

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison sedation effect of intranasal ketamine and midazolam in premedication of child herniorrhaphy surgery

Protocol summary

Study aim

Determining the difference in sedation effect of midazolam and intranasal ketamine in preoperative pediatric hernioraf surgery at Bouali Hospital in Sari in 1399-1400

Design

Random Allocation Clinical Trial with Parallel, Double-Blind, Randomized Phase 3 Groups on 36 Patients
Random Allocation is used for randomization

Settings and conduct

Children one to six years old undergoing herniorafi surgery in Buali Hospital, Sari. The method of administration is midazolam (0.5 mg / kg) or ketamine (5 mg / kg)The researcher, who has no information about the type of drug, is given intranasally to the child half an hour before the procedure in the pre-treatment room, due to the double-blindness.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age 1 to 6 years, physical condition according to the American Society of Anesthesia 1 or 2 (ASA PA), having informed consent of parents to participate in the study, patients who have a negative history of taking sedatives or analgesics in the past 24 hours, Patients with normal liver enzymes. , Patients who are normal in terms of psychological diseases, have food and drug allergies. Exclusion criteria: Allergy to any of the drugs used in premedication or during surgery, having any hemodynamic disorders, those with respiratory problems during surgery and airway disease
The upper extremities are irritated like a cold. , Parental dissatisfaction.

Intervention groups

Group of midazolam (0.5 mg / kg) intranasal and other group of ketamine (5 mg / kg) intranasal

Main outcome variables

Degree of children's relaxation, behavioral assessment, their heart rate, ease of separation from parents and their satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210904052371N2**

Registration date: **2021-10-26, 1400/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-26, 1400/08/04**

Update count: **0**

Registration date

2021-10-26, 1400/08/04

Registrant information

Name

Goli Aezi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 9875

Email address

gaezi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-17, 1400/07/25

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison sedation effect of intranasal ketamine and midazolam in premedication of child herniorrhaphy surgery	
Public title	The comparison sedation effect of intranasal ketamine and midazolam in premedication of child herniorrhaphy surgery
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Age range 1 to 6 years Physical condition according to the American Society of Anesthesia 1 or 2 (ASA PA) Having the informed consent of the parents to participate in the study Patients who have a history of sedative or analgesic use in the past 24 hours Patients with normal liver enzymes Patients who are normal in terms of psychological diseases They have no food or medicine allergies Exclusion criteria: Allergy to any of the drugs used in premedication or during surgery Having any hemodynamic disorders People who have respiratory problems during surgery and irritable upper airway disease such as colds Parental dissatisfaction
Age	From 1 year old to 6 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser • Data and Safety Monitoring Board
Sample size	Target sample size: 36
Randomization (investigator's opinion)	Randomized
Randomization description	The random assignment process is blockade and the Random Allocation software used to block 6 blocks of 6 has been created. Both drugs are colorless and the nurse in charge of preparing the drugs in syringes A and B fills in the anesthesia assistant according to the randomization block. Random letters A and B are injected into the child without knowing the type of medicine, and also the person who performs sedation and analgesia and evaluates the child's behavior is completely unaware of the type of medicine. Then the person doing the sedation and pain assessment and assessing the child's behavior was also completely unaware of the type of medication.
Blinding (investigator's opinion)	Double blinded
Blinding description	For bilateral blindness, patients are divided into two
	groups of 18 people. Half an hour before the procedure, one group of midazolam (0.5 mg / kg) intranasal and the other group of ketamine (5 mg / kg) intranasal in the syringe without the name of the drug is prescribed. Becomes. The degree of sedation, behavioral assessment, heart rate, ease of separation from parents and their satisfaction are reviewed and recorded.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Mazandaran University of Medical Sciences
Street address	Mazandaran University of Medical Sciences
City	Sari
Province	Mazandaran
Postal code	33131 - 48166
Approval date	2021-09-29, 1400/07/07
Ethics committee reference number	IR.MAZUMS.REC.1400.475
Health conditions studied	
<u>1</u>	
Description of health condition studied	The degree of sedation of the drug
ICD-10 code	Y47
ICD-10 code description	Sedatives, hypnotics and antianxiety drugs
Primary outcomes	
<u>1</u>	
Description	relaxation
Timepoint	The beginning of anesthesia until the end of anesthesia
Method of measurement	Ramsay Sedation Scale

2

Description

Behavioral evaluation

Timepoint

The beginning of anesthesia until the end of anesthesia

Method of measurement

Visual Analogue Scale

3

Description

heart beat

Timepoint

The beginning of anesthesia until the end of anesthesia

Method of measurement

monitor

4

Description

Ease of separation from parents

Timepoint

The beginning of anesthesia until the end of anesthesia

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

nausea and vomiting

Timepoint

End of Anesthesia Tick hours after anesthesia

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Midazolam (0.5 mg / kg) is given intranasally to a child half an hour before the procedure in a pre-treatment room by a researcher who has no knowledge of the type of drug due to bilateral blindness.

Category

Treatment - Drugs

2

Description

Intervention group: Ketamine (5mg / kg) is given intranasally to a child half an hour before the procedure in a pre-treatment room by a researcher who has no knowledge of the type of drug due to bilateral blindness.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Hamid Reza Efati

Street address

Pasdaran Boulevard, Bu Ali Sina Hospital

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Hamidreza Efati

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Goli Azzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available