Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of a Curcumin organogel on knee osteoarthritis: a randomized placebo trial

Protocol summary

Study aim
Evaluation of the effect of Curcumin organogel in the treatment of knee osteoarthritis

Design
Clinical trial with control group, double-blind, randomized, on 70 patients. Three-digit randomization code number was used for randomization

Settings and conduct
The study will be performed in the clinic on the randomly allocated patient using The Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaires and the final evaluation will be done by a caregiver.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having symptoms of pain in joint Osteoarthritis (at the Knee), stiffness, difficulty in flexion and extension, swelling for more than 3 months prior to the study, being free of any systemic or dermatological diseases, willing to refrain from using any lotion, gel, balm, moisturizer, cleanser, cosmetic or cream on the treatment areas during the treatment period, being able to give written informed consent in a manner approved by the Institutional Ethics Committee and complying with the requirements of the study, willing to avoid participation in any other interventional clinical trial for the duration of the current study and having no allergy to Curcumin and plants of the ginger family. Exclusion criteria include: showing a systemic or local allergic reaction to Curcumin OG, discontinuation of the treatment before the end of the intervention, or stopping it for at least three consecutive days, a decision to withdraw from the study, death, hospitalization, and moving to another city.

Intervention groups
In current study, the effect of Curcumin OG on the symptoms of patient suffering from knee osteoarthritis will be evaluated in comparison with the patients receiving Curcumin-free OG as placebo.

Main outcome variables
Reducing pain, stiffness and difficulty in knee movement of patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220531055045N1**
Registration date: **2022-06-11, 1401/03/21**
Registration timing: **prospective**

Last update: **2022-06-11, 1401/03/21**
Update count: **0**

Registration date
2022-06-11, 1401/03/21

Registrant information

Name
mohsen mohammady

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 4252 5694

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-06, 1401/03/16

Expected recruitment end date
2022-08-07, 1401/05/16

Actual recruitment start date
2022-06-16, 1401/03/26

Actual recruitment end date
2022-08-17, 1401/05/26

Trial completion date
2022-09-06, 1401/06/15

Scientific title
The effect of a Curcumin organogel on knee osteoarthritis: a randomized placebo trial

Public title
Curcumin organogel for osteoarthritis treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having symptom of pain in joint Osteoarthritis (at Knee), stiffness, difficulty in flexion and extension, swelling for more than 3 months prior to the study Being free of any systemic or dermatological diseases Willing to refrain from using any lotion, gel, balm, moisturizer, cleanser, cosmetic or cream on the treatment areas during the treatment period Being able to give written informed consent in a manner approved by the Institutional Ethics Committee and complying with the requirements of the study Willing to avoid participation in any other interventional clinical trial during current study No known allergy to Curcumin and plants of the ginger family

Exclusion criteria:
Showing a systemic or local allergic reaction to Curcumin organogel Discontinuation of the treatment before end of intervention, or stopping it for at least three consecutive days A decision to withdraw from the study Death Hospitalization Moving to another city

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **70**
Actual sample size reached: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Computer-generated randomization is employed, and the subjects are assigned with a three-digit randomization code number

Blinding (investigator's opinion)
Double blinded

Blinding description
After definite diagnosis of osteoarthritis and agreement to participate in the study, the patients will be interviewed and practically trained on how to use the Curcumin OGs. The patients in the intervention group will receive Curcumin OGs and the patients in the placebo group will receive curcumin-free placebo gels. However, both groups will receive similar educations and have no contact with each other. The clinical observer and the outcome assessor will also have no knowledge of the type of intervention during the study.

Placebo
Used

Assignment
Other

Other design features
not included.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences

City
shiraz

Province
Fars

Postal code
۷۱۴۶۸۶۴۶۸۵

Approval date
2022-04-30, 1401/02/10

Ethics committee reference number
IR.SUMS.AEC.1401.006

Health conditions studied

1

Description of health condition studied
Osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain, Stiffness, Difficulty in knee movement

Timepoint
Before, 1, 2, 4 and 8 weeks after intervention.

Method of measurement
The Western Ontario and McMaster Universities Arthritis Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Applying Curcumin OG 2% twice a day for 8 weeks on the knee area.
Category
Treatment - Drugs

2

Description
Control group: Applying Curcumin-free OG, twice a day, up to 8 weeks, on the knee area.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz University of Medical Sciences Clinics
Full name of responsible person
Gholamhossein Yousefi
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Karimkhan Zand Street, Shiraz University of Medical Sciences Clinics
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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?
No
Title of funding source
Personal
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Gholamhossein Yousefi
Position
Associate Professor of Pharmaceutics
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Person responsible for updating data

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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

Patients' information, Methodology and Results.

When the data will become available and for how long

As soon as the results are provided.

To whom data/document is available

People working in academic institutions or people working in pharmaceutical industries.

Under which criteria data/document could be used

Statistical and scientific analyses with respecting to intellectual rights

From where data/document is obtainable

Dr. Gholamhossein Yousefi using the phone 09123956292

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

Contact with investigators and official request expressing the reasons and the how of using data.

Comments

Any usage of information is solely permitted via official channels and by informing and citing to the investigators.