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 Haghighat

Name of organization / entity

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Iran (Islamic Republic of)

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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 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 x 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

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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7134814336
Phone
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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 Haghighat
Position
Medical Intern
Latest degree
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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 Haghighat, 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