Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A randomized controlled trial to evaluate the slow acting symptom modifying effect of colchicine in patients with osteoarthritis of the knee

Protocol summary

Summary

Objective: Assessment of the impact of slow-release colchicine in modifying the symptoms of knee osteoarthritis in comparison with placebo, Design: Double-blind and single center randomized clinical trial in 81 patients with knee osteoarthritis, Major eligibility criteria: Patients are considered as idiopathic knee osteoarthritis based on American college of rheumatology criteria, Kellgren & Lawrence radiographic criteria, clinical examination, and laboratory tests. Setting, conduct, and interventions: After recording the demographic data and characteristics of knee osteoarthritis, patients receive full-dose naproxen (maximum 1 g daily, Modava pharmaceutical company) for 2 weeks prior to beginning of the treatment. Then patients will randomize to two groups, colchicine group (0.5mg/bid, Modava pharmaceutical company) and placebo. Intervention will conduct for 4 months. All patients will continue previous treatment. Patients will follow up for using drugs and side effects by telephone. Main outcome measures: The baseline level of pain on visual analog scale (VAS), the rate of functional disability based on the Western Ontario and McMaster Universities arthritis index (modified WOMAC) and the health assessment questionnaire (ModHAQ) score will assess. These measurements will reassess in 3 th and 4th month of study.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015071623240N1**
Registration date: **2015-09-21, 1394/06/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-21, 1394/06/30

Registrant information

Name
Maryam Alsadat Mousavi
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 4444 5366
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ms.mousavi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized controlled trial to evaluate the slow acting symptom modifying effect of colchicine in patients with osteoarthritis of the knee

Public title

Effect of colchicine in osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. American college of rheumatology (ACR) criteria and radiographic Kellgren & Lawrence criteria for osteoarthritis; 2. Knee osteoarthritis; 3. Non existence of Calcium pyrophosphate dihydrate crystal deposition disease (CPPD) arthritis in other joints; 4. No History of gout and pseudo-gout; 5. No History of inflammatory diseases according to laboratory; 6. Non existence of liver, kidney, cardiovascular diseases, cardiomyopathy, moderate to severe neouropathy, GI problems, fibromyalgia, infection; 7. No History of knee joint replacement; 8. No concurrent use of drug interfering with colchicine; 9. No existence of these laboratory tests: White blood cells <3500/mm3 Hemoglobin <10 mg/dl Creatinine >1.3 mg/dl Amino transferase >45 IU uric acid >6.5 mg/dl 10. At least 2 months after intra-articular corticosteroids and 3 months after intra-articular hyaluronic acid; 11. Using 2 weeks naproxen; 12. At least 4-6 months after use of glucoseamine, chondroitine sulfate or methylsulfonylmethane (MSM); 13. No contra-indication of colchicine; 14. Co-operation. Exclusion criteria: 1. No use of drugs according to the study protocol; 2. Severe side effect of colchicine or placebo; 3. Aggravation of knee pain; 4. Using analgesics due to other problems; 5. Knee trauma or any other problems interfering with drug use in knee osteoarthritis; 6. Loss of follow-up.

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **81**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Next to Ayatollah Taleghani Hospital, Shahid Arabi St., Yemen St., Shahid Chamran Highway

City
Tehran

Postal code

Approval date
2012-03-11, 1390/12/21

Ethics committee reference number
in 115th session

Health conditions studied

1

Description of health condition studied
Knee osteorathritis

ICD-10 code
M 19.9

ICD-10 code description
Arthrosis, unspecified

Primary outcomes

1

Description
Health Assessment

Timepoint
3rd and 4th Months

Method of measurement
modified health assessment questionnaire (modHAQ)

2

Description
Knee pain

Timepoint
3rd and 4th Months

Method of measurement
Visual Analog Scale (VAS)

3

Description
Functional disability

Timepoint
3rd and 4th Months

Method of measurement
modified Western Ontario and McMaster Universities arthritis (modified WOMAC) index

Secondary outcomes

empty

Intervention groups

1

Description
Patients receive full-dose naproxen (maximum 1 g daily, Modava pharmaceutical company) for 2 weeks prior to

beginning of the treatment and then they give placebo.

Category

Placebo

2

Description

Patients receive full-dose naproxen (maximum 1 g daily, Modava pharmaceutical company) for 2 weeks prior to beginning of the treatment and then they give colchicine 0.5mg/bid (Modava pharmaceutical company).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Maryam Alsadat Mousavi

Street address

Imam Hossein Hospital, Madani Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Dr Maryam Alsadat Mousavi

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Maryam Alsadat Mousavi

Position

Medical Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Maryam Alsadat Mousavi

Position

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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

Data Dictionary

empty