Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between the effect of oral chloral hydrate and intranasal dexmedetomidine on pediatric sedation for EEG in Isfahan Imam Hossein Hospital, in 2017

Protocol summary

Study aim
The aim of this study is comparing the effect of chloral hydrate with dexmedetomidine on sedation for patients in EEG

Design
Clinical trial, phase 2, double blind, 60 patients between 3 month to 3 years old admitted based on EEG, randomized in two groups of chloral hydrate and dexmedetomidine.

Settings and conduct
This is a double blinded study on 60 patients admitted in EEG ward in Emam Hossein hospital of Isfahan, who receive chlore hydrate or dexmedetomidine will be compared about sedation

Participants/Inclusion and exclusion criteria
The patients With age of 3 months to 3 years who need EEG and without sensitivity to chloral hydrat and dexmedetomidine and with ASA1, ASA2

Intervention groups
The patient under EEG

Main outcome variables
Ramsy score scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180520039739N3**
Registration date: **2019-04-22, 1398/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-22, 1398/02/02**
Update count: **0**

Registration date
2019-04-22, 1398/02/02

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2019-05-21, 1398/02/31

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 dexmedetomidine on pediatric sedation for EEG in Isfahan Imam Hossein Hospital, in 2017

Public title
Comparison between the effect of oral chloral hydrate and intranasal dexmedetomidine on pediatric sedation for EEG

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with age of 3 month to 3 years Patients who

need EEG patients with ASA1,ASA2

Exclusion criteria:

Sensitivity to dexmedetomidine or chloral hydrate in past medical histoty

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization (random number table): even numbers for chlor hydrate and odds for dexmedetomidine

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and their nurses are not aware of the kind of drug and executor of plan will give the drug to thr nurses

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,hezarjarib Ave.

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Isfehan

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ندارد

Approval date

2017-04-25, 1396/02/05

Ethics committee reference number

IR.MUI.REq.1396.39975

Health conditions studied

1

Description of health condition studied

Sedation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sedation

Timepoint

In One houre

Method of measurement

Ramsy score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment with 50 mg/kg chloral hydrate 10% (Kimia teb pajohan gharb)30 minute before EEG

Category

Treatment - Drugs

2

Description

Intervention group: Treatment with 2 micro/kg dexmedetomidine (behestan daro) 30 minute before EEG

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam hosein hospital in esfahan

Full name of responsible person

Mohammad reza habibzadeh

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Sponsors / Funding sources

1

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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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available