

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparison of oral midazolam-ketamine and midazolam-pethidine as premedication in children who were admitted for surgery in fatemeh hospital in 2021

Protocol summary

Study aim

1. Finding best oral drop as premedication for pain control of intravenous cannulation, anxiety control and sedation
2. Comparison of side effects in both premedication (midazolam and ketamine or midazolam and pethidine) in children
3. Comparison of midazolam and ketamine with midazolam and pethidine in anxiety control of parent separation
4. Comparison of midazolam and ketamine with midazolam and pethidine in pain of intravenous cannulation
5. Comparison of midazolam and ketamine with midazolam and pethidine for improving cooperation during intravenous cannulation

Design

After choosing cases they will be randomly divided in two groups. Each group contains 20 pediatric patient who is having plastic surgery. A written consent is obtained from parents for participation of child in the study. The drop is given to the patients by a nurse who does not know which drop is it. Then the nurse will assess the effects of drop and write them in tables.

Settings and conduct

The study is performed in operation room of Hazrat Fatemeh hospital. The study is double blinded. The data is written in tables and will be analyzed with SPSS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pediatric patients between 1 to 5 years without any past medical history whom are admitted in operation room of Hazrat Fatemeh hospital. Exclusion criteria: having past medical history, recent upper respiratory infection, GI obstruction, ASA score more than 1, signs of ICP raising

Intervention groups

In this study we have two groups of pediatric patients whom are having plastic surgery. First group is given oral drop of midazolam and ketamine. The second group is having oral drop of midazolam and pethidine. There will be a comparison between the oral drops in their effect

and side effects before intravenous cannulation.

Main outcome variables

Pain score, anxiety, parent separation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210306050591N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

Parham Nikniaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 6391

Email address

parhamnik@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of oral midazolam-ketamine and midazolam-pethidine as premedication in children who were admitted for surgery in fatemeh hospital in 2021

Public title

A comparison of oral midazolam-ketamine and midazolam-pethidine as premedication in children who were admitted for surgery in fatemeh hospital in 2021

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age 1 to 5 year without any past medical history admitted for plastic surgery

Exclusion criteria:

past medical history systemic diseases recent upper airways diseases gastrointestinal obstruction having symptoms of high level of lcp asa number more than 1

AgeFrom **1 year** old to **5 years** old**Gender**

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

for randomization we use block randomization method. we put patients in to groups and use sealed envelope website for making sequence. in each block we have 4 cases. We use A for group whom are taking midazolam and ketamine and use B for the second group (pethidine and midazolam). At last we put cards with the blocks written on them in envelopes. by this method allocation concealment is done.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who give the drug to the children doesn't know the type of solution. The child who is taking the medicine doesn't know the type of medicine.

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

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Iran university of medical sciences, Hemat hyw, Tehran.

City

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۱۴۳۹۶۱۴۵۳۵

Approval date

2021-03-02, 1399/12/12

Ethics committee reference number

IR.IUMS.FMD.REC.1399.778

Health conditions studied**1****Description of health condition studied**

pediatric anesthesia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain score

Timepoint

15 minutes after intervention

Method of measurement

pain score scale

2**Description**

side effects

Timepoint

15 minutes after intervention

Method of measurement

visual

3**Description**

agitation

Timepoint

15 minutes after intervention

Method of measurement

Richmond agitation sedation scale (RASS)

Secondary outcomes

empty

Intervention groups

1

Description

Oral ketamine and midazolam drop is given pediatric patients between 1 to 5 years whom are having plastic surgery .

Category

Treatment - Drugs

2

Description

Intervention group: Oral pethidine and midazolam drop is given pediatric patients between 1 to 5 years whom are having plastic surgery .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Fatemeh(S) Hospital

Full name of responsible person

Parham Nikniaee

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Hazrate Fatemeh(S) Hospital, next to Shafagh park,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Web page address

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

Parham Nikniaee

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
study protocol Thesis and article
When the data will become available and for how long
2022
To whom data/document is available
every one
Under which criteria data/document could be used
for more information and if they cited the authors
From where data/document is obtainable
by email of the autor
What processes are involved for a request to access data/document
one month
Comments