

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the analgesic effect of oral Meloxicam and Diclofenac after knee arthroplasty

Protocol summary

Study aim

Determining and comparing the effects of oral meloxicam and diclofenac on pain control after knee replacement surgery

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 128 patients. "Random allocation" computer software will be used for randomization.

Settings and conduct

64 patients referred to Imam Khomeini Hospital (RA) in Urmia who are candidates for knee joint replacement surgery will be included in the study.

Participants/Inclusion and exclusion criteria

In this double-blind clinical trial study, 64 patients referred to Imam Khomeini Hospital (RA) in Urmia who are candidates for knee joint replacement surgery will be included in the study. Inclusion criteria: 1. Diagnosis of knee osteoarthritis based on the scales of the American Society of Anesthesiology (9) 2. candidate for knee joint replacement surgery 3. American Society of Anesthesiology grade 1 and 2 patients 4. No history of corticosteroid or hyaluronic acid injection into the joint during the past three months 5. No history of knee surgery or interventional treatment Exit criteria: 1. Age less than 18 years 2. consumption of painkillers during the last 7 days 3. Blood and coagulation disorders 4. severe heart failure, liver and kidney 5. Any absolute and relative contraindications to the use of drugs during the study 6. Nervous disorders and the impossibility of accurately understanding the sensation of pain 7. Pregnancy and breastfeeding 8. Patients using the intravenous form of morphine

Intervention groups

Patients will be divided into two groups in a simple random manner using the numbers given by "Random Allocation" computer software. In the meloxicam group, 15 mg of oral meloxicam and in the diclofenac group 100 mg of oral diclofenac will be given at 4, 24 and 48 hours

after surgery.

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056613N4**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

Registration date

2023-07-11, 1402/04/20

Registrant information

Name

aliakbar nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

nasiriali7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2024-03-17, 1402/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the analgesic effect of oral Meloxicam and Diclofenac after knee arthroplasty

Public title
Comparison of the analgesic effect of oral Meloxicam and Diclofenac after knee arthroplasty

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of knee osteoarthritis based on the scales of the American Society of Anesthesiology Candidate for knee joint replacement surgery American Society of Anesthesiology grade 1 and 2 physical status patients No history of corticosteroid or hyaluronic acid injections into the joint during the past three months No history of knee surgery or interventional treatment
Exclusion criteria:
 Age less than 18 years pain reliever use in the past 7 days Blood and coagulation disorders Severe heart-liver and kidney failure Any absolute and relative contraindications to the use of drugs during the study Nervous disorders and the inability to accurately perceive the sensation of pain Pregnancy and breastfeeding Patients using the intravenous form of morphine

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups in a simple random manner using the numbers given by "Random Allocation" computer software. The randomization method is such that each patient is given a code and then the codes are written on a piece of paper, and after mixing the pieces of paper together, a piece of paper is randomly taken out each time and the code is related to the patient. In a list, the first 25 codes will be in the case group and the second 25 will be in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The procedure will be performed blindly and without the knowledge of the patients and the surgeon, so the study will be double-blind. Also, with the advice of a pharmaceuticals expert, the pharmaceutical forms of the

two groups will be designed the same.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee in research of Imam Khomeini Medical Education Center of Urmia University of Medic
Street address
 Imam Khomeini Hospital, Ershad Street
City
 Urmia
Province
 West Azarbaijan
Postal code
 2245898115
Approval date
 2022-08-08, 1401/05/17
Ethics committee reference number
 IR.UMSU.HIMAM.REC.1401.091

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee

ICD-10 code
M17.9

ICD-10 code description
Osteoarthritis of knee, unspecified

Primary outcomes

1

Description
Intensity of pain

Timepoint
Pain intensity will be measured at 24, 48 and 72 hours after the operation.

Method of measurement
The intensity of pain after the operation of the patients will be measured using a visual analog index and scoring method from 0 (no pain) to 10 (unbearable pain).

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: In the intervention group, the oral form of 15 mg meloxicam will be administered.

Category

Treatment - Drugs

2

Description

Control group: In the control group, the same method will be used, but with the use of 100 mg diclofenac.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Urmia

Full name of responsible person

Reza Ghaderi

Street address

Imam Khomeini Hospital, Ershad Street

City

Urmia

Province

West Azarbaijan

Postal code

25486551237

Phone

+98 933 395 5273

Email

rezaqaderi20@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Reza Ghaderi

Street address

Imam Khomeini Hospital, Ershad Street

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 933 395 5273

Email

rezaqaderi20@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Urmia University of Medical Sciences

Proportion provided by this source

10

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

Oroumia University of Medical Sciences

Full name of responsible person

Ali Akbar Nasir

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emam khomini university hospital, Eeshad AVE,
Modarres Blvd, urmia, iran

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3345 7286

Email

Nasiriali7@gmail.com

Web page address

<https://umsu.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Ali Akbar Nasir

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data is shareable

When the data will become available and for how long

1 year after the results are published

To whom data/document is available

It will be available only for researchers working in
academic and scientific institutions b

Under which criteria data/document could be used

After analyzing the data.

From where data/document is obtainable

Imam Khomeini Hospital Urmia

What processes are involved for a request to access data/document

Refer to the Research Department of Imam Khomeini
Hospital in Urmia

Comments