

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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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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