

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of efficacy of oral chloral hydrate and intranasal midazolam in sedation for CT scan in children

#### Protocol summary

##### Summary

In a clinical trial, efficacy and safety of intranasal midazolam and oral chloral hydrate in induction of sedation of 60 children 1-18 years old referred to Ct scan unit of Shahid Sadoughi Hospital , will be evaluated. The patients will randomly be assigned to receive either 75 mg/kg/dose of chloral hydrate or 0.2mg/kg intranasal midazolam until Ramsay score of four is attained. Vital signs and 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 CT 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: **IRCT201107082639N4**

Registration date: **2011-07-21, 1390/04/30**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-07-21, 1390/04/30

##### 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 of research -Shaheed Sadoughi University of  
Medical Sciences , Yazd, Iran

##### Expected recruitment start date

2011-07-23, 1390/05/01

##### Expected recruitment end date

2012-03-19, 1390/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy of oral chloral hydrate and  
intranasal midazolam in sedation for CT scan in children

##### Public title

oral chloral hydrate and intranasal midazolam in  
sedation induction for CT scan

##### Purpose

Other

##### Inclusion/Exclusion criteria

Inclusion criteria:age 1-18 years old; children who are referred to CT scan center but don't obey; class 1 or 2 of ASA Exclusion criteria: use of chloral hydrate or midazolam in recently 48 hours ; gastritis or any other serious systemic diseases ; history of drugs allergy ; occurrence of severe systemic drugs 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

Bahonar square , central building on University

##### City

Yazd

##### Postal code

#### Approval date

2011-06-26, 1390/04/05

#### Ethics committee reference number

39321/1/17/پ

## Health conditions studied

### 1

#### Description of health condition studied

other disorders of the nervous system

#### ICD-10 code

G90-G99

#### ICD-10 code description

Other disorders of the nervous system

## Primary outcomes

### 1

#### Description

sedation until Ramsay score of four be attained

#### Timepoint

every 15 minutes

#### Method of measurement

clinical

### 2

#### Description

Efficacy of drugs in sedation induction

#### Timepoint

every 15 minutes

#### Method of measurement

clinical exam

## Secondary outcomes

### 1

#### Description

side effects

#### Timepoint

every 15 minutes

#### Method of measurement

clinical exam

### 2

#### Description

serious adverse events (hypotension, hypoxia and cyanosis, severe vomiting, irritability, apnea, laryngospasm, and bradycardia)

#### Timepoint

every 10 minutes

#### Method of measurement

clinical exam

### 3

#### Description

vital signs(blood pressure , pulse rate , respiratory rate

#### Timepoint

every 15 minutes

#### Method of measurement

clinical exam

### 4

#### Description

time to induction of sedation,

#### Timepoint

every 30 minutes

#### Method of measurement

clinical exam

### 5

#### Description

total stay time in CT scan unit

#### Timepoint

after 2 hours of drug use

#### Method of measurement

asking from parents

### 6

#### Description

caregiver's satisfaction

#### Timepoint

after 2 hours of drug use  
**Method of measurement**  
asking from caregiver

## Intervention groups

1

### Description

Chloral hydrate, 70 mg/kg single dose, orally

### Category

Treatment - Drugs

2

### Description

intranasal midazolam, 0.2mg/kg single dose

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Sadoughi hospital - CT scan unit

#### Full name of responsible person

Dr.Razieh Fallah

#### Street address

Shahid 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 ,Yazd,Iran

#### Full name of responsible person

Dr. Fatemah Ezodinee

#### Street address

Bahonar Square ,University central byilding

#### 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 ,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

Associate professor

#### Other areas of specialty/work

#### Street address

Shahid 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*