Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of Oral Compared with Intramuscular Ketamine for Analgesia and Procedural Sedation in Pediatric Patients Presenting to the Emergency Department of Imam Khomeini Hospital complex in 2026-2027: A Randomized Non-Inferiority Clinical Trial

Protocol summary

Study aim

To evaluate the non-inferiority in efficacy and safety of two oral ketamine doses versus intramuscular ketamine for pediatric procedural sedation and analgesia in the emergency department.

Design

A randomized, open-label, three-arm, parallel-group, Phase 2/3 clinical trial on 114 patients aged 1–15, using variable block randomization (1:1:1 ratio) to compare oral ketamine (10 and 15 mg/kg) with intramuscular ketamine (4 mg/kg).

Settings and conduct

Emergency Department of Imam Khomeini Hospital Complex, Tehran; block randomization; standardized clinical monitoring and data collection during sedation and recovery.

Participants/Inclusion and exclusion criteria

Inclusion: Patients aged 1–15 years requiring sedation for brief procedures (<=30 minutes), stable hemodynamics, baseline GCS 15, and parental written consent.
Exclusion: Ketamine hypersensitivity, head/ocular trauma, airway abnormalities, major systemic diseases (cardiac, pulmonary, hepatic/renal impairment), recent sedation, and high aspiration risk.

Intervention groups

Oral ketamine 10 mg/kg Oral ketamine 15 mg/kg Intramuscular ketamine 4 mg/kg

Main outcome variables

Primary outcome: Sedation success rate (achieving Pediatric Sedation State Scale [PSSS] score 2 or 3 without rescue medication). Secondary outcomes: Sedation onset, duration, time to discharge readiness, adverse events, and physician satisfaction

General information

Reason for update

Acronym

NIK-PedPSA

IRCT registration information

IRCT registration number: **IRCT20260710070117N1**
Registration date: **2026-09-20, 1405/06/29**
Registration timing: **prospective**

Last update: **2026-09-20, 1405/06/29**
Update count: **0**

Registration date

2026-09-20, 1405/06/29

Registrant information

Name

Taha Bayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-02, 1405/07/10

Expected recruitment end date

2027-07-01, 1406/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of Oral Compared with Intramuscular Ketamine for Analgesia and Procedural Sedation in Pediatric Patients Presenting to the Emergency Department of Imam Khomeini Hospital complex in 2026-2027: A Randomized Non-Inferiority Clinical Trial

Public title
Oral versus Intramuscular Ketamine for Pediatric Procedural Sedation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pediatric patients aged 1 to 15 years Clinical indication for procedural sedation and analgesia (PSA) for a therapeutic procedure such as laceration repair Hemodynamic and vital signs stability prior to intervention Written informed consent obtained from parents or legal guardians

Exclusion criteria:
Known hypersensitivity or previous adverse reaction to ketamine Suspected or confirmed open-globe eye injury Traumatic brain injury (TBI) Uncontrolled hypertension Requirement for a procedure exceeding standard emergency interventions (anticipated procedure duration >30 minutes) Glasgow Coma Scale (GCS) score < 15 Hemodynamic instability based on the treating physician’s clinical judgment Administration of any sedative agent within the preceding 24 hours Known congenital heart disease or active cardiac dysrhythmias Pre-existing underlying cardiac, respiratory, or neurological diseases Uncorrected mineralocorticoid deficiency Known or suspected hepatic failure/dysfunction Structural airway abnormalities or high risk of airway obstruction Increased risk of pulmonary aspiration based on fasting status or physician’s discretion Concomitant use of medications with significant potential for drug interaction with ketamine Obstructive sleep apnea (OSA) Known or suspected renal impairment/failure

Age
From **1 year** old to **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomized individually in a 1:1:1 allocation ratio to one of the following three groups: Oral ketamine 10 mg/kg Oral ketamine 15 mg/kg Intramuscular ketamine 4 mg/kg The randomization sequence will be generated by an independent researcher or statistician using statistical software and permuted blocks of varying sizes (4 and 6). No quasi-randomization method will be used, and no stratified randomization will be performed. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes containing the randomization assignments. Envelopes will be opened consecutively only after eligibility has been confirmed and written informed consent has been obtained. Outcome assessors and data analysts will remain blinded to treatment allocation.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address
Imam Khomeini Hospital Complex, End of Keshavarz Blvd

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Tehran

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Tehran

Postal code
1419733141

Approval date
2026-08-18, 1405/05/27

Ethics committee reference number
IR.TUMS.IKHC.REC.1405.223

Health conditions studied

1

Description of health condition studied
Pediatric Procedural Sedation and Analgesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Proportion of patients with successful procedural

sedation (defined as achieving a score of 2 or 3 on the Pediatric Sedation State Scale and successful completion of the procedure without the need for supplemental or rescue sedation)

Timepoint

From the time of drug administration until the completion of the procedure (evaluated at 5, 10, 15, 20, 25, and 30 minutes post-administration and immediately upon procedure completion)

Method of measurement

Pediatric Sedation State Scale

Secondary outcomes

1

Description

Time to sedation onset (the time elapsed in minutes from drug administration until achieving a score of 2 or 3 on the Pediatric Sedation State Scale)

Timepoint

From drug administration until achieving target sedation level (continuously monitored during the first 30 minutes)

Method of measurement

Digital stopwatch and recording based on the Pediatric Sedation State Scale assessment

2

Description

Total effective sedation duration (the time elapsed in minutes from the onset of adequate sedation until the patient returns to wakefulness)

Timepoint

From the onset of effective sedation until full awakening

Method of measurement

Digital stopwatch and clinical evaluation by the study observer

3

Description

Time to discharge readiness

Timepoint

During the recovery phase after procedure completion, assessed at 15, 30, 45, 60, 90, and 120 minutes post-procedure

Method of measurement

Pediatric Sedation State Scale assessment

4

Description

Incidence of acute adverse events including nausea, vomiting, respiratory events, emergence reactions, and hemodynamic instability

Timepoint

From the time of drug administration until final discharge from the emergency department

Method of measurement

Continuous pulse oximetry, non-invasive blood pressure monitoring, clinical observation, and standardized adverse event checklist

5

Description

Proportion of patients requiring supplemental dosing or rescue sedation due to inadequate sedation after 30 minutes or sedation failure

Timepoint

Within 30 minutes following the initial drug administration

Method of measurement

Clinical Case Report Form and patient medical record

6

Description

Physician satisfaction with the quality of sedation and procedural ease

Timepoint

Immediately after procedure completion

Method of measurement

5-point Likert satisfaction scale questionnaire

Intervention groups

1

Description

Intervention group 1: Patients in this group receive oral ketamine hydrochloride at a single dose of 10 milligrams per kilogram of body weight (maximum total dose 500 milligrams). The oral formulation is prepared using parenteral ketamine hydrochloride vial (concentration: 50 milligrams per milliliter), which is mixed in a 1 to 1 ratio with a sweet flavored syrup or fruit juice to mask the bitter taste and administered orally using an oral syringe. The child is monitored continuously for vital signs, sedation depth, and oxygen saturation. If adequate procedural sedation is not achieved within 30 minutes, rescue parenteral sedation is provided.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients in this group receive oral ketamine hydrochloride at a single dose of 15 milligrams per kilogram of body weight (maximum total dose 500 milligrams). The formulation is prepared using parenteral ketamine hydrochloride solution (concentration: 50 milligrams per milliliter) mixed in a 1 to 1 ratio with a sweet flavored syrup to enhance palatability, administered orally via syringe in a single dose. Continuous hemodynamic and sedation depth monitoring is performed. In case of inadequate sedation after 30 minutes, rescue sedation is administered according to protocol.

Category

Treatment - Drugs

3

Description
Control group: Patients in this active comparator control group receive intramuscular ketamine hydrochloride at a single dose of 4 milligrams per kilogram of body weight (maximum total dose 200 milligrams). The injection is administered deep into the vastus lateralis or deltoid muscle using injectable ketamine hydrochloride solution (concentration: 50 milligrams per milliliter). Continuous vital sign monitoring, sedation scoring, and post-procedure recovery evaluations are performed until discharge criteria are met.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex

Full name of responsible person
Taha Bayat

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emergency department, Imam Khomeini hospital complex, end of Keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Taha Bayat

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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
De-identified individual participant dataset containing baseline demographic characteristics, procedural sedation efficacy outcomes based on the Pediatric Sedation State Scale, hemodynamic parameters, sedation and recovery durations, and adverse event profiles; alongside the full study protocol, statistical analysis plan, analytic codes, and data dictionary.
When the data will become available and for how long
Beginning 6 months following the official publication of the primary trial results in a peer-reviewed scientific journal, and remaining accessible for a duration of 5 years.
To whom data/document is available
Qualified academic researchers, clinical investigators, and biostatisticians affiliated with recognized academic or research institutions.
Under which criteria data/document could be used
Exclusively for non-commercial, scientifically valid research purposes, systematic reviews, or meta-analyses, governed by an approved study proposal and the execution of a formal data use and confidentiality agreement.
From where data/document is obtainable
Directly obtainable upon formal written request directed to the corresponding author’s institutional email address.
What processes are involved for a request to access data/document
Interested researchers must submit a formal request comprising a brief research proposal, statistical analysis outline, and institutional ethics approval to the corresponding author. Following methodological review and approval by the principal investigator, a formal Data Use Agreement is signed, and the de-identified data files are securely transferred.
Comments
All shared data are strictly de-identified with no direct patient identifiers, ensuring that participant privacy and confidentiality are fully protected in compliance with research ethics principles and the International Committee of Medical Journal Editors standards.