Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of endotracheal administration of ketamine on sore throat after spinal surgery in patients under general anesthesia with endotracheal intubation: A randomized clinical trial

Protocol summary

Study aim

To evaluate the effect of endotracheal administration of ketamine on the incidence and severity of postoperative sore throat in patients undergoing elective spinal surgery under general anesthesia.

Design

This is a double-blind, randomized, placebo-controlled, superiority trial with parallel group assignment. Thirty-four patients undergoing elective spinal surgery under general anesthesia with endotracheal intubation will be randomly allocated to ketamine or normal saline groups using a computer-generated list. Participants, care providers, and outcome assessors will be blinded to group allocation. The study will be conducted at a single center over 18 months.

Settings and conduct

This single-center study will be conducted at Shahid Beheshti and Rohani Hospitals, affiliated with Babol University of Medical Sciences. After obtaining ethical approval and written informed consent, eligible patients will be randomly assigned to one of two groups. The intervention will be administered preoperatively in the operating room, and data will be collected postoperatively by blinded assessors using a standardized questionnaire.

Participants/Inclusion and exclusion criteria

Adult patients aged 20 to 60 years, classified as ASA I or II, undergoing elective spinal surgery under general anesthesia with endotracheal intubation will be included. Patients with a history of sore throat, asthma, COPD, recent NSAID use, smoking, or those requiring difficult intubation will be excluded.

Intervention groups

Intervention group: Patients receive 2 mL of ketamine (5 mg/mL) administered directly into the endotracheal tube before intubation. Control group: Patients receive 2 mL of normal saline administered in the same manner before intubation.

Main outcome variables

1-Incidence of sore throat after extubation 2-Severity of sore throat based on a 4-point scale 3-Time of onset of sore throat in hours after extubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241214064051N4**
Registration date: **2025-05-12, 1404/02/22**
Registration timing: **prospective**

Last update: **2025-05-12, 1404/02/22**
Update count: **0**

Registration date

2025-05-12, 1404/02/22

Registrant information

Name

Nima Amiresmaili

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-26, 1404/03/05

Expected recruitment end date

2025-11-26, 1404/09/05

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of endotracheal administration of ketamine on sore throat after spinal surgery in patients under general anesthesia with endotracheal intubation: A randomized clinical trial

Public title
Effect of ketamine administered into the trachea on sore throat after spinal surgery under general anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 60 years ASA physical status class I or II Candidates for elective spinal surgery in the prone position Under general anesthesia with endotracheal intubation Signed written informed consent
Exclusion criteria:
History of sore throat before surgery Patients with asthma or COPD Smokers Recent use of NSAIDs Patient unwilling to participate in the study Known allergy to ketamine or normal saline Mallampati score greater than 2 More than one attempt required for endotracheal intubation Intubation time exceeding 20 seconds
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who meet the inclusion criteria will be randomly assigned to two groups (ketamine or normal saline) in a 1:1 ratio using a computer-generated random number table. Each patient will receive a study drug according to a pre-coded syringe labeled with a 3-digit code, prepared in advance. The sequence of group allocation will be determined before the start of the study and followed throughout enrollment.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is designed as a double-blind randomized clinical trial. The patients, care providers, and outcome assessors are blinded to the group allocation. The study drugs (ketamine or normal saline) are prepared in identical syringes labeled with a unique 3-digit code. An anesthesia technician not involved in patient evaluation administers the drug according to the randomization list. Neither the patient nor the evaluating anesthesiology resident knows which drug has been administered. The codes will be revealed only after data collection is completed for all participants.
Placebo
Used
Assignment
Parallel
Other design features
This study is a double-blind, randomized, placebo-controlled, superiority clinical trial conducted at a single center. Randomization is performed using a computer-generated random number table. The intervention is administered preoperatively. Sore throat severity is assessed using a standardized 4-point scale at multiple time intervals postoperatively (1, 6, 24, 36, 48, 60, and 72 hours).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Babol University of Medical Sciences
Street address
School of Medicine, Babol University of Medical Sciences, Ganj Afrooz Street, Babol, Mazandaran, Iran
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Province
Mazandaran
Postal code
4717648991
Approval date
2024-03-05, 1402/12/15
Ethics committee reference number
IR.MUBABOL.REC.1402.230

Health conditions studied

1

Description of health condition studied
Postoperative sore throat following general anesthesia with endotracheal intubation
ICD-10 code
R07.0
ICD-10 code description
Pain in throat

Primary outcomes

1

Description
The primary outcome variable is the incidence of postoperative sore throat. It is measured using a 4-point severity scale at 1, 6, 24, 36, 48, 60, and 72 hours after extubation. The sample size was calculated based on expected differences in the incidence of sore throat between the ketamine and placebo groups.
Timepoint
1, 6, 24, 36, 48, 60, and 72 hours after extubation
Method of measurement
Sore throat will be measured using a standardized 4-point verbal rating scale, where 0 = no pain, 1 = mild, 2 = moderate, and 3 = severe.

Secondary outcomes

1

Description
Severity of postoperative sore throat will be evaluated using a 4-point verbal rating scale to assess the impact of intervention on pain intensity.
Timepoint
1, 6, 24, 36, 48, 60, and 72 hours after extubation
Method of measurement
4-point verbal rating scale (0 = no pain, 1 = mild, 2 = moderate, 3 = severe)

2

Description
Time of onset of postoperative sore throat will be recorded in hours after extubation, based on patient self-report, to evaluate the delay in symptom appearance due to the intervention.
Timepoint
Continuously assessed within the first 72 hours after extubation
Method of measurement
Patient self-report recorded via a structured questionnaire

Intervention groups

1

Description
Intervention group: The intervention group will receive 2 mL of ketamine with a concentration of 5 mg/mL, administered into the endotracheal tube immediately before intubation, as a single preoperative dose.
Category
Prevention

2

Description
Control group: The control group will receive 2 mL of normal saline administered into the endotracheal tube immediately before intubation, as a single preoperative dose.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rohani Hospital, Babol University of Medical Sciences
Full name of responsible person
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Maryam Khoshnevis
Position
Non-faculty specialist physician
Latest degree
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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