

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the efficacy of methotrexate in pain severity reduction and improvement of quality of life in patients with moderate to severe knee osteoarthritis

Protocol summary

Study aim

We aim to evaluate the efficacy of methotrexate in controlling pain and improving quality of life in patients with moderate to severe osteoarthritis.

Design

In this research, 100 patients with moderate to severe knee osteoarthritis with inclusion criteria and not having exclusion criteria referring to rheumatology clinics will be included. Patients will be randomly allocated to methotrexate and placebo groups and each patient will be given a specific code.

Settings and conduct

After patients selection, they will be randomly allocated to methotrexate or placebo groups. Patients in both groups will be treated for 6 months and will be evaluated before intervention and 3 and 6 months later for pain severity according to visual analogue scale (VAS), functional status according to WOMAC questionnaire and quality of life according to SF-12 questionnaire. Patients and the person evaluating the treatment outcome will be unaware of the allocated groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Knee osteoarthritis with effusion; age between 45-75 years; ability to walk; having pain score of >5 according to VAS and >48 according to WOMAC questionnaire; Exclusion criteria: Other knee disorders; concomitant hip and ankle osteoarthritis; bursitis and perarticular disease; radicular pains; physiotherapy or intraarticular injection during the past 6 months; psychological disease; history of knee surgery; inflammatory joint disease; rheumatoid arthritis; fibromyalgia; active or recurrent pseudogout; malignancy; systemic diseases including renal or hepatic failure, uncontrolled blood pressure, diabetes mellitus; asthma in need of corticosteroids; corticosteroid use in less than 5 weeks prior to study

Intervention groups

In both groups, glucosamine sulfate 1500 mg will be administered daily and in intervention group, methotrexate will be given 7.5 mg (3 pills) weekly and would increase to 15 mg. In placebo group, placebo will be given 3 pills weekly.

Main outcome variables

The main outcomes of the study are evaluating patients functional status using WOMAC (Western Ontario and McMaster Universities Osteoarthritis), pain severity using visual analogue scale and quality of life using SF-12 quality of life questionnaire which will be evaluated before intervention and 3 and 6 months after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170716035126N1**

Registration date: **2017-12-22, 1396/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-22, 1396/10/01**

Update count: **0**

Registration date

2017-12-22, 1396/10/01

Registrant information

Name

Afshin Habibzadeh

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status**Recruitment complete****Funding source**

none

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of methotrexate in pain severity reduction and improvement of quality of life in patients with moderate to severe knee osteoarthritis

Public title

Evaluating the efficacy of methotrexate in pain severity reduction and improvement of quality of life in patients with moderate to severe knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Knee osteoarthritis with effusion; age between 45-75 years; ability to walk; having pain score of >5 according to VAS and >48 according to WOMAC questionnaire

Exclusion criteria:

Exclusion criteria: Other knee disorders; concomitant hip and ankle osteoarthritis; bursitis and peritarticular disease; radicular pains; physiotherapy or intraarticular injection during the past 6 months; psychological disease; history of knee surgery; inflammatory joint disease; rheumatoid arthritis; fibromyalgia; active or recurrent pseudogout; malignancy; systemic diseases including renal or hepatic failure, uncontrolled blood pressure, diabetes mellitus; asthma in need of corticosteroids; corticosteroid use in less than 5 weeks prior to study

AgeFrom **45 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be randomized into two groups using random number blocks and using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the person evaluating the treatment outcome will be blinded to the allocated groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medicine Sciences, Daneshgah St.,

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Approval date

2017-11-05, 1396/08/14

Ethics committee reference number

IR.ARUMS.REC.1396.150

Health conditions studied**1****Description of health condition studied**

Knee osthoarthritis

ICD-10 code

M19.9

ICD-10 code description**Primary outcomes****1****Description**

pain

Timepoint

before intervention and three and six months after intervention

Method of measurement

using visual analogue scale (VAS)

Secondary outcomes

1

Description

functional status

Timepoint

before intervention and three and six months after intervention

Method of measurement

using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

2

Description

quality of life

Timepoint

before intervention and three and six months after intervention

Method of measurement

using SF-12 quality of life questionnaire

Intervention groups

1

Description

Both groups will be administered glucoseamine sulfate 1500 mg daily and then in intervention group, methotrexate with the dose of 7.5 mg (3 pills) weekly will be administered and then increased to 15 mg weekly.

Category

Treatment - Drugs

2

Description

both groups will be administered glucoseamine sulfate 1500 mg daily and in placebo group, placebo will be administered 3 pills weekly.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil Imam Khomeini Hospital

Full name of responsible person

Afshin Habibzadeh

Street address

Imam Khomeini Hospital, Ataei Ave.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Masoud Entezari Asl

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Afshin Habibzadeh

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Afsaneh Enteshari Moghaddam

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available