

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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 into two groups. Each group contains 20 pediatric patients who are 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 it is. Then the nurse will assess the effects of drop and write them in tables.

Settings and conduct

The study is performed in the 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 who are admitted in the 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 who are having plastic surgery. The first group is given oral drop of midazolam and ketamine. The second group is given 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

Age

From **1 year** old to **5 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target 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 sealedenvelope 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 blcoks 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 soluotion .The child who is taking the medicine doesn't know the tyep of medicene.

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, Hemat hyw,Tehran.

City

Tehran

Province

Tehran

Postal code

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 minuets 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 minuets 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

Street address

Hazrate Fatemeh(S) Hospital, next to Shafagh park, 21st., Asad abadi st. , Yousef abad st. Tehran

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Email

crtfatima@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Street address

Iran university of medical science Shahid Hemmat highway Tehran Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

admins@iums.ac.ir

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

Street address

No.12, mino st., sadeghieqomi st, Niavarn st., Tehran,

City

Tehran

Province

Tehran

Postal code

1976845676

Phone

+98 21 2273 6391

Fax

Email

parhamnik@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Parham Nikniaee

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Resident

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parhamnik@gmail.com

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+98 21 2273 6391

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parhamnik@gmail.com

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**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Parham Nikniaee

Position

Resident

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Province

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