Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of intranasal Midazolam, oral Melatonin and distraction method in reducing stress and pain caused by intravenous cannulation in children 3 to 10 years old

Protocol summary

Study aim

Evaluation of the effectiveness of inhaled midazolam and oral melatonin with the effectiveness of a non-pharmacological method in reducing pain and stress caused by intravenous line implantation in children referred to the emergency department of Imam Hossein Children's Hospital

Design

The clinical trial has a control group and with parallel groups, it is blinded and randomized. 120 children from 3 to 10 years old who have inclusion criteria are randomly divided into 4 categories of controls and interventions using a random allocation software.

Settings and conduct

After randomization, we assign children to one of the 4 study groups in emergency room. In the control group, the usual routine of emergency, and in the intervention groups, drugs or distraction method is presented. The nurse responsible for venipuncture and the researcher determining the score and stress are blinded.

Participants/Inclusion and exclusion criteria

Children aged 3 to 10 years who need venipuncture and whose parents have informed consent to their child's participation in the study. Whenever the age of the child allows, he/she will be informed about the study.
Exclusion criteria: hearing or vision impairment; acute or chronic hypnotic and analgesic use; history of sleep apnea; drug allergies; risk of aspiration; airway disorders.

Intervention groups

Children aged 3 to 10 years should go to the emergency room who are candidates for intravenous line insertion. These children fall into 4 groups. The control group has a venipuncture as a routine. The Melatonin group receives the appropriate dose of Melatonin orally 30 minutes before venipuncture. The Midazolam group receives the appropriate dose through the nose 15 minutes before venipuncture. The distraction card group focuses on the cards from 3 minutes before the venipuncture to the entire process.

Main outcome variables

Procedural pain and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220128053852N2**
Registration date: **2023-03-04, 1401/12/13**
Registration timing: **retrospective**

Last update: **2023-03-04, 1401/12/13**
Update count: **0**

Registration date

2023-03-04, 1401/12/13

Registrant information

Name

Minoo Saeidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3386 6266

Email address

minoo.saeidi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of intranasal Midazolam, oral Melatonin and distraction method in reducing stress and pain caused by intravenous cannulation in children 3 to 10 years old

Public title

Procedural pain and anxiety in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Parental consent No urgent need for venipuncture 3 to 10 years old childs

Exclusion criteria:

Hearing and vision disorders that prevent the child from interacting Dissatisfaction of parents to continue the study at any time during the intervention Chronic or acute use of a sedative drug The child has been taking painkillers, even acetaminophen, for the last 6 hours Symptoms of a child's airway disorder Patients with American Society of Anesthesiologists ’(ASA) classification from grade 3 upwards Urgent need for venipuncture including decreased level of consciousness, shocks, severe respiratory distress, uncontrolled seizures, arrhythmia Children at high risk for aspiration such as gastroesophageal reflux disease or gastrointestinal motility disorders

Age

From **3 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

we will use blocked randomsation. Using the Random Allocation software 2, for 4 study groups, 15 blocks of 8 were calculated for a sample size of 120 people, each person will be identified with a unique code (consisting of two letters and a Latin number). To assign the child to each of the 4 study groups, an envelope containing a unique code and treatment group will be delivered to the child's parents. The project associate nurse, who is stationed next to the nurse responsible for venipuncture, will open the envelope and specify the type of intervention before starting the venipuncture.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the nurse who performs the venipuncture also applies the analgesic method to the child. The nurse who records clinical signs before and after venipuncture is unaware of the type of analgesia applied. The same nurse also gives the child the scale of pain that the child is supposed to grade. The film that is to be taken from the child's facial expressions will be taken by the pediatric resident, but the pain and anxiety will be scored by the presenter and the project partner separately and based on the film. However, both of them are not aware of the type of painless intervention in the patient who will be graded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan, Imam Khomeini Ave, Imam hossein children university hospital

City

Isfahan

Province

Isfehan

Postal code

۸۱۹۵۱۶۳۳۸۱

Approval date

2021-12-19, 1400/09/28

Ethics committee reference number

IR.MUI.MED.REC.1400.696

Health conditions studied

1

Description of health condition studied

Procedural pain and anxiety in children

ICD-10 code

Y84.9

ICD-10 code description

Medical procedure, unspecified as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Pain caused by intravenous line insertion
Timepoint
Determining pain score during and after venipuncture
Method of measurement
Face, Legs, Activity, Cry, Consolability scale and Visual analogue scale

Secondary outcomes

1

Description
child anxiety
Timepoint
Child's stress before and during intravenous line insertion
Method of measurement
Children's Emotional Manifestation Scale

Intervention groups

1

Description
Control group: 3 to 10 year olds need venipuncture for which no intervention is applied
Category
Prevention

2

Description
Intervention group 1:Melatonin drug under the brand name Nem Life is given to the child at a dose of half a milligram per kilogram of the child's body weight and a maximum of 5 mg orally, 30 minutes before venipunctur
Category
Treatment - Drugs

3

Description
Intervention group 2: Midazolam ampoule with a dose of two tenths of a milligram per kilogram of body weight and a total volume of half a cc is used intranasally 15 minutes before inserting the intravenous line and once for the child. After administering the medicine in the nose, the nostril is kept closed for 30 seconds. Midazolam ampoule is produced by Kimidaro factory and is 5 mg.
Category
Treatment - Drugs

4

Description
Intervention group 3: Use of in-house distraction cards modeled after similar cards from Buzzy UK which are shown to the child 3 minutes before the venipuncture, and the co-nurse asks the child the questions on the back of the picture card that are related to the pictures and their details to distract her.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Children Hospital
Full name of responsible person
Minoo Saeidi
Street address
Isfahan, Imam Khomeini Ave, Imam Hossein Children Hospital
City
Isfahan
Province
Isfehan
Postal code
۸۱۹۵۱۶۳۳۸۱
Phone
+98 31 3386 6266
Fax
+98 31 3386 8286
Email
emamhossein_hospital@mui.ac.ir
Web page address
http://www.ehuch.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Minoo Saeidi
Street address
Isfahan, Hezar Jarib Ave, Isfahan University of Medicine
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Fax
+98 31 3668 8597
Email
dean@med.mui.ac.ir
Web page address
http://www.mui.ac.ir/fa
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Minoo Saeidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Imam Khomeini Ave, Imam Hossein Children Hospital
City
Isfahan
Province
Isfehan
Postal code
8195163381
Phone
+98 31 3386 6266
Email
minoo.saeidi@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Minoo Saeidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Imam Khomeini Ave
City
Isfahan
Province
Isfehan
Postal code
8195163381
Phone
+98 31 3386 6266
Email
minoo.saeidi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Minoo Saeidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Imam Khomeini Ave
City
Isfahan
Province
Isfehan
Postal code
8195163381
Phone
+98 31 3886 6266
Email
minoo.saeidi@gmail.com

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
All data except videos taken from a potential child can be shared after unidentified individuals.
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For academic use by faculty members of universities in

the country and around the world

From where data/document is obtainable

Email to Dr. Minoo Saeidi at minoo.saeidi@gmail.com

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

My email address is minoo.saeidi@gmail.com

Comments