Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation and comparison of the effect of preoperative use of celecoxib , gabapentin , combination of celecoxib with gabapantin and combination of celecoxib with dexamethasone and gabapantin in reducing postoperative pain in patients undergoing total knee replacement surgery

Protocol summary

Study aim
Evaluation and comparison of the effect of preoperative use of celecoxib alone, gabapentin alone, combination of celecoxib with gabapantin and combination of celecoxib with dexamethasone and gabapantin in reducing postoperative pain in patients undergoing total knee arthroplasty

Design
Clinical trial without control group with parallel, randomized, phase 3 groups on 144 patients

Settings and conduct
This study is performed in Kashani Hospital in Isfahan. Before surgery, patients receive different painkillers depending on their group. The patients will then undergo surgery and their pain will be assessed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years, first candidate for knee replacement surgery, Candidate for unilateral TKA surgery due to primary osteoarthritis, consent to participate in the study. Exclusion criteria: Lack of follow-up and examination of the patient's condition, patient death, chronic diseases

Intervention groups
Intervention group 1: Patients in this group are treated with two doses of 400 mg celecoxib alone before surgery. Intervention group 2: Patients in this group are treated with two doses of 300 mg gabapentin alone before surgery. Intervention group 3: In this group, patients in addition to 400 mg celecoxib, are treated with two doses of 300 mg gabapentin before surgery. Intervention group 4: Patients in this group will receive two doses of dexamethasone 4 mg in addition to celecoxib 400 mg and gabapentin 300 mg. The pain of all patients will be assessed by visual analog criteria at 24, 48 and 72 hours after surgery.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200217046523N10**
Registration date: **2021-02-04, 1399/11/16**
Registration timing: **prospective**

Last update: **2021-02-04, 1399/11/16**
Update count: **0**

Registration date
2021-02-04, 1399/11/16

Registrant information

Name
Aryan Rafiee Zadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3837 1582

Email address
rafieezadeh.a@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-18, 1399/11/30

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison of the effect of preoperative use of celecoxib , gabapentin , combination of celecoxib with gabapantin and combination of celecoxib with dexamethasone and gabapantin in reducing postoperative pain in patients undergoing total knee replacement surgery

Public title
The effect of preoperative use of celecoxib , gabapentin , combination of celecoxib with gabapantin and combination of celecoxib with dexamethasone and gabapantin on postoperative pain relief

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Candidate for unilateral TKA surgery due to primary osteoarthritis Satisfaction to participate in the study

Exclusion criteria:
Failure to follow up and examine the patient's condition Death of the patient Having chronic diseases

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of IsfahanUniversity of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-01-13, 1399/10/24

Ethics committee reference number
IR.MUI.MED.REC.1399.948

Health conditions studied

1

Description of health condition studied
Total Knee Arthroplasty

ICD-10 code
D86.86

ICD-10 code description
Sarcoid arthropathy

Primary outcomes

1

Description
Pain

Timepoint
24, 48 and 72 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in this group are treated with two doses of 400 mg celecoxib alone before surgery and their pain will be assessed by analog visual criteria at 24, 48 and 72 hours after surgery.

Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in this group are treated with two doses of 300 mg of gabapentin alone before surgery and their pain will be assessed by visual analog criteria at 24, 48 and 72 hours after surgery.

Category
Treatment - Drugs

3

Description
Intervention group 3: Patients in this group, in addition to 400 mg celecoxib, are treated with two doses of 300 mg gabapentin before surgery and their pain will be assessed by visual analog criteria at 24, 48 and 72 hours after surgery.
Category
Treatment - Drugs

4

Description
Intervention group 4: Patients in this group, in addition to celecoxib 400 mg and gabapentin 300 mg, will also receive two doses of dexamethasone 4 mg before surgery and their pain will be assessed by visual analog criteria at 24, 48 and 72 hours after surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Mehdi Motififard
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave,. Daneshgah Blvd, Isfahan
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Email
haghjoo.sh@med.mui.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Motififard
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments