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, Aboonasr 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
Fars
Postal code
714737-71348
Phone
+98 71 3212 7700
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
Rajaee Hospital
Full name of responsible person
Amir Reza Mesbahi
Street address
Rajaee Hospital, Chamran Blvd., Shiraz
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 cross of Moaref Educational Institutions, Khalili Ave., Shiraz
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?
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
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No.13,16 Meter Firestation Ave., Takhtjamshid Crossroad, Shiraz
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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