

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 child

**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 randomisation. 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**  
Isfahan

**Postal code**  
8195163381

**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 venipuncture

#### 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

Minoos Saeidi

##### Street address

Isfahan, Imam Khomeini Ave, Imam Hossein Children Hospital

##### City

Isfahan

##### Province

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##### Postal code

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+98 31 3386 6266

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##### 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

Minoos Saeidi

##### Street address

Isfahan, Hezar Jarib Ave, Isfahan University of Medicine

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Fax

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##### 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

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## 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

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## 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**

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**Other areas of specialty/work**

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**Email**

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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**

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](mailto:minoo.saeidi@gmail.com)

**What processes are involved for a request to access**

**data/document**

My email address is [minoo.saeidi@gmail.com](mailto:minoo.saeidi@gmail.com)

**Comments**