Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The effect of topical application of ajor oil on clinical indicators of knee osteoarthritis

Protocol summary

Study aim
The purpose of this study was to investigate the efficacy of ajor oil on clinical criteria of knee osteoarthritis

Design
Randomized double-blind, controlled clinical trial, parallel, phase 2-3 on 80 patients with moderate knee osteoarthritis (40 patients in each group) using computer randomization method

Settings and conduct
A selection of 80 patients diagnosed with knee osteoarthritis based on the American College of Rheumatology (ACR) diagnostic criteria and a knee specialist's opinion will be introduced to the research group after being justified about the study and taking informed consent to participate. In addition, a questionnaire including past medical history and clinical symptoms, along with scoring of knee pain severity based on WOMAC Osteoarthritis Index and VAS scale , will be recorded for the selected patients. Then, patients will be randomly assigned to groups A and B by sealed envelope system. The study will take place at the Mashhad University of Medical Sciences, Mashhad, Iran

Participants/Inclusion and exclusion criteria
Inclusion criteria for this study were as follow: Primary symptomatic osteoarthritis in at least one knee; A baseline visual analog scale (VAS) score higher than 30 at the beginning of the study; No adequate response to medical treatment (Meloxicam) after at least two weeks of administration before the start of the study. Exclusion criteria for this study were as follow: Medical treatment with corticosteroids, hormone replacement medications, or hyaluronic acid before the start of the study

Intervention groups
topical ajor oil three times a day, and routine treatment with meloxicam tablets Control group: topical olive oil three times a day, and routine treatment with meloxicam tablets

Main outcome variables
Improvement of clinical symptoms of osteoarthritis (pain, joint stiffness and physical performance)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190406043175N8**
Registration date: **2022-10-02, 1401/07/10**
Registration timing: **prospective**

Last update: **2022-10-02, 1401/07/10**
Update count: **0**

Registration date
2022-10-02, 1401/07/10

Registrant information

Name
fatemeh forouzanfar

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
2022-10-23, 1401/08/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of topical application of ajor oil on clinical indicators of knee osteoarthritis

Public title
The effect of ajor oil on knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Primary symptomatic osteoarthritis in at least one knee confirmed by clinical or radiological criteria (American College of Rheumatology (ACR) criteria). No adequate response to medical treatment (Meloxicam) after at least two weeks of administration before the start of the study. A baseline visual analog scale (VAS) score higher than 30 at the beginning of the study. Patients aged 40 to 80 years

Exclusion criteria:
The intra-articular injection of hyaluronic acid in the three months before the start of the study The 4-week treatment with oral corticosteroids before the start of the study Patients with a history of deep vein thrombosis Active liver or renal disease and malignancies Secondary osteoarthritis or suspected Patients treated with hormonal drugs Patients treated with anticoagulation drugs Patients with a history of ischemic or hemorrhagic stroke

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be done using online random sequence generators. The blocks will be consisting of four sites filled by letter A or B. The combination of letters A and B will generate six blocks as follow: AABB, ABBA, BBAA, BAAB, ABAB, BABA. A number between 1 to 6 will be selected randomly and the corresponding combination will be used to assign the patients. For example, if the number 3 came up, the block number 3 with the combination of “BAAB”, the assignment of first 4 patients will be assigned. For assignment remaining 56 patients in to 2 groups we will need 14 more blocks which will be selected as previously explained.

Blinding (investigator's opinion)
Double blinded

Blinding description
The blinding of randomized allocation will be done using closed envelopes method. the sequence of the patients will be placed inside a sealed envelope and upon arrival of the patient the envelope will be opened.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Mashhad University of Medical Sciences, Azadi Square, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2022-02-26, 1400/12/07

Ethics committee reference number
IR.MUMS.REC.1400.358

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain

Timepoint
Early intervention, four weeks after the intervention, eight weeks after intervention

Method of measurement
Western Ontario and McMasters Universities Osteoarthritis Index (Womac) questionnaire and Visual Analog Scale (VAS)

2

Description
Joint stiffness
Timepoint
Early intervention, four weeks after the intervention, eight weeks after intervention
Method of measurement
Western Ontario and McMaster Universities Arthritis Index (WOMAC)questionnaire and Visual Analog Scale (VAS)

3

Description
Physical performance
Timepoint
Early intervention, four weeks after the intervention, eight weeks after intervention
Method of measurement
Western Ontario and McMaster Universities Arthritis Index (WOMAC)questionnaire and Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ajor oil is made by the Pharmacological Research Center of Medicinal Plants. Its chemical composition consists of olive oil and brick's solutes. The concentration of ajor oil is similar to olive oil which is mixed with heated brick pieces. Then using a special bar called reverse soxhlet with mild heat, the absorbed olive oil within the brick pieces is extracted. Next, the extracted oil will be standardized using oleic acid. Patients will receive topical treatment with ajor oil three times a day (5-10 drops) and routine treatment using meloxicam tablets.
Category
Treatment - Drugs

2

Description
Control group: Olive oil three times a day topically (five to ten drops), and routine treatment with meloxicam tablets
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics affiliated to Mashhad University of Medical Sciences
Full name of responsible person
Hassan Rakhshandeh
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Hassan Rakhshandeh
Position
Assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available