

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

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**

Rajae Hospital

##### **Full name of responsible person**

Amir Reza Mesbahi

##### **Street address**

Rajae 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

**Street address**

No.13,16 Meter Firestation Ave., Takhtjamshid Crossroad, Shiraz

**City**

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**Province**

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**Postal code**

71577-63434

**Phone**

+98 71 3720 9719

**Email**

dralirezakarimi1988@gmail.com

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Ali Reza Karimi

**Position**

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**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

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**Email**

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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**