

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the sedative effect of oral ketamine, midazolam and chloral hydrate in children candidate for noninvasive diagnostic procedures

Protocol summary

Summary

The purpose of this study is evaluation of the effects of various sedative drugs in children during diagnostic procedures. This study is a randomized, double-blind, without placebo control that will be done in children 2 to 10 years candidate for CT scan or audiometry that have not any history of taking sedatives, opioids, anticonvulsants drug. 60 patients will be randomized to three groups and will receive midazolam, ketamine and chlorate hydrate. The separation of children from their parents, sedation and anxiety will be controlled every 5 minutes and patient movement measured in several minute and will be compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010612642N9**

Registration date: **2015-01-18, 1393/10/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-18, 1393/10/28

Registrant information

Name

Majid Golestani Eraghi

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3336 0547

Email address

dr.golestani@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the sedative effect of oral ketamine, midazolam and chloral hydrate in children candidate for noninvasive diagnostic procedures

Public title

Sedative effect of ketamine, midazolam and oral chloral hydrate in children

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Candidate for CT scan; candidate for audiometry; age between 2 to 10 years old; ASA I,II
exclusion criteria: History of taking sedative drugs, history of drug abuse, history of taking anticonvulsants, history of allergy

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research and Technology Ethics
Committee Shahid Beheshti University of Medical

Street address

Daneshjoo Ave-Velenjak

City

Tehran

Postal code

Approval date

2013-09-14, 1392/06/23

Ethics committee reference number

400/4012

Health conditions studied

1

Description of health condition studied

Oral sedation in children

ICD-10 code

F44.6

ICD-10 code description

Dissociative anaesthesia and sensory loss

Primary outcomes

1

Description

time of separating from parents

Timepoint

Every 5 min after administration

Method of measurement

Based on the examination by the research team

2

Description

sedation

Timepoint

Every 5 min after administration

Method of measurement

Based on the examination by the research team based
on sedatin score

3

Description

anxiety

Timepoint

Every 5 min after administration

Method of measurement

Based on the examination by the team on the anxiety
sedation table

4

Description

The children move during the procedure

Timepoint

0,15 and 30 minute after drug administration

Method of measurement

Based on the examination by the team on the anxiety
sedation table

Secondary outcomes

1

Description

Children waking time

Timepoint

Since taking oral medication

Method of measurement

Based on the examination by the team in minutes

2

Description

nausea

Timepoint

After taking oral medication

Method of measurement

Questions from Parents

Intervention groups

1

Description

Midazolam group, patients administered 0 / 5mg / kg
orally midazolam, and every 5 minutes to allow the
separation of children from their parents will controle

Category

Treatment - Drugs

2

Description

ketamin group, patients administered 5mg / kg orally ketamin, and every 5 minutes to allow the separation of children from their parents will controle

Category

Treatment - Drugs

3

Description

chlorate Hydrate group, patients administered 50mg / kg orally chlorate Hydrate, and every 5 minutes to allow the separation of children from their parents will controle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hospital, Makhsoos Ave, Lashkar Crossroad

Full name of responsible person

Majid Golestani Eraghi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Daneshjoo Ave- Velenjak

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology Shahid Beheshti University of Medical Sciences

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

Did you mean: گروه بیهوشی دانشگاه علوم پزشکی شهید بهشتی
Department of Anesthesiology, Shahid Behesht

Full name of responsible person

Farhad Safari

Position

Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Department of Anesthesiology, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Majid Golestani Eraghi

Position

Fellowship specialty intensive care

Other areas of specialty/work

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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