

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of three methods of verbal speaking intranasal injection of midazolam and ketamine intranasal injection in control of pain and stress associated with peripheral venous thrombosis in children

#### Protocol summary

##### Study aim

Comparison of three methods of verbal speaking intranasal injection of midazolam and ketamine intranasal injection in control of pain and stress associated with peripheral venous thrombosis in children

##### Design

The design of the study is a randomized clinical trial. The randomization method is blocked. Patients will be randomly divided into 4 groups based on 20 blocks. The sample size for each study group is 25.

##### Settings and conduct

All patients referred to the Ali Asghar Hospital, who needed peripheral venous will be enrolled. Patients will be randomly divided into 4 groups based on 20 blocks. The sample size for each study group is 25. A total of 100 patients will be examined. Data analyzer will be blind.

##### Participants/Inclusion and exclusion criteria

All patients referred to the Ali Asghar Hospital, who suffered from bronchiolitis will be enrolled. Inclusion criteria: patients over 1year, Parental consent for the child to participate in the project. Exclusion criteria: Immunodeficiency, Down syndrome, Chronic heart and pulmonary disease.

##### Intervention groups

Intervention groups: 1- Intranasal injection of Midazolam 0.2 mg / kg, 20 minutes before the procedure with the MAD. 2- Intervention group: Intranasal injection of Ketamine 5 mg/kg, 20 minutes before the procedure with the MAD. 3- Use verbal talk to calm children, before the procedure. Control group: No special action is taken before the procedure.

##### Main outcome variables

The number of pulses, The number of pulses, Breath rate, The severity of pain after the procedure, The amount of sedation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151003024317N8**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **prospective**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

##### Registration date

2019-09-28, 1398/07/06

##### Registrant information

##### Name

Mahdi Rezai

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8868 6772

##### Email address

rezaei.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-02, 1398/07/10

##### Expected recruitment end date

2020-03-15, 1398/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of three methods of verbal speaking intranasal injection of midazolam and ketamine intranasal injection in control of pain and stress associated with peripheral venous thrombosis in children

## Public title

Controlling of pain and stress associated with peripheral venous thrombosis in children

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over one year Parental consent for the child to participate in the project

### Exclusion criteria:

Immunodeficiency Down syndrome Chronic heart and pulmonary disease

## Age

From **1 year** old to **10 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 20 person. In each block, 15 individuals will be in intervention groups (5 from each group) and 5 will be in control group. A total of 5 blocks will be considered for sample size.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

### Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

##### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Approval date

2019-02-24, 1397/12/05

#### Ethics committee reference number

IR.IUMS.REC.1398.011

## Health conditions studied

### 1

#### Description of health condition studied

Peripheral vein in children

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Saturation of oxygen

#### Timepoint

10 minutes after the procedure

#### Method of measurement

Pulse Oximetry

### 2

#### Description

The number of pulses

#### Timepoint

10 minutes after the procedure

#### Method of measurement

Based on patient records

### 3

#### Description

Breath rate

#### Timepoint

10 minutes after the procedure

#### Method of measurement

Based on patient records

### 4

#### Description

The severity of pain after the procedure

#### Timepoint

10 minutes after the procedure

#### Method of measurement

Observational Scale of Behavioral Distress-Revised

### 5

#### Description

The amount of sedation

#### Timepoint

10 minutes after the procedure

**Method of measurement**

Observational Scale of Behavioral Distress-Revised

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Intranasal injection of Midazolam 0.2 mg / kg, 20 minutes before the procedure with the MAD.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: Intranasal injection of Ketamine 5 mg/kg, 20 minutes before the procedure with the MAD.

**Category**

Treatment - Drugs

**3**

**Description**

Intervention group: Use verbal talk to calm children, before the procedure.

**Category**

Behavior

**4**

**Description**

Control group: No special action is taken before the procedure.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ali Asghar Hospital

**Full name of responsible person**

Shabahang Jafarnejad

**Street address**

Ali Asghar Children's Hospital, Shaheed Dastgerdi Street (Zafar),

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1919816766

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Shabahang Jafarnejad

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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

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