

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial to Compare between the efficacy of of intra-articular Hyaluronic acid and oral atorvastatin in reducing pain, stiffness, and function of the knee in patients with mild to moderate knee osteoarthritis

Protocol summary

Summary

The purpose of the present study is to investigate and compare the potential effects of Hyaluronic acid and atorvastatin on the symptoms of knee osteoarthritis. This open, randomized, parallel study will be conducted on patients with knee osteoarthritis according to American College of Rheumatology (ACR) criteria. Patients will be enrolled from outpatient clinic of Imam Reza Hospital, Mashhad, Iran. Eligible patients are those who meet the ACR criteria of primary knee osteoarthritis, radiologically ascertained grade I or II of knee osteoarthritis on the Kellgren-Lawrence scale, had a pain score ≥ 60 (maximum 100) and age 50-70 years. Patients are not eligible if they have: secondary osteoarthritis, systemic disease like diabetes, history of Inflammatory arthritis, sever knee deformity (varus or valgus >50 degree), history of coagulopathy, sever cardiovascular disease and active infections. We will divide them randomly (via a random number table) into two groups; Group 1 (n=35) will receive intra-articular Hyaluronic acid (Hyaluron HEXAL 20 mg, Germany) each week for three weeks, and group 2 (n=35) will receive oral atorvastatin 40 mg/day orally (Sobhan Darou, Tehran, Iran) for six months. We will train all patients to answer the WOMAC questioner. They will be permitted to continue their usual treatment with analgesics and non-steroidal anti-inflammatory drugs (NSAIDs). However, they are urged not to use analgesics and NSAIDs 48 hours before physician visit to prevent scrambled test results. Symptoms will be scored by WOMAC index at enrollment and every month up to 6 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504141479N4**

Registration date: **2015-08-17, 1394/05/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-17, 1394/05/26

Registrant information

Name

Mohammadhassan Jokar

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

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+98 51 1859 8818

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Recruitment status

Recruitment complete

Funding source

Research vice president of Mashhad University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-07-06, 1393/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to Compare between the efficacy of of

intra-articular Hyaluronic acid and oral atorvastatin in reducing pain, stiffness, and function of the knee in patients with mild to moderate knee osteoarthritis

Public title
The effects of Hyaluronic acid and Atorvastatin on knee arthrosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria 1- Knee osteoarthritis according to ACR criteria 2- Age 50-70 years 3- Radiologically ascertained grade I or II of knee osteoarthritis on the Kellgren-Lawrence scale 4- Pain score=>60 (maximum 100)
Exclusion criteria 1- Secondary osteoarthritis 2- Systemic disease like diabetes 3- History of Inflammatory arthritis 4- Sever knee deformity (varus or valgus >50 degree) 5- History of coagulopathies 6- Sever cardiovascular disease 7- Active infections 8- Immunologic disorders 9- Taking anticoagulants 10- Hb<11 mg/dl, platelet count<150000/dl

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: via a random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad University of Medical sciences, Daneshgah street

City

Mashhad

Postal code

9177899191

Approval date

2013-03-02, 1391/12/12

Ethics committee reference number

IR.MUMS.REC.1391.901

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description

Knee osteoarthritis symptoms: knee pain, knee stiffness and knee function

Timepoint

At enrollment and after intervention : every month up to 6 months.

Method of measurement

WOMAC questionnaire

Secondary outcomes

1

Description

Drug side effects: in group 1: hypersensitivity reaction in injection site and exacerbation of knee pain. In group 2: musculoskeletal pain, skin rash and gastrointestinal symptoms

Timepoint

Every 1 month after intervention up to 6 months

Method of measurement

Taking history

Intervention groups

1

Description

Group 1: After sterilizing the injection site, we inject one ampoule of Hyaluronic acid (Hyaluron® HEXAL, Germany, 20mg/2cc) into the knee joint. We repeat the injection each week for three times

Category

Treatment - Drugs

2

Description

Group 2: Oral atorvastatin 40 mg (Sobhan Darou, Tehran, Iran) one tablet daily for 6 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Hassan Jokar

Street address

Daneshgah street

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice president for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Daneshgah street

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Mshhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice president 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Hassan Jokar

Position

Rheumatologist, Associated Professor

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Full name of responsible person

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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