

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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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parsa.alinezhad85@gmail.com

**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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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mohammadreza Ghazavi  
**Position**  
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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**