

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative study of the effect of nasal dexmedetomidine and oral chloral hydrate on pediatric sedation during electroencephalogram

Protocol summary

Study aim

Comparative study of the effect of nasal dexmedetomidine and oral chloral hydrate on pediatric sedation during electroencephalogram

Design

Clinical trial with control group with parallel groups, phase 2-3 on 64 patients

Settings and conduct

This study is performed in Imam Hossein Hospital in Isfahan. Patients will be treated with relaxation before the electroencephalogram in two ways. Data on heart rate, blood pressure, and sedation in patients are measured and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children 6 months to 6 years old, candidates for ECG for any reason, lack of proper cooperation for ECG, need to create sedation for ECG
Exclusion criteria: history of respiratory diseases, peptic ulcer, liver disease, presence of treatment with drugs that interact with chloral hydrate or dexmedetomidine, lack of written informed consent of parents for children to enter the study

Intervention groups

Intervention group 1: Patients in this group, before the intervention, receive intranasal dexmedetomidine from Abu Reihan company with dosage of 2-3 micrograms per kilogram and 10 minutes before the procedure.
Intervention group 2: Patients in this group will receive 5% chloral hydrate syrup at a dose of 50-100 mg per kg orally 10 minutes before the procedure before the intervention. Patients will be monitored by the Pediatric Anesthesia Fellowship during the electroencephalogram, and information about patients' heart rate, blood pressure before and during the procedure will be monitored and recorded every 5 minutes. For each patient, the sleep onset latency is also recorded.

Main outcome variables

Heart rate, blood pressure, sleep onset latency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051574N8**

Registration date: **2022-02-15, 1400/11/26**

Registration timing: **prospective**

Last update: **2022-02-15, 1400/11/26**

Update count: **0**

Registration date

2022-02-15, 1400/11/26

Registrant information

Name

Ghasem Mohammadsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 4005

Email address

mohammadsharifi.ghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-05, 1400/12/14

Expected recruitment end date

2022-05-04, 1401/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of nasal dexmedetomidine and oral chloral hydrate on pediatric sedation during electroencephalogram

Public title

Nasal dexmedetomidine and oral chloral hydrate during electroencephalogram

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 6 months to 6 years Candidate for electroencephalogram for any reason Lack of proper cooperation to perform electroencephalogram Need to create sedation for electroencephalogram

Exclusion criteria:

History of respiratory diseases, peptic ulcer, liver disease Existence of treatment with drugs that interact with chloral hydrate or dexmedetomidine Lack of written informed consent of parents for children to enter the study

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-02-01, 1400/11/12

Ethics committee reference number

IR.MUI.MED.REC.1400.780

Health conditions studied

1

Description of health condition studied

Electroencephalogram

ICD-10 code

R94.01

ICD-10 code description

Abnormal electroencephalogram [EEG]

Primary outcomes

1

Description

Heart rate

Timepoint

Before the start of the process and during the process at intervals of every 5 minutes

Method of measurement

Cardiac monitoring device

2

Description

Blood pressure

Timepoint

Before the start of the process and during the process at intervals of every 5 minutes

Method of measurement

Cardiac monitoring device

3

Description

Sleep onset latency

Timepoint

Before the start of the process and during the process at intervals of every 5 minutes

Method of measurement

Cardiac monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients in this group, before the intervention, receive intranasal dexmedetomidine from Abu Reihan company with dosage of 2-3 micrograms per

kilogram and 10 minutes before the procedure. Patients will be monitored by the Pediatric Anesthesia Fellowship during the electroencephalogram, and information about patients' heart rate, blood pressure before and during the procedure will be monitored and recorded every 5 minutes. For each patient, the sleep onset latency is also recorded.

Category

Treatment - Drugs

2**Description**

Intervention group 2: Patients in this group will receive 5% chloral hydrate syrup at a dose of 50-100 mg per kg orally 10 minutes before the procedure before the intervention. Patients will be monitored by the Pediatric Anesthesia Fellowship during the electroencephalogram, and information about patients' heart rate, blood pressure before and during the procedure will be monitored and recorded every 5 minutes. For each patient, the sleep onset latency is also recorded.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein hospital

Full name of responsible person

Mohammadreza Ghazavi

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No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

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**

Esfahan University of Medical Sciences

Full name of responsible person

Mohammadreza Ghazavi

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Full name of responsible person

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Position

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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

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments