

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison between the effect of oral chloral hydrate and intranasal Fentanyl on pediatric sedation for EEG .

#### Protocol summary

##### Study aim

identification of the effect of oral chloral hydrate and intranasal Fentanyl on pediatric sedation for EEG .

##### Design

The study is randomized by random allocation , random numbers into 2groups with31 patients.first group gets 50mg/kg oral chloral hydrate ,30 minutes before EEG and 2µg/kg intra nasal normal saline as placebo. 2nd group gets 2µg/kg intra nasal fentanyl,30 minutes before EEG and50mg/kg oral placebo with the same appearance to oral chloral hydrate. It is a randomized clinical trial with control groups, parallel groups , blinded ,randomized by random numbers.

##### Settings and conduct

this is a randomized clinical trial randomized by random numbers and two side blinded which will be done in imam hossein hospital isfahan 2019-2020.

##### Participants/Inclusion and exclusion criteria

enter:Children between 3months to 3years Candidate for EEG under sedation. exit: cancelling of EEG after administration of drug for any reason,drug reactions , respiratory problems

##### Intervention groups

first group gets 50mg/kg oral chloral hydrate ,30 minutes before EEG and 2µg/kg intra nasal normal saline as placebo. 2nd group gets 2µg/kg intra nasal fentanyl,30 minutes before EEG and50mg/kg oral placebo with the same appearance to oral chloral hydrate.

##### Main outcome variables

hemodynamic changes (systolic blood pressure,diastolic blood pressure, mean arterial pressure ,heart rate), degree of sedation by RAMSEY scale, before getting drugs, at 1,3,5,10 minutes after drug administration at the time of EEG and every 10 minutes in recovery.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20191205045618N1**

Registration date: **2020-03-16, 1398/12/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-16, 1398/12/26**

Update count: **0**

#### Registration date

2020-03-16, 1398/12/26

#### Registrant information

##### Name

amir khodarahmi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3622 5453

##### Email address

amirkhodarahmi1995@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-12-22, 1398/10/01

#### Expected recruitment end date

2020-06-14, 1399/03/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison between the effect of oral chloral hydrate and intranasal Fentanyl on pediatric sedation for EEG .

#### Public title

Comparison between the effect of oral chloral hydrate and intranasal Fentanyl on sedation

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

children between 3 months to years candidated for EEG

#### Exclusion criteria:

cancelling of EEG after administration of drug drug allergy respiratory problems

### Age

From **3 months** old to **3 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator

### Sample size

Target sample size: **62**

### Randomization (investigator's opinion)

Randomized

### Randomization description

random allocation

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Medicines are Delivered and Coded in Equal Volumes by the Researcher and the Anesthesiologist dose not know the groups

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committe of Isfahan University Medical Science

##### Street address

Building No.4, Isfahan University of Medical Sciences, Hezar Jerib Ave

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2019-10-09, 1398/07/17

### Ethics committee reference number

IR.MUI.MED.REC.1398.359

## Health conditions studied

### 1

#### Description of health condition studied

mean arterial pressure,o2 saturation,heart rate, respiratory rate ,degree of sedation by RAMSEY scale

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

mean arterial pressure

#### Timepoint

before administration of drugs, 1,3,5,10 minutes after administration at the time if EEG, every 10 minutes in recovery

#### Method of measurement

monitoring by manometer

### 2

#### Description

heart rate

#### Timepoint

before administration of drugs, 1,3,5,10 minutes after administration at the time if EEG, every 10 minutes in recovery

#### Method of measurement

monitoring by palseoxymeter

### 3

#### Description

degree of sedation

#### Timepoint

before administration of drugs, 1,3,5,10 minutes after administration at the time if EEG, every 10 minutes in recovery

#### Method of measurement

RAMSEY scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: first group gets 50mg/kg oral chloral hydrate ,30 minutes before EEG and 2µg/kg intra nasal normal saline as placebo

#### Category

Treatment - Drugs

## 2

### Description

Intervention group: 2nd group gets 2µg/kg intra nasal fentanyl, 30 minutes before EEG and 50mg/kg oral placebo with the same appearance to oral chloral hydrate.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Emam Hossein Hospital

**Full name of responsible person**

Amir Shafa

**Street address**

Emam Khomeini Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

815163381

**Phone**

+98 31 3386 6566

**Email**

emamhossein\_hospital@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo Javanmard

**Street address**

Hezar Jerib Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3792 9017

**Email**

sh\_haghjoo@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**

Amir Shafa

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Emam Khomeini Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8195163381

**Phone**

+98 31 3386 9141

**Email**

amir\_shafa@med.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir Shafa

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Emam Khomeini

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8195163381

**Phone**

+98 31 3386 9141

**Email**

amir\_shafa@med.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir Shafa

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Emam Khomeini

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8195163381

**Phone**

+98 31 3386 9141

**Fax****Email**

amir\_shafa@med.mui.ac.ir

## 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**

information of participants and results of the study

**When the data will become available and for how long**

1 year after publish of the letter

**To whom data/document is available**

all of the researchers that are interested to have access to these information

**Under which criteria data/document could be used**

by sending request

**From where data/document is obtainable**

the projects admin

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

by email

**Comments**