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 pharmaceutics 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
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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
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Subspecialist
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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