Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative Efficacy of Low-Dose Intravenous Ketamine Versus Intravenous Paracetamol in Preventing Post-Spinal Anesthesia Shivering: A Randomized Controlled Trial

Protocol summary

Study aim

To compare the efficacy and safety of intravenous low-dose ketamine versus intravenous paracetamol for preventing shivering after spinal anesthesia.

Design

Single-center, prospective, two-arm, parallel-group, double-blind randomized controlled trial of 80 patients (40 per group). Allocation was 1:1 using a computer-generated sequence and sequentially numbered, opaque, sealed envelopes.

Settings and conduct

Conducted in the operating rooms and post-anesthesia care unit of Shohadaye Tajrish Hospital, Tehran, Iran. Patients received standardized perioperative monitoring. Participants and outcome assessors were blinded; an independent anesthesiologist prepared the study drugs.

Participants/Inclusion and exclusion criteria

Adults aged 18–65 years, American Society of Anesthesiologists (ASA) physical status I–II, undergoing elective lower abdominal or lower-limb surgery under spinal anesthesia were included. Major exclusions were relevant drug allergy, significant cardiovascular, respiratory, hepatic or renal disease, pregnancy, and conditions affecting outcome assessment.

Intervention groups

Intervention group: Intravenous ketamine 0.25 mg/kg once. Control group: Intravenous paracetamol 15 mg/kg (maximum 1 g) once. Both were infused over 5–10 minutes immediately after completion of spinal anesthesia.

Main outcome variables

Primary outcome: clinically visible shivering (Crossley–Mahajan grade ≥2) within 60 minutes after spinal anesthesia. Secondary outcomes: maximum shivering grade, time to first detected shivering, heart rate, mean arterial pressure, oxygen saturation, adverse events, and rescue meperidine use. Shivering was assessed at 0, 5, 10, 15, 30, 45, and 60 minutes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049990N3**
Registration date: **2026-11-18, 1405/08/27**
Registration timing: **prospective**

Last update: **2026-11-18, 1405/08/27**
Update count: **0**

Registration date

2026-11-18, 1405/08/27

Registrant information

Name

Seyedpouzhia Shojaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

p.shojaei@sbmu.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-25, 1405/09/04

Expected recruitment end date

2027-05-25, 1406/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative Efficacy of Low-Dose Intravenous Ketamine Versus Intravenous Paracetamol in Preventing Post-Spinal Anesthesia Shivering: A Randomized Controlled Trial

Public title
Comparison of Effects of Low-Dose Intravenous Ketamine and Intravenous Paracetamol in Preventing Shivering After spinal Anesthesia

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
AGE 18-65 years Scheduled fior lower abdominal or lower limb surgery under spinal anesthesia ASA physical status 1or 2 Written informed consent to participate in the study

Exclusion criteria:
Known allergy to ketamine or paracetamol Pre-existing cardiovascular diseases Pre-existing respiratory diseases Pre-existing hepatic or renal diseases Use of sedatives or analgesics before surgery Pregnancy or lactation Neurological or psychiatric disorders

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be randomly assigned to one of two intervention groups, low-dose intravenous ketamine or intravenous paracetamol, using a computer-generated randomization table.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be double-blind. Participants and outcome assessors, including nurses and anesthesiologists responsible for assessing shivering, will be unaware of the assigned treatment and group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of the School of Medicine, Shahid Beheshti University of Medical Sciences

Street address
School of Medicine, Shahid Beheshti University of Medical Sciences, Koodakyar Street, Daneshjoo Boulevard, Velenjak, Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2026-10-20, 1405/07/28

Ethics committee reference number
IR.SBMU.MSP.REC.1405.535

Health conditions studied

1

Description of health condition studied
Post-spinal anesthesia shivering

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Percentage of patients developing shivering within 60 minutes after spinal anesthesia.

Timepoint
From the time of spinal anesthesia up to 60 minutes afterward

Method of measurement
Clinical observation by a blinded outcome assessor, recording the presence or absence of shivering.

Secondary outcomes

1

Description
Severity of shivering after spinal anesthesia

Timepoint
During the first 60 minutes after spinal anesthesia

Method of measurement
Clinical assessment and recording of shivering severity by a blinded outcome assessor

Intervention groups

1

Description
Ketamine was administered intravenously at a dose of 0.25 mg/kg as a single dose immediately after completion of spinal anesthesia. The medication was infused over 5–10 minutes.

Category
Treatment - Drugs

2

Description
Control group: Paracetamol was administered intravenously at a dose of 15 mg/kg (maximum 1 g) as a single dose immediately after completion of spinal anesthesia. The medication is infused over 5–10 minutes. The intervention was administered once during the perioperative period.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Tajrish Hospital

Full name of responsible person
Seyed Pouzhia Shojaei

Street address
Shohadaye Tajrish Hospital, Shahrdari St., Qods Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afsahin Zarghi

Street address
5th Floor, Building No. 2, Shahid Arabi St., Yemen St., Shahid Chamran Hwy., Tehran

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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
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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed Pouzhia Shojaei

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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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
There are currently no plans to share individual participant data (IPD).

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
Yes - There is 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

Title and more details about the data/document
Clinical Study Report1

When the data will become available and for how long
One month after publication of the results.

To whom data/document is available
All researchers

Under which criteria data/document could be used
For scientific research purposes, subject to patient confidentiality and approval by the principal investigator.

From where data/document is obtainable
Contact the principal investigator via the email address provided in the trial registration.

What processes are involved for a request to access data/document
Applicants submit their requests to the principal investigator by email. Each request will be reviewed, and the requested documents will be provided by email upon approval.

Comments