taleghani Street, Palestine Square, Tehran

City
Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 8897 4535

Fax
+98 21 8899 1829

Email
nejatbakhsh@tums.ac.ir

Web page address
https://spm.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Fatemeh Nejatbakhsh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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+98 21 8899 1829

Email
nejatbakhsh@tums.ac.ir

Web page address
https://spm.tums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Hannan Hajimahmoodi

Position
Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Tehran, Palestine Square, beginning of West Taleghani Street, North Sarparast Street, No. 27

City
Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 8897 4535

Fax
+98 21 8899 1829

Email
hhajimahmoodi@gmail.com

Web page address
https://spm.tums.ac.ir

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
Not applicable
Title and more details about the data/document
The anonymized data file (without patient identifying information) is held by the principal investigator. This file will be made available to researchers upon written request and approval by the principal investigator
When the data will become available and for how long
Access to the data is available on a case-by-case basis, upon written request submitted via email.
To whom data/document is available
Domestic researchers whose research project has been registered in the Nopa (NOPA) system may access the data.
Under which criteria data/document could be used
The data are available for the design of systematic reviews, meta-analyses, or other domestic studies.
From where data/document is obtainable
To obtain the data, an email should be sent to the principal investigator.
What processes are involved for a request to access data/document
Ten days after receipt of the email, following verification of the ethics code or the project's registration in the Nopa system, the information will be provided.
Comments
For foreign researchers, the information will be provided upon approval by the Vice-Dean for Research of the faculty.