Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy of chloral hydrate -hydroxyzine and chloral hydrate – oral midazolam in sedation induction for MRI in children

Protocol summary

Summary

In a randomized clinical trial , sixty children aged 1-7 years ,whom referred to MRI of Shahid Sadoughi Hospital and who don't naturally sleep and immobilize, will be randomly assigned to receive combination of 40 mg/kg of chloral hydrate and 1mg/kg hydroxyzine or 40 mg/kg of chloral hydrate and 0.5mg/kg oral midazolam. Efficacy of drugs in adequate sedation induction(Ramsay score of four) , time to induction of adequate sedation, total stay time in MRI unit , side effects and caregiver's satisfaction are also compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302092639N10**
Registration date: **2013-02-23, 1391/12/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-23, 1391/12/05

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 of Shahid Sadoughi University of Medical Sciences ,Yazd,Iran

Expected recruitment start date

2012-11-30, 1391/09/10

Expected recruitment end date

2013-03-30, 1392/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of chloral hydrate -hydroxyzine and chloral hydrate – oral midazolam in sedation induction for MRI in children

Public title

chloral hydrate -hydroxyzine and chloral hydrate – oral midazolam in sedation induction for MRI in children

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: 1. Children who are referred to MRI Unit but don't obey, 2. Age 1-7 years old 3. Class 1 or 2 of ASA 4. Do not receive a sedative hypnotic agent within the past 48 hours 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: **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

Shahid Sadoughi University of Medical Sciences ,Yazd,Iran

Street address

Bahonar Square, Central Building of University

City

Yazd

Postal code

Approval date

2012-11-21, 1391/09/01

Ethics committee reference number

119121/1/17

Health conditions studied

1

Description of health condition studied

CNS diseases

ICD-10 code

G90-G99

ICD-10 code description

Other disorders of the nervous system

Primary outcomes

1

Description

adequate sedation (Ramsay score of four is attained)

Timepoint

every 15 minutes

Method of measurement

clinical exam

2

Description

success in taking of MRI

Timepoint

every 15 minutes

Method of measurement

clinical exam

Secondary outcomes

1

Description

time to induction of adequate sedation

Timepoint

every 15 minutes

Method of measurement

clinical examination

2

Description

side effects

Timepoint

every 15 minutes

Method of measurement

clinical examination

3

Description

total stay time in MRI unit

Timepoint

Every 30 minutes

Method of measurement

asking from parents

4

Description

caregiver’s satisfaction

Timepoint

after two hours of drug use

Method of measurement

asking from caregiver

Intervention groups

1

Description

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

Category

Other

2

Description

40 mg/kg of chloral hydrate and 0.5mg/kg oral midazolam

Category

Other

Recruitment centers

1

Recruitment center
Name of recruitment center
MRI Unit of Shahid Sadoughi Hospital
Full name of responsible person
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research of Shahid Sadoughi University of Medical Sciences,Yazd,Iran
Full name of responsible person
Dr.Fatemeh Ezoddini
Street address
Bahonar Square , Central buliding of University
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 of Shahid 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
Name of organization / entity
Shahid Sadoughi University of Medical Sciences , Yazd , Iran
Full name of responsible person
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Associate professor, Pediatric Neurologist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Phone
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Fax
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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