

# 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

##### 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

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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

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##### 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

**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

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**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