

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of Oral Midazolam and Ketamine with Oral Midazolam and Promethazine in Pediatric Sedation

Protocol summary

Study aim

Comparison of efficacy of midazolam and oral ketamine with midazolam and oral promethazine in pediatric sedation

Design

A concealed, randomized, blinded, parallel group

Settings and conduct

This double blind clinical trial was performed on 102 children in ASA class 1 and 2 in the age group of 2 to 10 years old who referred to Imam Sari Hospital. blinded in the patient and physician and nurse.

Participants/Inclusion and exclusion criteria

Inclusive Criteria: Pediatric with 2 to 10 years old

Exclusive Criteria: cold or infection, the history of the use of sedative drugs and non satisfaction

Intervention groups

Oral midazolam 0.5 mg kg plus ketamine 5 mg per kilogram for the first group and oral midazolam 0.5 mg kg plus promethazine at a rate of 1 mg per kilogram for the second group

Main outcome variables

The degree of sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180717040509N2**

Registration date: **2018-09-30, 1397/07/08**

Registration timing: **retrospective**

Last update: **2018-09-30, 1397/07/08**

Update count: **0**

Registration date

2018-09-30, 1397/07/08

Registrant information

Name

Mahboubeh Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3321 7982

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-05-21, 1394/02/31

Actual recruitment start date

2014-11-22, 1393/09/01

Actual recruitment end date

2015-05-21, 1394/02/31

Trial completion date

2015-06-20, 1394/03/30

Scientific title

Comparison of Oral Midazolam and Ketamine with Oral Midazolam and Promethazine in Pediatric Sedation

Public title

Effect of Oral Midazolam and Ketamine in Pediatric Sedation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pediatric between 2 to 10 years olds

Exclusion criteria:

Children with Upper Respiratory Tract Infection

Dissatisfaction to participate in the study Grade 3, 4, 5 or 6 of American Anesthesiology Association (ASA) Use of Sedative and Narcotic drugs Prohibited for Sedation Head

Truama History of Cardiovascular Disease Eye Trauma
History of Central Nervous System (CNS)

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **102**

Actual sample size reached: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization, ASA Class

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are allocated randomly to groups by nurses.

These patients will not know what group they are in.

Also, the pharmacist, without the knowledge of the

investigator, will encode the desired drugs. In this way,

the investigator, doctor and nurse will also be unaware of

the name of the drug they received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of
Medical Science

Street address

Moallem Square

City

Sari

Province

Mazandaran

Postal code

4817844818

Approval date

2014-11-19, 1393/08/28

Ethics committee reference number

IR.MAZUMS.REC.13930828

Health conditions studied

1

Description of health condition studied

Pediatric Sedation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sedation

Timepoint

Every 5 minutes to 40 minutes

Method of measurement

Ramsay Sedation Scale

2

Description

Pediatric's behavior

Timepoint

Every 5 minutes to 40 minutes

Method of measurement

Houpt Checklist

3

Description

Crying Rate

Timepoint

Every 5 minutes to 40 minutes

Method of measurement

Houpt Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Combination of Oral Midazolam (0.5 mg/kg) from Iran Pharmaceutical Chemistry Company and Oral Ketamine (5mg/kg) from Gmbh ROTEXMEDICA, Germany mixed with 20 cc fruit juice (cherry juice of Takdaneh: construction of Iran) was given to a child at a dose

Category

Treatment - Drugs

2

Description

Control group:Combination of Oral Midazolam (0.5 mg/kg) from Iran Pharmaceutical Chemistry Company and Oral Promethazine (1 mg/kg) from Tehran

Pharmaceutical Company mixed with 20 cc fruit juice (cherry juice of Takdaneh: construction of Iran) was given to a child at a dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Farzad Bozorgi

Street address

Amirmazandarani Street

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Sari

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4811633131

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Sari University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Farzad Bozorgi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Position

Assistant Professor

Latest degree

Specialist

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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