Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Efficacy of Oral Chloral Hydrate and Intranasal Midazolam on Sedation in Children Aged 6 Months to 6 Years During Echocardiography: A Randomized Clinical Trial

Protocol summary

Study aim
To compare the efficacy of oral chloral hydrate and intranasal midazolam on sedation in children aged 6 months to 6 years during echocardiography.

Design
Double-blind randomized clinical trial with two parallel groups; 100 children will be allocated to two groups using block randomization (block size of 4), with allocation concealment using opaque, sequentially numbered, sealed containers.

Settings and conduct
The study will be conducted at Afzalipour Hospital, Kerman, in 2026. Study drugs will be prepared by an independent researcher, and the anesthesiologist, the investigator performing echocardiography, the data collector and the data analyst will be unaware of the group allocation. Echocardiography will be performed once a Modified Ramsay Sedation Score of 3 or higher is reached.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 6 months to 6 years referred for echocardiography requiring sedation; ASA physical status class I or II; Written informed consent from parents. Exclusion criteria: Parental refusal; Nasal structural abnormality; Anticipated airway problem; Known allergy to midazolam or chloral hydrate; Organ dysfunction; Cardiac dysrhythmia; Intellectual disability.

Intervention groups
Midazolam group (n=50): Intranasal midazolam 0.2 mg/kg, diluted with normal saline to a final volume of 0.5 mL and divided equally between both nostrils. Chloral hydrate group (n=50): Oral chloral hydrate syrup 50 mg/kg (maximum 2 g), mixed 1:1 with fruit juice. If adequate sedation is not achieved within 10 minutes, an additional dose of intranasal midazolam 0.1 mg/kg will be given.

Main outcome variables
Sedation duration; Sedation onset time; Recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230409057864N5**
Registration date: **2026-11-08, 1405/08/17**
Registration timing: **prospective**

Last update: **2026-11-08, 1405/08/17**
Update count: **0**

Registration date
2026-11-08, 1405/08/17

Registrant information
Name
ALI MADADI MAHANI
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 34 3272 4988
Email address
madadimahaniali@gmail.com

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-12-22, 1405/10/01

Expected recruitment end date
2027-07-22, 1406/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Efficacy of Oral Chloral Hydrate and Intranasal Midazolam on Sedation in Children Aged 6 Months to 6 Years During Echocardiography: A Randomized Clinical Trial

Public title
Comparison of Oral Chloral Hydrate Syrup and Intranasal Midazolam for Calming Young Children During Echocardiography (Heart Ultrasound)

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 6 months to 6 years Referred for transthoracic echocardiography requiring sedation ASA physical status class I or II Written informed consent obtained from parents or legal guardians

Exclusion criteria:
Refusal of parents or legal guardians to participate Nasal structural abnormality Anticipated airway problem Known allergy to midazolam or chloral hydrate Organ dysfunction Cardiac dysrhythmia Intellectual disability

Age
From **6 months** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible children will be individually allocated to the oral chloral hydrate group or the intranasal midazolam group (1:1) using block randomization with a block size of 4. Each of the six possible permutations of a 4-block (AABB=1, ABAB=2, ABBA=3, BBAA=4, BABA=5, BAAB=6) is assigned a number, and numbers between 1 and 6 are selected using a random number table to generate the allocation sequence. For allocation concealment, an independent researcher will write each group assignment on a card according to the random sequence and place it in an opaque, sealed container of identical shape and weight, numbered in the same order. After enrollment and parental consent, the next numbered container will be opened by the nurse responsible for drug administration, and the child will receive the drug written on the card. Thus, the group of the next participant cannot be known in advance.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study drugs will be prepared by an independent researcher who has no other role in the study. The drug will be given by a nurse who is not involved in sedation monitoring, outcome assessment or data analysis. The pediatric anesthesiologist who monitors the children during sedation (care provider), the investigator who performs echocardiography, and the data collector who records the outcomes (outcome assessor) will be unaware of the group allocation, because the drug will be given before the child enters the echocardiography room. The data analyst will receive the data with coded group labels and will not know which code belongs to which drug until the analysis is complete. Because the two drugs are given by different routes (oral and intranasal), the parents and the nurse who gives the drug cannot be blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Afzalipour Hospital, Kerman University of Medical Sciences

Street address
Research Ethics Committee, Afzalipour Hospital, Kerman University of Medical Sciences, Imam Khomeini Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2026-10-19, 1405/07/27

Ethics committee reference number
IR.KMU.AH.REC.1405.128

Health conditions studied

1

Description of health condition studied
Procedural sedation in children aged 6 months to 6 years undergoing transthoracic echocardiography

ICD-10 code
Z01.8

ICD-10 code description
Other specified special examinations

Primary outcomes

1

Description
Sedation duration
Timepoint
From achieving a Modified Ramsay Sedation Score of 3 or higher until eye opening
Method of measurement
Modified Ramsay Sedation Scale and recording of time (in minutes) using a stopwatch

2

Description
Sedation onset time
Timepoint
From study drug administration until achieving a Modified Ramsay Sedation Score of 3 or higher
Method of measurement
Modified Ramsay Sedation Scale and recording of time (in minutes) using a stopwatch

3

Description
Recovery time
Timepoint
From the end of echocardiography until spontaneous eye opening
Method of measurement
Observation and recording of time (in minutes) using a stopwatch

Secondary outcomes

1

Description
Parental satisfaction
Timepoint
Before discharge
Method of measurement
10-point satisfaction scale (1 = lowest to 10 = highest satisfaction)

2

Description
Heart rate
Timepoint
Before drug administration and at 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20 minutes after drug administration
Method of measurement
Vital signs monitor (beats per minute)

3

Description
Oxygen saturation (SpO2)
Timepoint
Before drug administration and at 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20 minutes after drug administration
Method of measurement
Pulse oximeter (percent)

4

Description
Echocardiographer satisfaction with sedation quality and image quality
Timepoint
Immediately after completion of echocardiography
Method of measurement
10-point satisfaction scale for sedation quality and 5-point scale for echocardiographic image quality

5

Description
Adverse effects (SpO2 below 95%, bradycardia, nausea, vomiting and other complications)
Timepoint
From drug administration until discharge
Method of measurement
Observation, vital signs monitoring and recording in the adverse effects checklist

Intervention groups

1

Description
Intervention group: Children in this group (n=50) will receive intranasal midazolam at a dose of 0.2 mg/kg. Midazolam injection vials (5 mg/mL) manufactured by Caspian Tamin Pharmaceutical Company (Iran) will be used. The calculated dose will be drawn from the vial, diluted 1:1 with 0.9% normal saline to a final volume of 0.5 mL, and administered slowly with a needle-free 1-mL syringe or sterile dropper, 0.25 mL into each nostril, with the child in the supine position. If adequate sedation (Modified Ramsay Sedation Score of 3 or higher) is not achieved within 10 minutes, an additional dose of intranasal midazolam 0.1 mg/kg will be given.
Category
Treatment - Drugs

2

Description
Control group: Children in this group (n=50) will receive oral chloral hydrate syrup (250 mg/5 mL or 500 mg/5 mL) manufactured by Caspian Tamin Pharmaceutical Company (Iran) at a dose of 50 mg/kg (maximum 2 g). The calculated dose will be mixed 1:1 with sour cherry juice or fruit syrup and given orally by the parents or a nurse. If adequate sedation (Modified Ramsay Sedation Score of 3 or higher) is not achieved within 10 minutes, an additional dose of intranasal midazolam 0.1 mg/kg will be given.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Afzalipour Hospital

Full name of responsible person
Maryam Ahmadipour

Street address
Afzalipour Hospital, Kerman University of Medical Sciences, Imam Khomeini Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 8000

Email
hsharifi@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Hamid Sharifi

Street address
Vice Chancellery for Research and Technology, Kerman University of Medical Sciences, Ebn-e-Sina Street, Jahad Boulevard, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7619813159

Phone
+98 34 3132 8000

Email
sharifihami@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Maryam Ahmadipour

Position
Assistant Professor of Pediatric Cardiology

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Afzalipour Hospital, Kerman University of Medical Sciences, Imam Khomeini Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 8000

Email
hsharifi@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Maryam Ahmadipour

Position
Assistant Professor of Pediatric Cardiology

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Afzalipour Hospital, Kerman University of Medical Sciences, Imam Khomeini Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 8000

Email
hsharifi@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person
Maryam Ahmadipour

Position
Assistant Professor of Pediatric Cardiology

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Afzalipour Hospital, Kerman University of Medical Sciences, Imam Khomeini Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 8000

Email
hsharifi@kmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Participants are children, and the ethics approval and the informed consent signed by their parents only permit the study researchers to access the data. To protect participant confidentiality, individual participant data will not be shared, and only aggregate results will be published.

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
Not applicable

Analytic Code
Not applicable

Data Dictionary
No - There is not a plan to make this available