Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Najmeh Davoudian
Name of organization / entity
Mashhad University of Medical Science
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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 revising 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 revising 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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Person responsible for updating data

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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

Data Dictionary	*empty*