

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparative evaluation of the effect of 2% Atorvastatin gel versus Diclofenac gel on clinical symptoms of patients with knee osteoarthritis

Protocol summary

Study aim

Study of topical Atorvastatin gel effect on clinical symptoms of patients with knee osteoarthritis

Design

Parallel, drug-control, double blind, and randomized clinical trial

Settings and conduct

The statistical population included patients referred to the rheumatology clinic of Bou Ali hospital in Tehran. Patients were randomly divided into two groups: The first group received atorvastatin gel and the second group received diclofenac gel. The Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire was used to evaluate the pain, stiffness, physical function for a total period of 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of mild to moderate knee osteoarthritis by a rheumatologist, No other topical treatment usage at least two weeks before the study, No oral Atorvastatin usage, No other systemic analgesics or anti-inflammatory usage at least two weeks before the study, Obtaining informed consent from the patients. Patients aged between 40 and 75 years old; Exclusion criteria: Unwilling to continue or to participate in the study any further, Patients with other knee joint disorders: (Rheumatoid Arthritis, Gout, Pseudo Gout, Infected Arthritis), Knee corticosteroid injection in the past 3 months, Joint replacement, Pregnancy and lactation, Sensitivity to study drugs

Intervention groups

Intervention group: Atorvastatin Gel prepared by researcher, Knee local use, 2 times a day, for 3 months
Control group: Diclofenac Gel 1 % (Razak), 2 times daily, for 3 months

Main outcome variables

The WOMAC questionnaire was used to evaluate the pain, stiffness, physical function at the beginning of study, 4 weeks, 8 weeks, 12 weeks after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N6**

Registration date: **2020-08-17, 1399/05/27**

Registration timing: **retrospective**

Last update: **2020-08-17, 1399/05/27**

Update count: **0**

Registration date

2020-08-17, 1399/05/27

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-20, 1396/09/29

Expected recruitment end date

2018-09-20, 1397/06/29

Actual recruitment start date

2018-05-06, 1397/02/16

Actual recruitment end date

2019-04-21, 1398/02/01

Trial completion date

2019-07-19, 1398/04/28

Scientific title

A comparative evaluation of the effect of 2% Atorvastatin gel versus Diclofenac gel on clinical symptoms of patients with knee osteoarthritis

Public title

Comparison of the effect of 2% Atorvastatin gel on clinical symptoms of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of mild to moderate knee osteoarthritis by a rheumatologist based on clinical symptoms and knee X-ray No other topical treatments usage at least two weeks before the study No oral Atorvastatin usage No other systemic analgesics or anti-inflammatory usage at least two weeks before the study Obtaining informed consent from the patients patients aged between 40 and 75 years old

Exclusion criteria:

Those who need to use other oral or intravenous analgesics Unwilling to continue or to participate in the study any further Patients with other knee joint disorders: (Rheumatoid Arthritis, Gout, Pseudo Gout, Infected Arthritis) Knee corticosteroid injection in the past 3 months Joint replacement Pregnancy and lactation Sensitivity to study drugs

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was done randomly so that 40 people were selected using the numbers table. These people were randomly assigned through "Random Sequence Generation" method by random numbers table in Excel software and were divided into two Atorvastatin and Diclofenac groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patient who had the necessary condition to enter the study were assigned randomly into two groups of drugs and drug-control. Patients and doctors were unaware of the medication or drug-control intervention, and patients and medication were coded by someone who did not intervene in the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

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Approval date

2017-08-26, 1396/06/04

Ethics committee reference number

IR.IAU.PS.REC.1396.103

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

Knee Osteoarthritis

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

Pain

Timepoint

At the beginning of the study, 4 weeks, 8 weeks, 12 weeks after treatment

Method of measurement

WOMAC Questionnaire

2**Description**

Stiffness

Timepoint

At the beginning of the study, 4 weeks, 8 weeks, 12 weeks after treatment

Method of measurement

WOMAC Questionnaire

3

Description

Physical Function

Timepoint

At the beginning of the study,4weeks,8weeks,12weeks after treatment

Method of measurement

WOMAC Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Atorvastatin Gel prepared by researcher, Knee local use, 2 times a day for 3 months

Category

Treatment - Drugs

2

Description

Control group: diclofenac gel 1 % (Razak) ,2 times daily, for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali hospital

Full name of responsible person

Dr. Maryam Gharavi

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Damavand avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Niloofar Sadat Mousanejad

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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