

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of whole fruit and medolla powder of *Elaeagnus angustifolia* supplementation on clinical manifestation, inflammatory factors, matrix metalloproteinase enzymes, oxidative stress and nutritional status of patients with knee osteoarthritis

Protocol summary

Summary

In the present study the effect of whole fruit and medolla powder of *Elaeagnus angustifolia* supplementation in comparison with placebo (corn starch+Isomaltose) on clinical manifestation, inflammatory factors, matrix metalloproteinase enzymes, oxidative stress and nutritional status of patients with knee osteoarthritis will be evaluated. To achieve this objective, 90 volunteer female patients with bilateral primary osteoarthritis of knee who are referred to university clinic, will be randomly divided into three groups (including 2 intervention groups and one control group). The patients in the first intervention group will receive 15 grams of whole fruit powder of *Elaeagnus angustifolia* and the patients in the second intervention group will receive 15 grams of medolla powder of *Elaeagnus angustifolia* and patients in placebo group will receive corn starch and Isomaltose for 8 weeks. WOAMC (Western Ontario and McMaster Osteoarthritis questionnaire) will be used for evaluation the clinical manifestations (pain, joint stiffness and disability) of the patients. Before and after intervention, beside the anthropometric and dietary intake assessments, 5 cc of fasting blood will be drawn for determining total antioxidant and Malondialdehyde (MDA), Interleukin-1(IL-1), Interleukin-10 (IL_10), Tumor necrosis factor-alpha (TNF-alpha), Matrix metalloproteinase-1(MMP-1) and Matrix metalloproteinase-13 (MMP-13).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208241197N13**

Registration date: **2013-04-14, 1392/01/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-14, 1392/01/25

Registrant information

Name

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Name of organization / entity

Faculty of Health & Nutrition, Tabriz Univ. of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Nutrition research center, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-01, 1392/01/12

Expected recruitment end date

2013-08-30, 1392/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of whole fruit and medolla powder of *Elaeagnus angustifolia* supplementation on clinical manifestation, inflammatory factors, matrix metalloproteinase enzymes,

oxidative stress and nutritional status of patients with knee osteoarthritis

Public title

Whole fruit and medolla powder of *Elaeagnus angustifolia* effect on osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1.Female 2.Age: 40-70 years 3.Bilateral primary osteoarthritis of knee (according to ACR classification) 4.Body mass index of 25-29.9 Exclusion criteria: 1.Secondary osteoarthritis 2.Active synovitis 3.Neurological disorder that affects movement, muscle control and balance 4.Uncontrolled hypertension, diabetes, cardiovascular disorders, chronic kidney disorders and functional liver disorders 5.Using Furosemid, Probenecid, Anticoagulants, Hydantoin, Sulfonamides, Methotrexate, Lithium salts, Beta blockers and muscle relaxants 6.Smoking 7.Having an allergic reaction to *Elaeagnus angustifolia* 8. Daily use of *Elaeagnus angustifolia*

Age

From **40 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

This is a double blind study in which the researcher and patients will be blinded to the group assignments. The patients will receive the supplements by another person who is not involved in doing the assessment and chemical analysis. Patients will be informed about the type of supplements (whole fruit and medolla powder of *Elaeagnus angustifolia* and placebo) however they will not be aware about the group assignments.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tabriz University of Medical Sciences

Street address

Golgasht Street, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2013-01-07, 1391/10/18

Ethics committee reference number

91171

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M-17

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description

pain

Timepoint

Onset and after the study

Method of measurement

WOMAC questionnaire

2

Description

joint stiffness

Timepoint

Onset and after the study

Method of measurement

WOMAC questionnaire

3

Description

disability

Timepoint

Onset and after the study

Method of measurement

WOMAC questionnaire

Secondary outcomes

1

Description

Plasma total antioxidant capacity and MDA level

Timepoint

Onset and at the end of the study

Method of measurement

Antioxidant capacity = Randox kit, MDA= Fluorometry

2

Description

Serum IL-1, IL-10 and TNF-alpha levels

Timepoint

Onset and at the end of the study

Method of measurement

IL-1:ELISA kit; IL-10:ELISA kit; TNF-alpha: ELISA kit

3

Description

Serum MMP-1 and MMP-13 levels

Timepoint

Onset and at the end of the study

Method of measurement

MMP-1:ELISA kits; MMP-13:ELISA kit

4

Description

Nutritional status and dietary intake

Timepoint

Onset and at the end of the study

Method of measurement

Dietary intake: 24 hours questionnaires; Nutritional status: Weight: Standard scale, Height: Stadiometer

Intervention groups

1

Description

Intervention 1: Oral administration of 15 grams whole fruit powder of *Elaeagnus angustifolia* (prepared by the researcher) for 8 weeks

Category

Treatment - Other

2

Description

Intervention 2: Oral administration of 15 grams medolla powder of *Elaeagnus angustifolia* (prepared by the researcher) for 8 weeks

Category

Treatment - Other

3

Description

Intervention3: Oral administration of 15 grams corn starch+Isomaltose for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology centre, Sina hospital

Full name of responsible person

Aliasghar Ebrahimi

Street address

Rheumatology centre of Sina hospital, Tabriz
University of Medical Sciences, Tabriz-Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of
Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of
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City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nutrition faculty, Tabriz University of Medical
Sciences.

Full name of responsible person

Zeinab Nikniaz

Position

Ph.D student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty