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 tow weeks before the study, No oral Atorvastatin usage, No other systemic analgesics or anti-inflammatory usage at least tow 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: (Rhumatoid Arthrities, Gout, Pseudo Gout, Infected Arthrities), 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,4weeks,8weeks,12weeks 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
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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 cilinical symptoms and knee X-ray No other topical treatments usage at least tow weeks before the study No oral Atorvastatin usage No other systemic analgesics or anti-inflammatory usage at least tow 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: (Rhumatoid Arthrities, Gout, Pseudo Gout, Infected Arthrities) 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 tow groups of drugs and drug-control. Patients and doctors were unaware of the medication or drug-control interventio, 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
کمیته اخلاق واحد علوم دارویی دانشگاه علوم پزشکی آزاد اسلامی تهران

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Dr Shariati Ave., Gholhak, YakhchalAve., Islamic Azad university of Pharmaceutical Sciences Branch

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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,4weeks,8weeks,12weeks after treatment

Method of measurement
WOMAC Questionnaire

2

Description
Stiffness

Timepoint
At the beginning of the study,4weeks,8weeks,12weeks 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Other areas of specialty/work
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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