Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Sep 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 refereed 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
Reza Mahdavi
Name of organization / entity
Faculty of Health & Nutrition, Tabriz UniV. of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1335 7584
Email address
mahdavir@tbzmed.ac.ir

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 Frosemid, 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 Medical Sciences
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
Street address
Nutrition faculty, Tabriz University of Medical Sciences, Tabriz-Iran
City
Tabriz
Postal code
Phone
+98 41 1334 1113

Fax
Email
znikniaz@hotmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Nutrition research center, nutrition faculty, Tabriz University of Medical Sciences
Full name of responsible person
Reza Mahdavi
Position
Professor
Other areas of specialty/work
Street address
Nutrition faculty, Tabriz University of Medical Sciences, Tabriz-Iran
City
Tabriz
Postal code
Phone
+98 41 1334 1113
Fax
Email
mahdavirez@hotmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Nutrition research centre, nutrition faculty, Tabriz University of Medical Sciences.
Full name of responsible person
Reza Mahdavi
Position
professor
Other areas of specialty/work
Street address
Nutrition faculty, Tabriz University of Medical Sciences, Tabriz-Iran
City
Tabriz
Postal code
Phone
+98 41 1334 1113
Fax
Email
mahdavirez@hotmail.com
Web page address

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