

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

clinical

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

Secondary outcomes

1

Description

side effects

Timepoint

every 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

every 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

Street address

Shaheed Sadoughi Hospital, Sina Blvd, Shahid Ghandi Blvd

City

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Email

FALLAH@ssu.ac.ir

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