# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)
**Phone**
+98 21 4444 5366
**Email address**
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**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 4444 5366

**Fax**

**Email**

ms.mousavi@sbmu.ac.ir

**Web page address**

## Person responsible for scientific 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**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 4444 5366

**Fax**

**Email**

ms.mousavi@sbmu.ac.ir

**Web page address**

## Person responsible for updating data

**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**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 4444 5366

**Fax**

**Email**

ms.mousavi@sbmu.ac.ir

**Web page address**

## 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*