

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6646 9824

Email address

nima.amiresmaili@yahoo.com

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

City

Babol

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

Shahram Seyfi

Street address

School of Medicine, Babol University of Medical Sciences, Ganj Afrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4717648991

Phone

+98 911 218 2557

Fax

Email

shahram.seyfi@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

School of Medicine, Babol University of Medical Sciences, Ganj Afrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4717648991

Phone

+98 911 218 2557

Fax

Email

maryamkhoshnevis8@gmail.com

Web page address

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

Mazandaran

Postal code

4717648991

Phone

+98 911 218 2557

Fax**Email**

maryamkhoshnevis8@gmail.com

Web page address**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

Specialist

Other areas of specialty/work

Anesthesiology

Street address

School of Medicine, Babol University of Medical Sciences, Ganj Afrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4717648991

Phone

+98 911 218 2557

Fax**Email**

maryamkhoshnevis8@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Mazandaran

Postal code

4717648991

Phone

+98 911 218 2557

Fax**Email**

maryamkhoshnevis8@gmail.com

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Full name of responsible person

Maryam Khoshnevis

Position

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

School of Medicine, Babol University of Medical Sciences, Ganj Afrooz Street, Babol, Mazandaran, Iran

City

Babol

Province**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