

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of clinical efficacy of Intranasal administration of midazolam and ketamine in managing pain and distress associated with peripheral IV access in children presenting to emergency departments of IUMS

Protocol summary

Study aim

The aim of this study is to evaluate the clinical efficacy and analgesic and sedative effects of intranasal administration of Ketamine And Midazolam in peripheral IV access in children presenting to the emergency department.

Design

Two arm parallel open-label randomized controlled trial of 100 children ; No control group; randomization with RRAApp software

Settings and conduct

Children presenting to the emergency department of hospitals of Iran University of Medical Sciences are divided into two groups. Midazolam or ketamine is administered intranasally before the procedure. Heart rate and blood oxygen percentage are recorded by a portable pulse oximeter, pain, and sedation by the Observational Scale Of Behavioral distress-Revised (OSBD-R) and possible complications, procedure success, parents and nurses satisfaction through observation and checklist

Participants/Inclusion and exclusion criteria

Inclusion Criteria: all the children aged one to 10 years old, who need hospitalization and peripheral IV access for diagnostic and therapeutic measures Exclusion criteria: level 1 triage, parental dissatisfaction, history of drug allergies, severe underlying diseases

Intervention groups

Intranasal administration of ketamine (5 mg/kg) or midazolam (0.2 mg/kg) with the use of a syringe, before accessing IV line

Main outcome variables

OSBD-R score in two group Success rate of peripheral IV Access; Heart rate and blood oxygen Saturation; Satisfaction of parents and nurses;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048242N1**

Registration date: **2020-08-10, 1399/05/20**

Registration timing: **retrospective**

Last update: **2020-08-10, 1399/05/20**

Update count: **0**

Registration date

2020-08-10, 1399/05/20

Registrant information

Name

Iman Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5422 1337

Email address

jafarnejad.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-07-19, 1398/04/28

Actual recruitment end date

2020-05-12, 1399/02/23

Trial completion date

2020-05-12, 1399/02/23

Scientific title

Comparison of clinical efficacy of Intranasal administration of midazolam and ketamine in managing pain and distress associated with peripheral IV access in children presenting to emergency departments of IUMS

Public title

Comparison of intranasal midazolam and ketamine in peripheral IV access in children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1 to 10 years-old Children Emergency department or wards admission Needing IV access for diagnostic and therapeutic interventions

Exclusion criteria:

Patients with critical or emergency conditions, or in other words, have level 1 triage and are treated in the resuscitation room All cases in which parents do not consent to sedation and analgesia prior to peripheral intravenous access All patients with a history of allergies to ketamine or midazolam Age less than one year or over 10 years Existence of serious underlying heart disease including heart failure, electrical heart disorders, congenital heart defects Presence of advanced liver or kidney disease, including renal failure or dialysis, history of kidney or liver transplantation, congenital metabolic disorders Children with cerebral palsy, cystic fibrosis and epilepsy Congenital or acquired jaw and facial abnormalities

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The type of drug prescribed is randomized by simple randomization among the participants by using the RRAApp software. For this purpose, in the order of participation in the research, the participants will receive midazolam or ketamine based on the group they are assigned by RRAApp software. Allocation concealment is not carried out.

<http://clinicalresearch-apps.com/RRAApp.html>

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

Iran University of Medical Sciences Research Ethics Committee

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran
University of Medical Sciences, fifth floor of the headquarters

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.IUMS.FMD.REC.1398.143

Health conditions studied

1

Description of health condition studied

Pain and distress associated with peripheral IV access in children in emergency department

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Observational Scale Of Behavioral distress-Revised Score

Timepoint

20 min after intervention

Method of measurement

Observational Scale Of Behavioral distress-Revised (OSBD-R)

2

Description

Success rate of accessing peripheral Intravenous line

Timepoint

20 min after the intervention

Method of measurement

Researcher observation based on the presence or lack of physical restraint during the procedure

Secondary outcomes

1

Description

Heart Rate

Timepoint

10 and 20 minutes after the intervention

Method of measurement

Portable Pulse Oximeter

2

Description

Oxygen Saturation

Timepoint

10 and 20 minutes after the intervention

Method of measurement

Portable Pulse Oximeter

3

Description

Satisfaction of parents

Timepoint

Once after the end of the procedure

Method of measurement

5 point likert scale

4

Description

Satisfaction of nurses

Timepoint

Once after the end of the procedure

Method of measurement

5 point likert scale

Intervention groups

1

Description

Intervention group 1: Intranasal ketamine administration, at a dose of 5 mg/kg from a 50 mg/cc ketamine ampule, produced by Rotexmedica, Germany, twenty minutes before peripheral intravenous access, once via intranasal route, at half the dose in each nostril with a conventional syringe

Category

Other

2

Description

Intervention group 2: Intranasal midazolam administration, at a dose of 0.2 mg/kg from a 5 mg/cc midazolam ampule, produced by Darou Paksh pharmaceutical company, twenty minutes before peripheral intravenous access, once via intranasal route, at half the dose in each nostril with a conventional syringe

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Asghar Children's Hospital

Full name of responsible person

Gholamreza Bayazian, MD.

Street address

Ali-Asghar Children's Hospital, Shahid Vahid Dastgerdi Street, Moddares Highway, Tehran, Iran

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2

Recruitment center

Name of recruitment center

Shohadaye hafte-tir hospital, Emergency department

Full name of responsible person

Mohamad Amin Zare, MD.

Street address

Tehran, at the end of Shahid Rajaei Street, Shahreri intersection

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3

Recruitment center

Name of recruitment center

Hazrat Rasool akram hospital, Emergency department

Full name of responsible person

Taghi Riyahi, MD.

Street address

Tehran, Sattar Khan St., Niyayesh St., Corner of Mansouri Street, Hazrat Rasool Akram Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

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Tehran, Hemmat Highway next to Milad Tower, Iran
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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

Iman Mehrabi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

Iman Mehrabi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information related to the study protocol, OSBD-R score including four steps, statistics related to the success of the procedure, statistical information and tables and graphs, informed consent form, satisfaction of parents and nurses, information related to heart rate and blood oxygen percentage.

When the data will become available and for how long

Starting one year after publication

To whom data/document is available

To anyone whom may benefit from reviewing the information provided, in regard to progressing scientific knowledge

Under which criteria data/document could be used

The use of data by mentioning the source, in case of advancement of scientific knowledge, is unrestricted

From where data/document is obtainable

Contact the email address regarding data acquisition: imannnehrabi@gmail.com Iman Mehrabi, MD.

What processes are involved for a request to access data/document

Send an email stating the reason for the need to access the information

Comments