Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of Turmeric extract (Curcuma) versus Russian olive extract on the pain, function and quality of life in the patients with knee osteoarthritis

Protocol summary

Study aim

We aim to evaluate and compare the effect of two important drugs on pain relief and improvement of symptoms and function of patients with knee osteoarthritis.

Design

A phase 3 and single blind clinical trial with standard design (parallel controls), will be performed on 50 patients with knee osteoarthritis. Computer-based random assignments are as follows: Group A: Oral treatment with Elartrit capsule + exercise training Group B: Oral treatment with curcumin capsule + exercise training

Settings and conduct

Patients Referring to physical medicine clinics of Isfahan University of Medical Sciences (Alzahra & Amin) in 1398 and 1399

Participants/Inclusion and exclusion criteria

This study will be performed on 50 patients with mild to moderate knee osteoarthritis referred to physical medicine clinics of Isfahan University of Medical Sciences (Alzahra and Amin) in 1398. The following patients will not be included in the study: Other body joints involvement, systemic diseases, liver and kidney diseases, neuropathy, coagulation diseases, analgesic use before study

Intervention groups

Group A will be treated orally with 250 mg Elartrit capsules (containing Russian olive extract) of the Reyhaneh Pharmaceutical Company (every 12 hours for 15 days, after meal). In addition, they will be instructed to perform stretching the hamstring and calf muscles as well as the quadriceps strengthening exercises for 30 days in the morning, noon and night, three times in each set and doing those for 30 seconds each time. Group B will be treated orally with 370 mg capsules of curcumin of Razak Pharmaceutical Company (every 12 hours for 15 days, after meal). These patients will also be given stretching and strengthening exercises similar to Group A.

Main outcome variables

The VAS and KOOS questionnaire, and the Roles and Maudsley scale will be completed before treatment, 2 and 4 weeks after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191216045760N1**
Registration date: **2020-02-15, 1398/11/26**
Registration timing: **prospective**

Last update: **2020-02-15, 1398/11/26**
Update count: **0**

Registration date

2020-02-15, 1398/11/26

Registrant information

Name

Sadegh Baradaran Mahdavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-29, 1398/12/10

Expected recruitment end date
2020-08-22, 1399/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of Turmeric extract (Curcuma) versus Russian olive extract on the pain, function and quality of life in the patients with knee osteoarthritis

Public title
Comparison of Curcuma and Russian olive in the Treatment of Knee Osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 45 years Patients diagnosed with knee osteoarthritis according to the American College of Rheumatology criteria with symptoms for at least 3 months Knee X-ray as grade 2 or 3 of Kellgren-Lawrence (K-L) classification Patients' willingness to participate in the study after providing complete information about the project's goals
Exclusion criteria:
Clinical findings in other joints of the body such as hip, wrist or spine. Evidence of neuropathy such as radiculopathy or peripheral neuropathy Systemic inflammatory disease such as RA, AS Fibromyalgia or endocrine and metabolic diseases Corticosteroid use in the past 48 hours or intra-articular injection of Corticosteroid in the past 4 months Taking NSAIDs in the past week Psychiatric disease Severe blood dyscrasia, coagulopathy, current warfarin use Liver failure or liver tests more than 1.5 times of normal values Biliary Disease PUD or reflux history (GERD) Renal Failure - Uncontrolled hypertension Lack of medication compliance in the patient
Age
From **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Using a computer-based randomization method, 50 people will be randomly assigned in to two groups (Group A, N=25 and Group B, N=25). The list will be given to the senior researcher. Patients will be assigned in to treatment A or treatment B by a designated peer after recruitment (by sequential sampling) according to the determined numbers.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the primary investigator and supervisor are considered as physicians who are fully aware of the purpose of the study and the type of treatment. Patients will not be informed about the statistical purposes of the study and how the treatments are supposed to be compared. Patients will be informed of the name of their medication (as the treatment will be performed on an outpatient basis with the drug capsules available on the market). The researcher who evaluates the outcomes, as well as the statistical consultant and data analyst, does not know about the treatment A or B (Elartrit or curcumin, respectively) and the patients' names. Therefore, this study is a single-blind study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-12-04, 1398/09/13
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.521

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee pain intensity
Timepoint
Before treatment, 2 and 4 weeks after treatment
Method of measurement
VAS (Visual Analogue Scale)

2

Description
Symptoms of disease and quality of life
Timepoint
Before treatment, 2 and 4 weeks after treatment
Method of measurement
Knee injury and Osteoarthritis Outcome Score (KOOS)

3

Description
Function
Timepoint
Before treatment, 2 and 4 weeks after treatment
Method of measurement
Roles and Maudsley score

Secondary outcomes

empty

Intervention groups

1

Description
The itervention group will be orally treated with 250 mg Elartrit capsules (containing Russian olive extract) of Reyhaneh Isfahan Pharmaceutical Company (every 12 hours for 15 days, after meal). In addition, they will be instructed to perform stretching the hamstring and calf muscles as well as the quadriceps strengthening exercises for 30 days in the morning, noon and night, three times in each set and doing those for 30 seconds each time.
Category
Treatment - Drugs

2

Description
The control group will be orally treated with 370 mg curcumin capsules of Razak Pharmaceutical Company (every 12 hours for 15 days, after meal). In addition, they will be instructed to perform stretching the hamstring and calf muscles as well as the quadriceps strengthening exercises for 30 days in the morning, noon and night, three times in each set and doing those for 30 seconds each time.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Sadegh Baradaran Mahdavi
Street address
Sofeh Blvd
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8174675731
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2

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
Sadegh Baradaran Mahdavi
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Ebne Sina St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Babak Vahdatpour
Street address
Hezar Jarib St
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Postal code
8174673461
Phone
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Email

Alzahra@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Sadegh Baradaran Mahdavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

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

Undecided - It is not yet known if there will be 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

This study will publish information about the main outcomes and results of the study. There is currently no plan to disseminate other patient information even in an undetectable manner.

When the data will become available and for how

long

After publishing the results

To whom data/document is available

No limit

Under which criteria data/document could be used

Citing the source

From where data/document is obtainable

Downloading the article from the journal's website or contacting the author of the article

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

Downloading the article from the journal's website or contacting the author of the article

Comments

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