

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of postoperative nebulized ketamine for pain management after tonsillectomy in children: a randomized controlled trial

Protocol summary

Study aim

To determine the efficacy and safety of postoperative nebulized ketamine in reducing pain and improving recovery outcomes after tonsillectomy in children, aiming to provide evidence for an opioid-sparing analgesic strategy in pediatric surgery.

Design

Prospective, randomized, double-blind, placebo-controlled clinical trial Randomization: Stratified block randomization (1:1 allocation) into Group K (nebulized ketamine) or Group P (placebo), stratified by age (5-7 vs. 8-12 years) to minimize confounding. Computer-generated sequence stored securely by a research pharmacist; allocation concealed using opaque, sealed envelopes. Blinding: Double-blind. Patients, parents/guardians, clinicians (surgeons, anesthesiologists, nurses), and outcome assessors blinded. Nebulized ketamine and saline prepared in identical vials/syringes, labeled with unique study numbers, indistinguishable in appearance.

Settings and conduct

Taleghani care university hospital's pediatric surgical ward and PACU. Patients, parents/guardians, clinicians (surgeons, anesthesiologists, nurses), and outcome assessors blinded.

Participants/Inclusion and exclusion criteria

Inclusion: ASA I-II, no ketamine allergy, no psychiatric/neurological disorders, chronic pain syndromes, severe asthma, or recent respiratory infections. Exclusion: Emergency surgery, recent opioid use.

Intervention groups

Nebulized ketamine (1 mg/kg, max 50 mg, diluted in 5 mL saline) administered via standard nebulizer device in the PACU, delivered over 10-15 minutes under continuous monitoring

Main outcome variables

To determine the efficacy and safety of postoperative nebulized ketamine in reducing pain and improving

recovery outcomes after tonsillectomy in children, aiming to provide evidence for an opioid-sparing analgesic strategy in pediatric surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251109067931N1**

Registration date: **2026-01-24, 1404/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2026-01-24, 1404/11/04**

Update count: **0**

Registration date

2026-01-24, 1404/11/04

Registrant information

Name

Mohsen Ariannik

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1290

Email address

dr.ariannik@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-20, 1404/10/30

Expected recruitment end date

2027-01-20, 1405/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of postoperative nebulized ketamine for pain management after tonsillectomy in children: a randomized controlled trial

Public title
nebulized ketamine for pain management

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 5-12 years scheduled for elective tonsillectomy ASA I-II
Exclusion criteria:
ketamine allergy psychiatric/neurological disorders chronic pain syndromes severe asthma recent respiratory infections Emergency surgery recent opioid use

Age
From **5 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified block randomization (1:1 allocation) into Group K (nebulized ketamine) or Group P (placebo), will be stratified by age (5-7 vs. 8-12 years) to minimize confounding. Computer-generated sequence will be stored securely by a research pharmacist; allocation will be concealed using opaque, sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients, parents/guardians, clinicians (surgeons, anesthesiologists, nurses), and outcome assessors will be blinded. Nebulized ketamine and saline prepared in identical syringes, labeled with unique study numbers, indistinguishable in appearance.

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

7th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

tehran

Province

Tehran

Postal code

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Approval date

2026-01-13, 1404/10/23

Ethics committee reference number

IR.SBMU.MSP.REC.1404.690

Health conditions studied

1

Description of health condition studied

post operative pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Numeric rating scale (NRS) pain score

Timepoint

Pain is assessed at baseline, 15, 30, 60, 90, 120 minutes, and 4, 8, 12, 24, and 48 hours post-operatively.

Method of measurement

Numeric rating scale (NRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: nebulized ketamine (1 mg/kg, max 50 mg) administered via jet nebulizer 15 minutes in the post-anesthesia care unit (PACU)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani university hospital

Full name of responsible person

Mohsen Arian Nik

Street address

Beside Shahid Beheshti University of Medical Sciences, Arabi St., Student Blvd., Valenjak, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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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

Mohsen Arian Nik

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after individuals are
anonymized.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

Each member of the academic staff or student by
requesting via academic email.

From where data/document is obtainable

email to: dr.ariannik@gmail.com m.ariannik@sbmu.ac.ir

What processes are involved for a request to access data/document

Three to seven working days after receiving the email.

Comments