

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of *Elaeagnus Angustifolia* and *Zingiber* extract in pain and disability of patient with osteoarthritis

Protocol summary

Summary

The study is a double blind placebo control clinical trial on patients with knee osteoarthritis referred to a rheumatology clinic in Sari. There are 40 patients in both group. After selecting the patients by inclusion and exclusion criteria, they will be divided to 2 subgroup according their VAS score (moderate: 4-7 and severe: 8-10) and will be given drug or placebo randomly. Before drug or placebo administration, knee radiography, serum creatinine, liver enzymes, ESR, blood pressure will be done. Weight, height, and business will be recorded. Drug is the extract of *Elaeagnus Angustifolia* and *Zingiber* that will be prescribed in 200 mg capsules. Placebo consisted of starch powder that will be put in the same capsules. Drug and placebo will be administrated 2 times per day for 2 months by a trained physician. In the end of study, we measure the drug effect by visual analogue scale, patient and physician global assessment, and drug usage for pain control in last week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812121828N3**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

Maryam Mobini

Name of organization / entity

Mazandaran University of Medical Sciences and

Health Services

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Deputy of research of Mazandaran University of medical sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Elaeagnus Angustifolia* and *Zingiber* extract in pain and disability of patient with osteoarthritis

Public title

The effect of *Elaeagnus Angustifolia* and *Zingiber* extract in pain and disability of patient with osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Osteoarthritis, 2-Age between 50-60 years old, 3-moderate to severe pain, 4- agreement to participation. Exclusion criteria: 1-other types of osteoarticular diseases, 2-uncontrolled hypertension, 3- heart failure(class 3 or 4), 4-chronic renal failure, 5- liver dysfunction, 6-peptic ulcers, 7-history of bronchospasm, 8- history of myocardial infarction or cerebrovascular

accidents in last 12 months, 9- increased ES.

Age

From **50 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mazandarn university of medical sciences

Street address

Imam Khomeini Hospital, Sari

City

Sari

Postal code**Approval date**

2010-04-03, 1389/01/14

Ethics committee reference number

88147

Health conditions studied**1****Description of health condition studied**

Osteoarthritis

ICD-10 code

Arthrosis

ICD-10 code description

M15-M19

Primary outcomes**1****Description**

Pain

Timepoint

2 months

Method of measurement

visual analogue scale, patient and physician global assessment the patient and drug usage for pain control in last week

Secondary outcomes**1****Description**

Complications

Timepoint

2 month

Method of measurement

questionnaire

Intervention groups**1****Description**

placebo

Category

Placebo

2**Description**

Extract of *Elaeagnus Angustifolia* and *Zingiber* (200 mg, 2 times per day for 2 months)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rheumatology clinic in Tooba clinic

Full name of responsible person**Street address****City**

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of research of Mazandaran University of medical sciences

Full name of responsible person

Dr Ahmad Ali Enayati

Street address

Deputy of research, Mazandaran university of medical sciences

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of research of Mazandaran 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

Mazandaran university of medical sciences

Full name of responsible person

Dr. Maryam Mobini

Position

Rheumatologist

Other areas of specialty/work

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Dr Maryam Mobini

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

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Email

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