Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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 analyser

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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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

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Mehdi Khanbabayi Gol

Position
MSc in Nursing Education

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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