

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of efficacy and safety of chloral hydrate, combination of chloral hydrate - promethazine and combination of chloral hydrate - hydroxyzine in sedation induction for electroencephalography of children

Protocol summary

Summary

In a clinical trial, efficacy and safety of chloral hydrate, combination of chloral hydrate - promethazine and combination of chloral hydrate - hydroxyzine in sedation induction of 90 children 1-7 years old referred to electroencephalography unit, will be evaluated. The patients will randomly be assigned to receive single dose either 40 mg/kg of chloral hydrate or combination 1mg/kg promethazine and 40 mg/kg of chloral hydrate or combination 1mg/kg hydroxyzine and 40 mg/kg of chloral hydrate until Ramsay score of four is attained. Vital signs and adverse effect will be evaluated in children for one hour after drug use. Efficacy of drugs in adequate sedation induction, time to induction of adequate sedation, total stay time in EEG unit, side effects and caregiver's satisfaction are also compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204262639N8**

Registration date: **2012-07-28, 1391/05/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-28, 1391/05/07

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

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Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid sadoughi Medical Sciences University

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of chloral hydrate, combination of chloral hydrate - promethazine and combination of chloral hydrate - hydroxyzine in sedation induction for electroencephalography of children

Public title

chloral hydrate, combination of chloral hydrate - promethazine and combination of chloral hydrate - hydroxyzine in sedation induction for electroencephalography of children

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: 1. Children who are referred to EEG center but don't obey, 2. Age 1-7 years old 3. Class 1 or 2 of ASA Exclusion criteria: 1. Presence of gastritis or any

other serious systemic diseases 2. Severe systemic reaction 3. History of allergy to drug 4. The patient does not use the drug completely

Age

From **1 year** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ali-ebn-Abitaleb School of Medicine, Islamic Azad University, Yazd Branch, Yazd, Iran

Street address

Danesh amose square, near to Shah Vali Hospital

City

Yazd

Postal code

Approval date

2012-07-08, 1391/04/18

Ethics committee reference number

105101091302009

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

success in recording of EEG

Timepoint

every 15 minutes

Method of measurement

clinical exam

2

Description

adequate sedation (Ramsay score of four is attained)

Timepoint

every 15 minutes

Method of measurement

clinical exam

Secondary outcomes

1

Description

total stay time in EEG unit

Timepoint

every 30 minutes

Method of measurement

asking from parents

2

Description

side effects

Timepoint

every 15 minutes

Method of measurement

clinical exam

3

Description

time to induction of adequate sedation

Timepoint

every 15 minutes

Method of measurement

clinical exam

4

Description

caregiver's satisfaction

Timepoint

after one hour of drug use

Method of measurement

asking from caregiver

Intervention groups

1

Description

combination of 1mg/kg hydroxyzine and 40 mg/kg of chloral hydrate

Category

Treatment - Other

2**Description**

combination 1mg/kg promethazine and 40 mg/kg of chloral hydrate

Category

Treatment - Other

3**Description**

single dose 40 mg/kg of chloral hydrate

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**Pediatric Neurology Clininc of Shahid sadoughi
Medical Sciences University**Full name of responsible person**

Dr.Razieh Fallah

Street address

Taleghani BLVD

City

Yazd

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Ali-ebn-Abitaleb School of Medicine, Islamic Azad
University, Yazd Branch, Yazd, Iran**Full name of responsible person**

Dr.razieh Fallah

Street address

Shahid Sadoughi Hospital

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceAli-ebn-Abitaleb School of Medicine, Islamic Azad
University, Yazd Branch, Yazd, Iran**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**Shahid Sadoughi University of Medical Sciences
,Yazd,Iran**Full name of responsible person**

Dr.Razieh Fallah

Position

Pediatric neurologist , Associate professor

Other areas of specialty/work**Street address**

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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*