

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 chloral 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 hydrate 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

Name

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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 history

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 the 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.

City

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Province

Isfahan

Postal code

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 hour

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

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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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**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

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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