Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Low-Dose Ketamine on Sleep Quality During the Early Postoperative Days After Major Abdominal Surgery: A Randomized, Double-Blind Clinical Trial

Protocol summary

Study aim

To evaluate the effect of intraoperative low-dose ketamine on postoperative sleep quality using the Sleep Numerical Rating Scale on postoperative days 1and 3.

Design

A single-center, two-arm, parallel-group, randomized, double-blind, placebo-controlled clinical trial involving 120 participants (60 per group), with 1:1 allocation using a computer-generated randomization sequence.

Settings and conduct

The trial will be conducted at Taleghani Hospital in Tehran in adults undergoing elective major abdominal surgery. Participants will receive low-dose ketamine or placebo, with participants, care providers, outcome assessors, and the data analyst blinded to allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18–80 years. ASA Physical Status I–III. Elective major abdominal surgery Provision of written informed consent exclusion criteria: Minor surgery Severe hepatic or renal failure Severe psychiatric disorder History of Severe Sleep Disturbance. Refusal to participate in the study.

Intervention groups

Ketamine Group: 0.25 mg/kg bolus, followed by a 0.1 mg/kg/h infusion until the end of surgery. Placebo Group: Bolus and infusion of saline with the same volume.

Main outcome variables

Postoperative sleep quality on days 1–3, postoperative pain, need for rescue analgesia, and adverse effects, including dizziness, hallucinations, nightmares, and agitation.

General information

Reason for update

Because the number of eligible patients undergoing hepatobiliary surgery at Ayatollah Taleghani Hospital has decreased, and achieving the required sample size has become difficult, continuing to recruit exclusively from patients undergoing hepatobiliary surgery has become challenging. This reduction in patient referrals and surgical procedures, particularly in recent months, has significantly affected the recruitment process. Therefore, we kindly request your consideration and approval to modify the study's target population from patients undergoing major hepatobiliary surgery to patients undergoing major abdominal surgery to facilitate recruitment of the required sample size. The other major aspects of the study design, including the randomized, double-blind clinical trial design, the intervention under investigation, and the primary outcome, will remain unchanged. We will amend the protocol and other relevant study documents accordingly to reflect this modification.

Acronym

IRCT registration information

IRCT registration number: **IRCT20260711070122N1**
Registration date: **2026-07-25, 1405/05/03**
Registration timing: **prospective**

Last update: **2026-08-31, 1405/06/09**
Update count: **1**

Registration date

2026-07-25, 1405/05/03

Registrant information

Name

negarsadat Namazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-08-01, 1405/05/10
Expected recruitment end date
2027-07-31, 1406/05/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Low-Dose Ketamine on Sleep Quality During the Early Postoperative Days After Major Abdominal Surgery: A Randomized, Double-Blind Clinical Trial

Public title
The Effect of Ketamine on Sleep Quality After AbdominalSurgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age range: 18–80 years Patients with ASA physical status I–III Candidates for elective major abdominal surgery Extubation at the end of surgery or within the first postoperative hours Ability to comprehend and complete the sleep and pain questionnaires Written informed consent
Exclusion criteria:
Minor surgery, such as uncomplicated cholecystectomy Expected need for mechanical ventilation beyond the first postoperative night Preoperative hepatic encephalopathy Severe renal failure Severe psychiatric illness, active psychosis, or hallucinations Severe preoperative insomnia (Athens Insomnia Scale [AIS] score ≥ 6) Chronic ketamine use Substance abuse Declining to participate in the study
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization: In this study, the unit of randomization will be the individual patient. After assessment of eligibility criteria and written informed consent, eligible patients will be allocated in a 1:1 ratio to either the ketamine or placebo group. Simple randomization will be used, and no stratified or cluster randomization will be performed. Before participant recruitment begins, the random allocation sequence will be generated using computer-generated random numbers by an independent individual who will have no role in participant recruitment, intervention delivery, outcome assessment, or data analysis. According to this sequence, each participant enrolled consecutively will be assigned to one of two groups: ketamine or placebo. To ensure allocation concealment, the master randomization list will be accessible only to the independent pharmacist or nurse responsible for preparing the study medication. The investigator responsible for assessing eligibility and enrolling participants will not have access to the allocation sequence. After eligibility has been confirmed and written informed consent obtained, the next sequential study number will be assigned to the participant, and the independent individual will prepare the study medication corresponding to that number. Ketamine and placebo will be prepared in identical syringes or infusion pumps, with identical appearance, volume, and labeling. Participants, surgeons, anesthesiologists, intensive care unit nurses, outcome assessors, and the data analyst will remain unaware of treatment allocation until data collection and analysis are complete.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a randomized, double-blind, placebo-controlled clinical trial. Participants, healthcare providers, outcome assessors, and the data analyst will be blinded to group allocation. Patients will be randomly assigned in a 1:1 ratio to ketamine or placebo using a computer-generated sequence. The study drugs will be prepared by an independent pharmacist or nurse and will be identical in appearance, volume, and labeling.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Velenjak - Moghaddas Ardebili St.
City
Tehran

Province
Tehran
Postal code
1985914674
Approval date
2026-07-19, 1405/04/28
Ethics committee reference number
IR.SBMU.RETECH.REC.1405.225

Health conditions studied

1

Description of health condition studied
Early postoperative sleep disturbance in patients undergoing major abdominal surgery
ICD-10 code
G47
ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
The incidence of postoperative sleep disturbance on the first postoperative day. Postoperative sleep disturbance is defined as an Athens Insomnia Scale (AIS) score of 6 or higher or a Sleep Numerical Rating Scale (Sleep NRS) score of 6 or lower. Patients meeting at least one of these criteria will be considered to have postoperative sleep disturbance.
Timepoint
after the first and third postoperative nights.
Method of measurement
Measurement will be performed using the Athens Insomnia Scale and the Sleep Numerical Rating Scale.

Secondary outcomes

1

Description
Postoperative pain intensity at rest and during coughing or movement, measured using the Visual Analog Scale. A score of 0 indicates no pain, and a score of 10 indicates the worst imaginable pain.
Timepoint
On postoperative days 1 and 3, after the first and third postoperative nights.
Method of measurement
Postoperative pain intensity at rest and during coughing or movement, measured using the Visual Analog Scale. A score of 0 indicates no pain, and a score of 10 indicates the worst imaginable pain.

Intervention groups

1

Description
Intervention group: Following induction of general anesthesia, patients will receive an intravenous bolus of ketamine at 0.25 mg/kg body weight, followed by a continuous intravenous infusion of ketamine at 0.1 mg/kg/h until skin closure. Ketamine administration will be limited to the intraoperative period and will not be continued after surgery. Other anesthetic care and postoperative pain management will be provided according to the center’s standard protocol
Category
Prevention

2

Description
Control group: Following induction of general anesthesia, patients will receive an intravenous bolus of normal saline, followed by a continuous infusion of normal saline at an equivalent volume and rate until skin closure. Placebo administration will be limited to the intraoperative period and will not be continued after surgery. Other anesthetic care and postoperative pain management will be provided in accordance with the center’s standard protocols.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Anesthesiology Research Center, Taleghani Hospital
Full name of responsible person
Negarsadat Namazi
Street address
Department of Anesthesiology, School of Medicine, Anesthesiology Research Center, Ayatollah Taleghani Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Negarsadat Namazi
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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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

2

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Negarsadat Namazi
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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
Anesthesiology Research Center, Taleghani Hospital

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Negar Namazi
Position
medical doctor
Latest degree
Medical doctor
Other areas of specialty/work
Psychology
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Person responsible for updating data

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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
Deidentified individual participant data will not be shared because no formal data-sharing plan has been established, and access to study data will be restricted to authorized members of the research team to protect participant confidentiality.

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