

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Yazd

#### Postal code

#### Phone

+98 35 1822 4000

#### Fax

#### 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*