

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

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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

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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