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 emam 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

Isfehan

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 and50mg/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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan

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