

# 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)

##### Phone

+98 11 3321 7982

##### Email address

m.eslami@mazums.ac.ir

##### 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

**City**

Sari

**Province**

Mazandaran

**Postal code**

4811633131

**Phone**

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farzad722001@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Farzad Bozorgi

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Amir Mazandarani Street

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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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Assistant Professor

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mahboubeh Eslami

**Position**

Employee

**Latest degree**

Master

**Other areas of specialty/work**

Medical Informatics

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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