Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative study of the effect of nasal dexmedetomidine and oral chloral hydrate on sedation of children during MRI

Protocol summary

Study aim
Comparison of the effects of nasal dexmedetomidine and oral chloral hydrate on sedation in children during MRI

Design
Using the randomized block method, individuals are divided into two groups of 70 people and then the treatment is performed on them by the clinical caregiver. The study is an unblinded clinical trial, which is conducted as a four-way permutation block method in the rand function of Excel software.

Settings and conduct
Using a randomized block design, subjects were divided into two groups. The study was an unblinded clinical trial conducted at Al-Zahra Hospital using the rand function of Excel software for randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children who are candidates for MRI who require sedation for any reason and whose parents have consented to participate in the study. Exclusion criteria: Patients with a history of respiratory disease, gastric ulcer or liver disease, treatment with drugs that interact with chloral hydrate or dexmedetomidine, the presence of a specific underlying disease that affects the interpretation of objectives such as sedation duration, any previous allergic reaction to chloral hydrate or dexmedetomidine.

Intervention groups
first group: Children in this group will receive 5% chloral hydrate syrup at a dose of 50-100 micrograms/kg orally 10 minutes before the operation. In addition, for chloral hydrate, an initial dose of 50 micrograms/kg is given. If sedation is not sufficient, the dose will be 100 micrograms/kg. In the second group: Children in this group will receive intranasal dexmedetomidine at a dose of 2-3micrograms/kg 10minutes before the operation. The prescribed dose will start with a dose of 2micrograms/kg and if sedation is not sufficient, one microgram/kg will be added.

Main outcome variables
Sedation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221108056446N15**
Registration date: **2025-02-09, 1403/11/21**
Registration timing: **prospective**

Last update: **2025-02-09, 1403/11/21**
Update count: **0**

Registration date
2025-02-09, 1403/11/21

Registrant information

Name
Mehdi Mahmoodkhani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-19, 1403/12/01

Expected recruitment end date
2025-06-22, 1404/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
A comparative study of the effect of nasal dexmedetomidine and oral chloral hydrate on sedation of children during MRI

Public title
Nasal dexmedetomidine and oral chloral hydrate on sedation in children

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Children who are candidates for MRI and require sedation for any reason. The child's parents must consent to participate in the study.

Exclusion criteria:
Patients with a history of respiratory diseases Stomach ulcers or liver disease Treatment with drugs that interact with chloral hydrate or dexmedetomidine The presence of a specific underlying condition that affects the interpretation of goals such as duration of sedation Any previous allergic reaction to chloral hydrate or dexmedetomidine

Age
From **6 months** old to **10 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
With the convenience sampling method, the referring individuals who are eligible for the study are randomly divided into two groups: case and control. In this study, the division of individuals is done using the four-way permutation block method. In this method, A represents the individual who receives the intervention and B represents the individual who is in the control group. Considering the four-way block, we give the AABB permutation code 0, the ABAB permutation code 1, ABBA code 2, BAAB code 3, BBAA code 4, and BABA codes 5 to 9. Then, using the random number table, we randomly select a starting point and then consider the numbers in rows or columns. Considering the order of the numbers in the table, we assign the corresponding permutation to each number we encounter. Finally, 70 people will be divided into two groups.

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
Esfahan University of Medical Sciences

Street address
Hazar Jarib Street, Azadi Square

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2025-01-09, 1403/10/20

Ethics committee reference number
IR.MUI.MED.REC.1403.430

Health conditions studied

1

Description of health condition studied
Sedation

ICD-10 code
T88.52

ICD-10 code description
Failed moderate sedation during procedure

Primary outcomes

1

Description
Sedation

Timepoint
Patients were examined every 5 minutes and then every 10 minutes for up to an hour.

Method of measurement
The AVPU scale is used to assess a child's level of alertness and sleepiness.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Chloral hydrate will be administered orally. Children in this group will receive 5% chloral hydrate syrup at a dose of 50-100 micrograms/kg orally 10 minutes before the procedure. In addition, for chloral hydrate, a dose of 50 micrograms/kg is initially given. If

sedation is not sufficient, the dose will be 100 micrograms/kg.

Category

Behavior

2

Description

Control group: Nasal dexmedetomidine will be administered. Children in this group will receive intranasal dexmedetomidine at a dose of 2-3 micrograms/kg 10 minutes before surgery. The prescribed dose is started at 2 micrograms/kg and if sedation is not sufficient, 1 microgram/kg is added.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hussein Children's Hospital
Full name of responsible person
Mohamadreza Ghazavi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Gholamreza Asgari
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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

Esfahan University of Medical Sciences

Proportion provided by this source

1

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
Esfahan University of Medical Sciences
Full name of responsible person
Mohamadreza Ghazavi
Position
Assistant Professor
Latest degree
Specialist
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Person responsible for scientific inquiries

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Person responsible for updating data

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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