

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the efficacy of *Elaeagnus angustifolia* extract (Elartrit) drug in comparison with meloxicam on pain relief and functional improvement of patients with knee osteoarthritis referred to physical medicine and rehabilitation clinics of Shiraz University of Medical Sciences

Protocol summary

Study aim

Evaluation of the efficacy of *Elaeagnus angustifolia* extract (Elartrit) in comparison to Meloxicam in pain relief and function improvement in patients with knee osteoarthritis

Design

Randomized double blind trial with a control group and an intervention group in parallel, with a single phase and a sample size of 60. The randomization method used is permutation block randomization.

Settings and conduct

Samples are selected from patients with knee osteoarthritis seeking medical care at Imam Reza Clinic and Rajaei Hospital in Shiraz and are entered into the study after gaining their informed consent. Permutation block randomization will be used. In the control group patients will receive 15 mg of meloxicam daily for 10 days and in the intervention group 2 Elartrit capsules daily for 1 month. The person conducting the questionnaires and the data analyzer will be blinded. Finally, the effect on pain reduction and function improvement will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent, having manifestations of osteoarthritis, 40 to 60 years of age, and not having periarticular diseases. Exclusion criteria: certain systemic diseases, use of certain drugs, drug hypersensitivity, pregnancy or lactation, severe obesity, neural damage, neuropathy or radiculopathy, severe knee arthritis, history of knee fracture, trauma, joint replacement or injection, and inability to complete questionnaires.

Intervention groups

Treatment in the control group includes 15 mg of meloxicam daily for 15 days. Treatment in the intervention group includes 2 Elartrit (*Elaeagnus*

angustifolia extract) capsules daily for 1 month. Patients in both groups will be educated on lifestyle modifications and exercises suitable for knee pain, and all patients will be given omeprazole to take if needed.

Main outcome variables

Degree of pain and function of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220502054724N1**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name

Mohammad Haghghat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 1467

Email address

mammadht@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01
Expected recruitment end date
2023-07-23, 1402/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of Elaeagnus angustifolia extract (Elartrit) drug in comparison with meloxicam on pain relief and functional improvement of patients with knee osteoarthritis referred to physical medicine and rehabilitation clinics of Shiraz University of Medical Sciences

Public title
Effect of Elartrit in knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Filling and signing the consent form Having pain and other clinical manifestations of knee osteoarthritis in the last month Being between 40 to 60 years old Not having any periarticular disease around the joint in question

Exclusion criteria:

High grade arthritis according to radiology Presence of diabetes mellitus Presence of rheumatologic and collagen vascular diseases such as gout and lupus Presence of concomitant radiculopathy Presence of neural damage and neuropathy Presence of brucellosis Presence of any malignancy Presence of a history of significant liver disease Presence of a history of significant kidney disease Presence of a history of significant cardiac disease Presence of a history of significant pulmonary disease A body mass index greater than 42 Presence of a history of knee joint replacement in the knee being studied Presence of a history of trauma or fracture in the knee being studied Presence of bleeding disorders Presence of an inability to communicate and to complete questionnaires Presence of a history of allergic or hypersensitivity reaction to the drugs being used Presence of a history of injections in the last 3 months within or around the joint being studied Presence of a state of pregnancy or lactation Patients taking anticoagulant medications Presence of a history of gastrointestinal and stomach disease Use of warfarin and ticlopidine

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Permutation block randomization will be used for random allocation, in which "A" represents the patient receiving meloxicam and "B" represents the patient receiving Elartrit. In this method there will be a total of 6 possible quadruple permutations. In the next step, using a random number, codes 0 to 9 will be assigned to each of these permutations (i.e. ABAB Code 0, BABA Code 1, AABB Code 2, BBAA Code 3, BAAB Code 4, and ABBA Code 5 to 9). In this way, the required random list of 60, including 15 blocks of 4 ($4 \times 15 = 60$ total number of samples) will be obtained and the order of assignment to each sample will be determined. The method of using the random number table will be such that the starting point will be selected randomly and 15 numbers from 0 to 9 will be selected randomly (column-wise or row-wise) and the permutation assigned to each of the numbers will be determined. The permutations will be placed side by side from left to right, and the allocation of the total of 60 people to groups A and B (30 people in each group) will be determined. Thus, two lists of 30 people, consisting of the groups A and B, will be obtained randomly. For concealment purposes, this random sequencing method will be given to another person who is not aware of the research process, and the questionnaires will be completed by this person who is unaware of the group divisions.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: in this study, it is not possible to blind the participants because the participants are aware of their intervention (their drug). Clinical care giver: the caregiver is instructed on how to conduct the questionnaire and is not aware of the patient's intervention. Researcher: in this study, it is not possible to blind the researcher as he is aware of the intervention used in each case. The outcome assessor: the completed questionnaires are given to an individual who is not aware of the intervention performed and he/she is asked to determine the degree of pain relief and improvement of function according to the questionnaires. Data analyzer: the questionnaires are finally given to an individual to review the information. This individual will not be aware of any of the steps of the study nor of the classification of the interventions performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Research Department of the School of Medicine, Building No. 3, School of Medicine, Imam Hossein square,

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸۴۵۷۹۴

Approval date

2022-05-23, 1401/03/02

Ethics committee reference number

IR.SUMS.MED.REC.1401.104

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.9

ICD-10 code description

Osteoarthritis of knee, unspecified

Primary outcomes

1

Description

Pain caused by knee osteoarthritis

Timepoint

Before starting the intervention; 2, 4, and 8 weeks later

Method of measurement

Visual analog scale; Western Ontario and McMaster Universities Arthritis Index; Oxford knee scale; Patient satisfaction

Secondary outcomes

1

Description

Degree of knee dysfunction

Timepoint

Before starting the intervention; 2, 4, and 8 weeks later

Method of measurement

Western Ontario and McMaster Universities Arthritis Index; Oxford knee scale; Patient satisfaction

Intervention groups

1

Description

Control group: Treatment in this group includes taking 15 mg of meloxicam daily for 15 days, as well as educating patients in the clinic on lifestyle modifications and exercises suitable for knee pain. In addition, all patients will be given omeprazole to take if required daily in the morning in fasting state.

Category

Treatment - Drugs

2

Description

Intervention group: Treatment in this group includes taking 2 Elartrit capsules daily for 1 month, as well as educating patients in the clinic on lifestyle modifications and exercises suitable for knee pain. In addition, all patients will be given omeprazole to take if required daily in the morning in fasting state.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam reza rehabilitation clinic

Full name of responsible person

Mani Ramzi

Street address

Namazi Square

City

Shiraz

Province

Fars

Postal code

714737-71348

Phone

+98 71 3212 7700

Email

motahari@sums.ac.ir

2

Recruitment center

Name of recruitment center

Rajae hospital

Full name of responsible person

Amirreza Mesbahi

Street address

Chamran Blvd

City

Shiraz

Province

Fars

Postal code

7194815711

Phone

+98 71 3636 4001

Email

Rajaeehospital@sums.ac.ir

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

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

In front of Maaref school; Khalili Avenue

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3628 1506

Email

Info@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Haghghat

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Flat 6 Ahoora Building, 36/1 Ghasrodasht Ave.

City

Shiraz

Province

Fars

Postal code

7193687936

Phone

+98 71 3626 1467

Email

mammadht@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Haghghat

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Flat 6 Ahoora Building, 36/1 Ghasrodasht Ave.

City

Shiraz

Province

Fars

Postal code

7193687936

Phone

+98 71 3626 1467

Email

mammadht@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Haghghat

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Flat 6 Ahoora Building, 36/1 Ghasrodasht Ave.

City

Shiraz

Province

Fars

Postal code

7193687936

Phone

+98 71 3626 1467

Email

mammdht@gmail.com

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

Yes - There is a plan to make this available

Title and more details about the data/document

All available data are shareable after rendering individuals unidentifiable.

When the data will become available and for how long

Access period begins one year after publishing of results.

To whom data/document is available

Everyone can access this information.

Under which criteria data/document could be used

If the information in this study helps to improve the science process.

From where data/document is obtainable

Mohammad Haghghat, mammadht@gmail.com

What processes are involved for a request to access data/document

Upon receiving such a request, all authors of the study will be consulted and all information will be sent within a maximum of three weeks if permitted by all authors.

Comments