Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Intraoperative Ketamine vs Magnesium for Acute Postoperative Pain in Unilateral Knee Replacement Surgery during regional anesthesia: A randomized Controlled Trial

Protocol summary

Study aim

To evaluate effectiveness of intraoperative ketamine infusion vs magnesium sulphate infusions in reducing acute post operative pain in patients who have undergone unilateral knee replacement.

Design

Two arm, parallel group, randomized controlled trial with participant and outcome assessor blinding at a single center. Sixty four participants will be randomly allocated using the lottery method.

Settings and conduct

The study will be conducted at Evercare Hospital Lahore. Eligible participants will provide informed consent and undergo random allocation to ketamine or magnesium. Other anesthesia and perioperative medications will be standardized. Participants and the outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria

Adults over 18 years scheduled for elective unilateral total knee replacement, of either sex, with American Society of Anesthesiologists physical status I to III, able to consent and report pain. Patients with contraindications to ketamine or magnesium, chronic pain, opioid dependence, relevant medication use, neurological disorders, pregnancy, uncontrolled cardiovascular disease, or severe hepatic or renal impairment will be excluded.

Intervention groups

The ketamine group will receive intravenous ketamine 0.5 mg/kg followed by 2 to 5 micrograms/kg/minute infusion during surgery. The magnesium group will receive magnesium sulfate 40 mg/kg before induction followed by 15 mg/kg infusion until skin closure.

Main outcome variables

The primary outcome is acute postoperative pain measured using the Numerical Rating Scale from 0 to 10 at 24 hours. Secondary outcomes include opioid consumption, adverse effects, time to rescue analgesia, and persistent postoperative pain at 6 months.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260924071176N1**
Registration date: **2026-09-29, 1405/07/07**
Registration timing: **retrospective**

Last update: **2026-09-29, 1405/07/07**
Update count: **0**

Registration date

2026-09-29, 1405/07/07

Registrant information

Name
Asma Bhatti
Name of organization / entity
College of physicians and surgeons Pakistan
Country
Pakistan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-30, 1404/03/09

Expected recruitment end date

2026-09-30, 1405/07/08

Actual recruitment start date

2025-05-27, 1404/03/06

Actual recruitment end date
2026-09-23, 1405/07/01
Trial completion date
2026-09-23, 1405/07/01

Scientific title
Intraoperative Ketamine vs Magnesium for Acute Postoperative Pain in Unilateral Knee Replacement Surgery during regional anesthesia: A randomized Controlled Trial

Public title
Intraoperative Ketamine vs Magnesium for Acute Postoperative Pain in Unilateral Knee Replacement Surgery during regional anesthesia: A randomized Controlled Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged >18 years Patients scheduled for elective unilateral total knee replacement surgery Both male and female patients Patients classified as ASA physical status I–III Patients able to provide informed consent before surgery Patients able to understand and report their pain score
Exclusion criteria:
Allergy or contraindication to ketamine or magnesium Pre-existing chronic pain conditions (fibromyalgia, neuropathic pain) Current opioid dependence or substance abuse history (alcohol, illicit drugs) Use of medications effecting NMDA receptors (SSRIs, SNRIs, antipsychotics) and if already on calcium channel blockers. Neurological disorders (epilepsy, h/o seizures, increases ICP) Pregnant or breastfeeding Uncontrolled cardiovascular disease (arrythmias, ischemic heart disease) Severe hepatic or renal impairment (liver cirrhosis, creatinine clearance <30 mL/min)
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **64**
Actual sample size reached: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants will be randomly allocated to one of two parallel groups (ketamine or magnesium) using a simple randomization method by lottery. The individual participant will be the unit of randomization. The random allocation sequence will be generated using the lottery method, with participants assigned to either the ketamine or magnesium group according to the selected allocation. Participants and the outcome assessor will remain unaware of group allocation throughout the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and the outcome assessor will be blinded to group allocation. Participants will not be informed whether they receive ketamine or magnesium. The outcome assessor will be unaware of the treatment group during postoperative outcome assessment. The treating anesthesia team will know the group allocation for administration of the study drug.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Research Committee Evercare Hospital Lahore
Street address
D1 Commercial , NECHS Block D 1 Nespak Housing Society Lahore
City
Lahore
Postal code
54000
Approval date
2025-04-30, 1404/02/10
Ethics committee reference number
IRC/25/04/001

Health conditions studied

1

Description of health condition studied
Acute postoperative pain after unilateral knee replacement surgery
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Acute postoperative pain intensity
Timepoint
24 hours after surgery

Method of measurement
Numerical Rating Scale from 0 to 10

Secondary outcomes

1

Description
Postoperative opioid consumption
Timepoint
Within 24 hours after surgery
Method of measurement
Total opioid dose consumed during the first 24 postoperative hours.

2

Description
Opioid-related side effects and adverse events
Timepoint
Postoperative period
Method of measurement
Nausea, vomiting, hallucinations, agitation, hypotension, bradycardia, and muscle weakness.

3

Description
Pain intensity
Timepoint
24 hours after surgery
Method of measurement
Numerical Rating Scale from 0 to 10

4

Description
Time to first rescue analgesia
Timepoint
Postoperative period
Method of measurement
Time from completion of surgery to first request for rescue analgesia.

5

Description
Persistent postoperative pain / chronic pain development
Timepoint
6 months after surgery
Method of measurement
Assessment of postoperative pain at six months.

Intervention groups

1

Description
Intervention group: Ketamine group. Participants will receive intraoperative ketamine infusion in addition to standardized perioperative anesthetic and analgesic management. Ketamine will be administered as an intravenous bolus of 0.5 mg/kg followed by a continuous intravenous infusion at 2–5 mcg/kg/min. The infusion will be started before surgical incision and continued throughout the intraoperative period.
Category
Treatment - Drugs

2

Description
Intervention group: Magnesium group. Participants will receive intraoperative magnesium sulfate infusion in addition to standardized perioperative anesthetic and analgesic management. Magnesium sulfate will be administered intravenously at a dose of 40 mg/kg over 15 minutes before induction of anesthesia, followed by a continuous intravenous infusion of 15 mg/kg during the surgical procedure until skin closure.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Evercare Hospital Lahore
Full name of responsible person
Dr. Asma Bhatti
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Evercare Hospital Lahore
Full name of responsible person
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ateeq.rehman@evercare.pk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Evercare Hospital Lahore
Proportion provided by this source
20
Public or private sector
Private
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
Evercare Hospital Lahore
Full name of responsible person
Dr. Asma Bhatti
Position
Fellow Pain Medicine
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Ethical concerns
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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available