# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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
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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 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*