Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of efficacy of oral chloral hydrate and promethazine in sedation induction for electroencephalography in children

Protocol summary

Summary

In a clinical trial, efficacy and safety of promethazine and chloral hydrate in induction of sedation of 60 children 1-18 years old referred to electroencephalography unit, will be evaluated. The patients will randomly be assigned to receive either 100 mg/kg/dose of chloral hydrate or 1mg/kg promethazine until Ramsay score of four is attained. If the child is not sedated after 30 minutes of drug use, the second dose of drug in half of the first dose will be administered. Vital signs, level of consciousness, cyanosis, respiratory state, vomiting, dystonia, and extra pyramidal adverse effect will be evaluated in children for two hours after drug use. Efficacy of drugs in sedation induction, time to induction of sedation, total stay time in EEG unit, serious adverse events (hypotension, hypoxia and cyanosis, severe vomiting, irritability, apnea, laryngospasm, and bradycardia), and caregiver's satisfaction are also compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903032639N2**
Registration date: **2010-05-24, 1389/03/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-05-24, 1389/03/03

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for research of Shaheed Sadoughi University of Medical Sciences and Health Services, Yazd, Iran

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of oral chloral hydrate and promethazine in sedation induction for electroencephalography in children

Public title

Comparison of effectiveness of chloral hydrate and promethazine in electroencephalography

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: children who are referred to EEG center but don't obey, age 1-18 years old, class 1 or 2 of ASA
Exclusion criteria: Presence of gastritis or any other serious systemic diseases, severe systemic reaction

Age

From **1 year** old to **18 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shaheed Sadoughi University of Medical Sciences and Health Services
Street address
Boali street, Safaeeh
City
Yazd
Postal code
Approval date
2010-05-04, 1389/02/14
Ethics committee reference number
14693/1/17/پ

Health conditions studied

1

Description of health condition studied
epilepsy
ICD-10 code
G40, G47
ICD-10 code description
Epilepsy and paroxysmal disorders

Primary outcomes

1

Description
sedation until Ramsay score of four be attained
Timepoint
every 15 minutes
Method of measurement
clinical

Secondary outcomes

1

Description
side effects
Timepoint
evert 15 minutes
Method of measurement
clinical exam

2

Description
level of consciousness based on GCS number
Timepoint
every 15 minutes
Method of measurement
clinical exam

3

Description
time to induction of sedation,
Timepoint
eyery 30 minutes
Method of measurement
clinical exam

4

Description
vital signs(blood pressure , pulse rate , respiratory rate
Timepoint
every 10 minutes
Method of measurement
clinical exam

5

Description
serious adverse events (hypotension, hypoxia and cyanosis, severe vomiting, irritability, apnea, laryngospasm, and bradycardia)
Timepoint
every 10 minutes
Method of measurement
clinical exam

6

Description
caregiver’s satisfaction
Timepoint
after 2 hours of drug use
Method of measurement
asking from caregiver

7

Description

total stay time in EEG unit

Timepoint

after 2 hours of drug use

Method of measurement

asking from parents

8

Description

Efficacy of drugs in sedation induction for EEG

Timepoint

after 2 hours of drug use

Method of measurement

asking from parents

Intervention groups

1

Description

Promethazin, 1mg/kg single dose, Orally

Category

Treatment - Drugs

2

Description

Chloral hydrate, 70 mg/kg single dose, orally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Sadoughi hospital - EEG unit

Full name of responsible person

Dr. Razieh Fallah

Street address

Shaheed Sadoughi Hospital, Sina Blvd, Shahid Ghandi Blvd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research -Shaheed Sadoughi University of Medical Sciences and Health Services

Full name of responsible person

Dr. Fatemah Ezodinee

Street address

Bahonar Square

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of research -Shaheed Sadoughi University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shaheed Sadoughi University of Medical Sciences and Health Services

Full name of responsible person

Dr. Razieh Fallah

Position

Assistant professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty