

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the efficacy of curcuma drug in comparison with meloxicam on pain relief and functional improvement of patients with knee osteoarthritis

Protocol summary

Study aim

Determining the effectiveness of Curcuma Longa oral drug in comparison with meloxicam oral drug in reducing pain and improving performance patients with knee osteoarthritis

Design

randomized clinical trial, comparison of two arm parallel, double blinded, randomized on 60 patients in phase 3 blocked and cluster random method is used

Settings and conduct

study will be on patient of rehabilitation clinics and sort them in two groups and after filling the consent form it will be started ,intervention group will take two tablet of curcuma daily and control group will take 1 meloxicam daily

Participants/Inclusion and exclusion criteria

Inclusion criteria : completing a consent form, having symptoms of knee osteoarthritis in at least one recent month, age between 40 and 60, lack of the presence of any other disease around the affected limb. Exclusion criteria: having diabetes, having diseases such as Rheumatism, gout, collagen vascular and lupus, very severe osteoarthritis of the knee based on radiology, having accompanying radiculopathy, having brucella, BMI above 42, history of trauma, fracture and injury to the affected joint, nerve damage and neuropathies, inability to communicating and completing questionnaires, history of knee replacement on the affected side, history of allergies to drugs used in the study, history of significant heart, kidney, liver and lung disorders, pregnant and lactating women, history of injection in the affected joint or in addition in the last 3 months , patients taking anticoagulants, cancer patients, history or gastrointestinal disorders and stomach problems, consuming warfarin and ticlopidine and aspirin, uncontrolled hypertension.

Intervention groups

1 group will take two curcuma tablets daily for 1 month 2 group will take 15 mg of meloxicam daily for 10 days

Main outcome variables

pain , knee dysfunction , morning stiffness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220513054837N1**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

Alireza Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3720 9719

Email address

dralirezakarimi1988@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-28, 1401/06/06

Expected recruitment end date

2023-02-25, 1401/12/06

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of curcuma drug in comparison with meloxicam on pain relief and functional improvement of patients with knee osteoarthritis

Public title
comparison of curcuma with meloxicam in knee osteoarthritis pain relief

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
completing and signing a consent form having symptoms of knee osteoarthritis in at least one recent month age between 40 and 60 lack of the presence of any other disease around the affected limb
Exclusion criteria:
having diabetes having diseases such as Rheumatism, gout, collagen vascular and lupus having accompanying radiculopathy history of trauma, fracture and injury to the affected joint, nerve damage and neuropathies history of knee replacement on the affected side history of allergies to drugs used in the study history of significant heart, kidney, liver and lung disorders pregnant and lactating women BMI above 42 having brucellosis history of injection in the affected joint or in addition in the last 3 months inability to communicating and completing questionnaires patients taking anticoagulants cancer patients history or gastrointestinal disorders and stomach problems consuming warfarin and ticlopidine and aspirin uncontrolled hypertension very severe osteoarthritis of the knee based on radiology

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

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To make the study random, the blocked and cluster random method is used. Patients also in terms of age and the severity of the symptoms of the disease is divided into categories. The list will be prepared by a computer with the same block length and the secretary of the clinic divides patients based on the list.

Blinding (investigator's opinion)
Double blinded

Blinding description

The blinding of the study is that the statistical expert and the questioner will not know the prescribed Medications to patients, but patients will not be blind in this study. For each patient to separately, first the cause and then the stages of research and the drugs used and their side effects will be explained and a written letter of satisfaction is taken.

Placebo
Not used

Assignment
Factorial

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

No.13, 16 meter Fire station Ave.,tatkt jamshid cross road, Aboonahr Blvd., Shiraz Town

City

Shiraz

Province

Fars

Postal code

7157763434

Approval date

2022-05-23, 1401/03/02

Ethics committee reference number

IR.SUMS.MED.REC.1401.086

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M19.90

ICD-10 code description

Unspecified osteoarthritis, unspecified site

Primary outcomes

1

Description

Pain rate based on the score obtained from the Visual Analog Scale questionnaire in the study

Timepoint

before and after starting treatment in second , forth and fifth weeks

Method of measurement

Filling in the questionnaire VAS by the patient and

reading the questionnaire information

2

Description

knee disability based on the score obtained from the Oxford knee Scale in the study

Timepoint

before and after starting treatment in second , forth and fifth weeks

Method of measurement

Filling in the questionnaire OKS by the patient and reading the questionnaire information

3

Description

Morning stiffness based on the score obtained from the Western Ontario and McMaster Universities Arthritis Index in the study

Timepoint

before and after starting treatment in second , forth and fifth weeks

Method of measurement

Filling in the questionnaire WOMAC by the patient and reading the questionnaire information

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1, Treatment in group 1 includes taking 15 mg of meloxicam orally daily for ten days and patients will be taught the method of correcting the way of life and Omeprazole will be prescribed also if needed so they take it fasting.

Category

Treatment - Drugs

2

Description

Intervention group: 2, treatment in group 2 will include two turmeric tablets (curcuma longa) (turmeric extract) daily for one month, each tablet contains 450 mg of turmeric rhizome powder and 50 mg of turmeric extract and patients will be taught the method of correcting the way of life and Omeprazole will be prescribed also if needed so they take it fasting.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Imam Reza Rehabilitation Clinic

Full name of responsible person

Mani Ramzi

Street address

Emam Reza Clinic , Namazi Square

City

Shiraz

Province

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Postal code

714737-71348

Phone

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Email

motahari@sums.ac.ir

2

Recruitment center

Name of recruitment center

Shahid Chamran Hospital

Full name of responsible person

Seyed Ali Hashemi

Street address

Shahid Chamran Hospital,Shahid Chamran Blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

71948-15644

Phone

+98 71 3624 0101

Email

chamhosp@sums.ac.ir

3

Recruitment center

Name of recruitment center

Rajae Hospital

Full name of responsible person

Amir Reza Mesbahi

Street address

Rajae Hospital, Chamran Blvd., Shiraz

City

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Province

Fars

Postal code

7194815711

Phone

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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 cross of Moaref Educational Institutions, Khalili Ave., Shiraz

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Shiraz

Province

Fars

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7134814336

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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?**

No

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

Ali Reza Karimi

Position

Medical Intern

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

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

Shiraz University of Medical Sciences

Full name of responsible person

Ali Reza Karimi

Position

Medical Intern

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**

Shiraz University of Medical Sciences

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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 existing data will be reachable after making people
unidentifiable
**When the data will become available and for how
long**

starting access period one year after publish
To whom data/document is available
all personal
Under which criteria data/document could be used
if data from this study could help improve sciences trend
.
From where data/document is obtainable
alireza karimi 09015613559
**What processes are involved for a request to access
data/document**
after sending request , a call will be made with
cooperative personal and if there are no disagreement ,
requesting data will be send to them in 4 weeks period .
Comments