

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

To evaluate the effect of nanomicelle curcumin on the rate of improvement in symptoms of knee osteoarthritis patients

Protocol summary

Summary

Objective: To evaluate the effect of nanomicelle curcumin on the rate of improvement in symptoms of knee osteoarthritis patients Design: A double-blind, block-randomized clinical trial. Study population: Knee osteoarthritis patients referring to Imam Reza Hospital of Mashhad, Iran. Inclusion criteria: Primary knee osteoarthritis with grade II and III base on Kellgren-Lawrence grading scale; having knee pain at least for six months; age between 45 and 65 years; and having primary osteoarthritis. Exclusion criteria: Secondary osteoarthritis (due to trauma); knee arthroscopic surgery in less than six months; use of corticosteroids less than six months; history of allergy; use of medications affecting coagulation process (e.g., warfarin, heparin, clopidogrel, dipyridamole, and aspirin); genu varum, genu valgus, and pes planus patients; and patients with anserine bursitis. Sample size: 80 cases. Study intervention: The control group received 40 mg of placebo (similar components of curcumin capsules but without curcumin) and the intervention group was administered 40 mg of nanomicelle curcumin capsule every 12 hours for six weeks. Both participant and the researcher are blind to the medication because of the capsules are similar in packaging.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100629884N1**

Registration date: **2017-04-11, 1396/01/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-11, 1396/01/22

Registrant information

Name

Najmeh Davoudian

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-20, 1396/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the effect of nanomicelle curcumin on the rate of improvement in symptoms of knee osteoarthritis patients

Public title

The effectiveness of curcumin on knee osteoarthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Primary knee osteoarthritis with grade II and III base on Kellgren-Lawrence grading scale; having

knee pain at least for six months; age between 45 and 65 years; and having primary osteoarthritis. Exclusion criteria: Secondary osteoarthritis (due to trauma); knee arthroscopic surgery in less than six months; use of corticosteroids less than six months; history of allergy; coagulation disorders and coronary heart disease; use of medications affecting coagulation process (e.g., warfarin, heparin, clopidogrel, dipyridamole, and aspirin); genu varum, genu valgus, and pes planus patients; and patients with anserine bursitis

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Allocation to group is based on block-randomized. Both participant and the researcher are blind to the medication because of the capsules are similar in shape and packaging.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

91779-48564

Approval date

2016-08-03, 1395/05/13

Ethics committee reference number

IR.MUMS-fm.REC.1395.40

Health conditions studied

1

Description of health condition studied

Knee arthrosis

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes

1

Description

Clinical outcomes including pain, stiffness, and physical function

Timepoint

Before and 6 weeks after intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index

Secondary outcomes

1

Description

Hepatic effects

Timepoint

After intervention

Method of measurement

Physical examination and levels of liver transaminases

Intervention groups

1

Description

The control group: Who are receiving 40 mg of placebo (similar components of curcumin capsules but without curcumin) in 12 hours for 6 weeks

Category

Treatment - Drugs

2

Description

The intervention group: Who are receiving 40 mg nanomicelle curcumin capsule in 12 hours for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person
Zahra Mirfeizi
Street address
Emam Reza Hospital, Emam Reza Sq
City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of
Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Rheumatology ward, Emam Reza Hospital, Emam
Reza Sq
City
Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Najmeh Davoudian
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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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

