

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of Sedative Effect of Intranasal Midazolam Spray and Chloral Hydrate in Children with Head Trauma for Imaging in Emergency Department

Protocol summary

Study aim

Our purpose of this study is to compare the efficacy, safety and side effects of intranasal midazolam and oral chloride hydrate in the sedation of children with head trauma in order to perform imaging, in order to provide a safe and appropriate way of doing this.

Design

Randomized, parallel group, double-blind, placebo-controlled clinical trial

Settings and conduct

In this study, children with head trauma referring to the emergency department who require CT scan of the head are divided into two groups using randomized blocking method. Intranasal midazolam at a dose of 0.3 mg/ kg or syrup of chloral hydrate at a dose of 75 mg/ kg are used for children sedation. Ramsay sedation scale was used for assessment of sedation level. A score of four are considered as adequately sedated. If it does not reach this level after 20 minutes, one third of the dose of the initial drug is repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Alert children 1-8 years with head trauma require a CT scan that does not have the necessary co-operation to do it. Exclusion criteria: nasal allergy; known contraindications to the use of study drugs and receiving a sedative hypnotic agent within the past 48 hours.

Intervention groups

The intervention group receives a single dose of intranasal midazolam 0.3 mg / kg and oral syrup. The control group receives oral chloral hydrate and intranasal placebo.

Main outcome variables

The main outcome of the study is the efficacy and safety of Intranasal Midazolam and the success in performing CT scan.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038549N4**

Registration date: **2018-04-11, 1397/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-11, 1397/01/22**

Update count: **0**

Registration date

2018-04-11, 1397/01/22

Registrant information

Name

Farhad Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3786 8804

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sedative Effect of Intranasal Midazolam Spray and Chloral Hydrate in Children with Head Trauma for Imaging in Emergency Department

Public title

Evaluation of the effect of oral chloral hydrate and intranasal midazolam on sedation of children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The child is alert with head trauma requires CT scan of head Lack of cooperation for CT scan American Society of Anesthesiology (ASA) class 1 or 2

Exclusion criteria:

Receiving a sedative hypnotic agent within the past 48 hours Gastritis Serious systemic disease Nasal allergy to drugs Obesity (body mass index.30) Known contraindications to the use of study drugs (eg, hypersensitivity),

Age

From **1 year** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

A computer-generated random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs were packed by the pharmacist. Each packet contained a nasal spray and syrup. The packets were named A and B following the codes. In one packet, there are intranasal Midazolam and oral placebo, and in another packet, there are an equal volume of chloral hydrate syrup and the intranasal placebo. Patients are randomized to receive one of the packets. The patients and their parents and the nurses are unaware of the contents of the drugs. Data collectors, outcome assessors and data analysts are all kept blinded to the allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Alzahra hospital, Sofe Ave., Shahid Keshvari Blvd.

City

Isfahan

Province

Isfahan

Postal code

817777645

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.MUI.RES.1396.3.516

Health conditions studied

1

Description of health condition studied

Head trauma

ICD-10 code

S00

ICD-10 code description

Superficial injury of head

Primary outcomes

1

Description

Sedation level of the patient. A score of four is considered

Timepoint

Every 5 minutes

Method of measurement

Physical exam

2

Description

Success in CT scan doing

Timepoint

After refer to the radiology department

Method of measurement

Performing or not performing a CT scan

Secondary outcomes

1

Description

Side effects

Timepoint

every 5 minutes

Method of measurement

Physical exam

2**Description**

Vital signs (blood oxygen saturation level, pulse rate and respiratory rate per minute)

Timepoint

Every 5 minutes

Method of measurement

Physical exam

3**Description**

The time interval from taking the drugs to the adequate sedation

Timepoint

Every 5 minutes

Method of measurement

Ramsay sedation scale

4**Description**

The interval time between drug taking and CT scan performing

Timepoint

Every 5 minutes

Method of measurement

Record time

5**Description**

The time interval from taking the drug to the child's full consciousness

Timepoint

Every 5 minutes

Method of measurement

Record time

6**Description**

The parents' satisfaction

Timepoint

After the child's consciousness

Method of measurement

Question from parents

Intervention groups**1****Description**

Control group: Syrup chloral hydrate 75 mg / kg and placebo intranasal

Category

Treatment - Drugs

2**Description**

Intervention group: Intranasal midazolam 0.3 mg / kg and oral placebo

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra and Kashani hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Shaghayegh haghjooy javanmard

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

10

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

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Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable