Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

193954631

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

City
tehran

Province
Tehran

Postal code
1985717412

Phone
+98 21 2303 1290

Email
info@sbmu.ac.ir

Web page address
https://taleghani.sbmu.ac.ir/

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.

City
tehran

Province
Tehran

Postal code
193954631

Phone
+98 21 2243 9780

Email
info@sbmu.ac.ir

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

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

City
Tehran

Province
Tehran

Postal code
1985717412

Phone
+98 21 2303 1290

Email
dr.ariannik@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohsen Arian Nik

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Assistant professor

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Phone
+98 21 2303 1290

Email
dr.ariannik@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohsen Arian Nik
Position
Assistant professor
Latest degree
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Anesthesiology
Street address
Shahid Beheshti University of Medical Sciences, Arabi St., Student Blvd., Valenjak, Tehran
City
Tehran
Province
Tehran
Postal code
1985717412
Phone
+98 21 2303 1290
Email
dr.ariannik@gmail.com

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