Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, recieve 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
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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
Isfehan
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, recieve 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

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave,. Daneshgah Blvd, Isfahan

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haghjoo.sh@med.mui.ac.ir

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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No. 7, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Mohammadreza Ghazavi

Position

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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