

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison of the effect of adding dexmedetomidine, fentanyl and magnesium sulfate to bupivacaine in the management of acute pain after knee replacement surgery.

Protocol summary

Study aim

Comparison of the effect of adding dexmedetomidine, fentanyl, magnesium sulfate to bupivacaine in the management of acute pain after knee replacement surgery.

Design

In this double-blind clinical trial, eligible patients are randomly assigned to one of four groups to receive bupivacaine in combination with either fentanyl, dexmedetomidine, magnesium sulfate, or normal saline. All patients receive standard anesthetic care according to institutional protocols, with drug preparation and administration performed by personnel not involved in patient care or outcome assessment. Postoperative pain intensity will be compared among the four groups.

Settings and conduct

This study will be conducted as a randomized controlled clinical trial using permuted blocks of four, with a double-blind design (blinding both participants and outcome assessors), parallel groups, with control group, and a total of 120 patients who are candidates for total knee arthroplasty and referred to Imam Reza Hospital in Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA class I or II; candidates for unilateral total knee arthroplasty; operated on by a single surgeon. Exclusion criteria: contraindications to spinal anesthesia; hypersensitivity to study medications; blood pressure >160 mmHg.

Intervention groups

Intervention group 1: 20 mg of bupivacaine solution plus 25 micrograms of sterile fentanyl; Intervention group 2: 20 mg of bupivacaine solution plus 25 micrograms of sterile dexmedetomidine; Intervention group 3: 20 mg of bupivacaine solution plus 50 mg of magnesium sulfate; Intervention group 4: 20 mg of bupivacaine solution plus 1 cc of normal saline

Main outcome variables

Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N58**

Registration date: **2025-08-02, 1404/05/11**

Registration timing: **retrospective**

Last update: **2025-08-02, 1404/05/11**

Update count: **0**

Registration date

2025-08-02, 1404/05/11

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3334 7054

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-31, 1402/08/09

Expected recruitment end date

2024-08-18, 1403/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of adding dexmedetomidine, fentanyl and magnesium sulfate to bupivacaine in the management of acute pain after knee replacement surgery.

Public title
Comparison of the effect of adding dexmedetomidine, fentanyl, magnesium sulfate to bupivacaine

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
ASA class I or II Scheduled for unilateral total knee arthroplasty Procedure performed by a single surgeon
Exclusion criteria:
Contraindications to spinal anesthesia Patients with hypersensitivity to any of the study medications Patients with a blood pressure greater than 160 mmHg

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyster

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study with a sample size of 120 participants, block permutation randomization will be used for allocation. Given that there are four study groups, participants are initially divided into two categories: groups A and B, with group A representing groups 1 (fentanyl) and 2 (dexmedetomidine), and group B representing groups 3 (magnesium sulfate) and 4 (control). Each block consists of four participants, with six possible arrangements: BBAA, AABB, ABAB, BABA, ABBA, and BAAB. The sequence of blocks will be determined randomly using the Random Allocation Software by selecting numbers from 1 to 6. For example, if block 6 (BAAB) and then block 2 (AABB) are selected, the allocation order for enrolled participants will be BAABAABB. In the second stage, each category (A and B) will be further randomized into its two subgroups, ensuring that each participant is ultimately assigned to one of the four main study groups. Thus, in this method, the letter A initially stands for groups 1 and 2, and B for groups 3 and 4; subsequently, members of each letter group are randomly allocated to one of their respective subgroups, resulting in a final allocation to one of the four study arms.

Blinding (investigator's opinion)

Double blinded

Blinding description
The thesis results analyst who will analyze the expected result and also the participants will be unaware of the type of procedure performed and will be blind during the study; Therefore, this study will be conducted in a double-blind manner. Since the participants will be unaware of the type of drug used, in this study they will not know what type of drug will be used in other patients. The injectable medications and placebo will be prepared in identical syringes of the same volume, shape, and color by the anesthesiologist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5165665631

Approval date
2023-08-27, 1402/06/05

Ethics committee reference number
IR.TBZMED.REC.1402.390

Health conditions studied

1

Description of health condition studied
Pain Intensity

ICD-10 code
G89.11

ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
Pain Intensity

Timepoint
They will be measured at 1, 2, 4, 6, 12, 18, and 24 hours

after surgery.

Method of measurement

The Visual Analog Scale (VAS) was used to assess pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In Group 1, patients will receive 20 mg of bupivacaine solution combined with 25 micrograms of sterile fentanyl, and their postoperative pain intensity will be assessed at predetermined time points.

Category

Treatment - Drugs

2

Description

Intervention group 2: In Group 2, patients will receive 20 mg of bupivacaine solution combined with 25 micrograms of sterile dexmedetomidine, and their postoperative pain intensity will be assessed at predetermined time points.

Category

Treatment - Drugs

3

Description

Intervention group 3: In Group 3, patients will receive 20 mg of bupivacaine solution combined with 50 mg of magnesium sulfate, and their postoperative pain intensity will be assessed at predetermined time points.

Category

Treatment - Drugs

4

Description

Control group: In Group 4, patients will receive 20 mg of bupivacaine solution combined with 1 cc of normal saline, and their postoperative pain intensity will be assessed at predetermined time points.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mahdi Nazari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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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