Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparative study of four conservative treatments for patients with knee osteoarthritis

Protocol summary

Study aim
Determination of therapeutic effect and treatment difference in administration of celecoxib with intravenous injection in patients with osteoarthritis

Design
Blocked randomized, Parallel group trial with blinded outcome assessment, Clinical trial with control group

Settings and conduct
In this method, patients suffering from knee DJD refer to orthopedic clinic of Hamadan Besat Hospital because of knee pain. First, an experienced person is examined the patients and a radiologic imaging (lateral,AP,rozenberg view)have be done for the patient. Before a patient is injected, a questionnaire is based on VAS sacore and the test and the patient's pain intensity is given and filled. Patients are then re-visited at intervals of three weeks, six weeks, and three months, and their VAS is measured. During this period, the investigator is not aware of the injected drug

Participants/Inclusion and exclusion criteria
1. Patients with knee osteoarthritis with grade of 2 and 3 2. Agree to participate in the study 1. osteoarthritis degrees 0, 1, 4 2. Unstable joint 3. Hemorrhagic disorders 4. Knee joint infections in injection site 5. The history of surgery in the last year 6. History of knee infection in the last year 7. Failure to follow the patient

Intervention groups
The first group (A) received celecoxib 200 mg twice daily with intradermal injection of placebo. The second group (B) uses the same selcocide distraction with intra-articular injection of a 40-mg depotmedol injection. The third group (C) received celecoxib 200 mg twice daily with an injection of hyaluronic acid (a medicine containing 10 mg in 2.5 cc) The fourth group (D) of celecoxib with the same dose, with injection of depotomeric ampoules, receives hyaluronic acid (combination) ampoules.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190114042360N1**
Registration date: **2019-08-19, 1398/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-19, 1398/05/28**
Update count: **0**

Registration date
2019-08-19, 1398/05/28

Registrant information

Name
Maryam Zamanirafe

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3821 8792

Email address
zamanirafe.maryam@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-08-20, 1398/05/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparative study of four conservative treatments for patients with knee osteoarthritis

Public title
Study of four conservative treatment of osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with knee osteoarthritis grade of 2 and 3 Agree to participate in the study
Exclusion criteria:
Osteoarthritis grade 0, 1, 4 Unstable joint Bleeding disorders Joint and pathogenic infection of injection site Surgery history in the last year History of knee infection in the last year Unable to follow the patient
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to one of four groups: the first group (A) receives 200 mg of celecoxib twice daily with intradermal injection of placebo (distilled water). The second group (B) is the same as the intracellular injection of celecoxib A 40-mm dipomedulum ampoule is used jointly. The third group (C) received celecoxib 200 mg twice daily with an injection of hyaluronic acid (a medicine containing 10 mg in 2.5 cc). The fourth group (D) of celecoxib with the same dose was injected with depotomeric ampoules, hyaluronic acid Combination). The 8th block means that the first patient is treatment A, the second patient treatment C, the patient D treatment, the fourth patient B treatment, the patient the treatment B, the sixth patient D treatment, the seventh patient C treatment, the eighth patient A, and until the end of the work Until all samples are completed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the researcher only receives the received code of the injected drug into the knee joint and carries out follow-up follow-up.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences
Street address
Hamedan University of Medical Sciences,Park Blvd, Hamadan Town
City
Hamedan
Province
Hamadan
Postal code
6517838698
Approval date
2019-04-27, 1398/02/07
Ethics committee reference number
IR.UMSHA.REC.1398.036

Health conditions studied

1

Description of health condition studied
Osteoarthritis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain
Timepoint
before and 1,3 and 6 weeks after of injection
Method of measurement
use of Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Injection of placebo in the knee
Category
Placebo

2

Description

Intervention group: First intervention group: Injection of Ampule-40, 1 vial of 1 ml of pharmaceutical Exir Company-Iran in knee

Category

Treatment - Drugs

3

Description

Intervention group: Second Intervention group: Injection of Ampule-40, 1 vial of 1 ml of pharmaceutical Exir Company-Iran in knee and Injections of 20 mg 2 ml intrajoint hyaline ampoule made by Fidia Italy

Category

Treatment - Drugs

4

Description

Intervention group: Third intervention group: Injections of 20 mg 2 ml intrajoint hyaline ampoule made by Fidia Italy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat hospital

Full name of responsible person
Maryam Zamani Rafe

Street address
Besat Hospital, Masqineh Road, Shahid Motahari Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeed Bashirian

Street address
Hamedan University of Medical Sciences , Facing the People's Park, Hamedan

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6517838698

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s_bashirian@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Maryam Zamanirafe

Position
Intern

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available