

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 913 686 3733

Email address

mahmoodkhani@med.mui.ac.ir

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

Isfahan

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

Street address

Imam Khomeini Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

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Position
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Latest degree
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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