Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The comparison of premedication effect of intranasal Ketamin and Midazolam in sedation and ease of separation from parents in children 2-6 years old admitted for elective urological surgery

Protocol summary

Summary

The aim of study is the comparison of premedication effect of intranasal Ketamin and Midazolam in sedation of children and ease of separation from parents. The children ages 2-6 years old admitted for elective urological surgery at Razi educational hospital of Rasht. This study will be performed on 70 uncooperative children. All children fasted for 8 hours before being transferred to the operating room (OR). Before entering OR at randomized blocks children divided into two groups (Ketamin and Midazolam). Thirty minutes before entering operating in group Ketamin: intranasal Ketamin 5mg/kg maximum 1 cc in each nostril and in group Midazolam: intaranasal Midazolam 0/5mg/kg with the same volume is administered. Drugs are administered with syringe 2 cc in each nostril while patients are in supine position. All patients' physiological parameters are controlled and recorded before and after drug administration and every 5 minutes until transferring of the patient to the operating room. At the time of the transfer of the patient to the OR, ease of separation from parents, on the basis of four-point scale and the degree of sedation in children based on a 5-point scale is checked. All patients receive similar general anesthesia. Recovery time and postoperative complications include nausea and vomiting will be checked in all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082411766N4**
Registration date: **2016-09-21, 1395/06/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-21, 1395/06/31

Registrant information

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Guilan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research of Guilan University of Medical Sciences

Expected recruitment start date

2016-10-11, 1395/07/20

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of premedication effect of intranasal Ketamin and Midazolam in sedation and ease of separation from parents in children 2-6 years old admitted for elective urological surgery

Public title

The comparison of premedication effect of intranasal

Ketamin and Midazolam in sedation of children and ease of separation from parents

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children 2 to 6 years old with the weight of 10-20 kg;No history of allergy to any of the medications;No history of central nervous system drugs; Lack of disease involving the central nervous system, or psychological disorders Exclusion criteria:Emergency surgery;children or their parents refuse to take the medicine; estimate that duration of surgery is less than 1 hour or more than 3 hours.

Age

From **2 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Beheshti free way.apposite of Sepah bank, Building of vice chancellor of research of Guilan University of Medical Sciences

City

Rasht

Postal code

4193713194

Approval date

2016-05-10, 1395/02/21

Ethics committee reference number

IR.GUMS.REC.1395.49

Health conditions studied

1

Description of health condition studied

social anxiety disorder of childhood

ICD-10 code

F93.2

ICD-10 code description

Social anxiety disorder of childhood

Primary outcomes

1

Description

Sedation of children

Timepoint

During transfer to the operating room

Method of measurement

based on 5-point scale

2

Description

Facilitate the separation of children from parents

Timepoint

During transfer to the operating room

Method of measurement

based on 4-point scale

3

Description

Recovery time

Timepoint

Since time to enter recovery unit until exit from recovery unit

Method of measurement

Time(in minutes)

Secondary outcomes

1

Description

post operation side effects(nausea,vomiting, apnea,hallucination)

Timepoint

In recovery unit

Method of measurement

Yes/No

Intervention groups

1

Description

Intervention 1: Intaranasal Midazolam 0.5mg/kg are administered.Ampule Midazolam with 5mg/cc Midazolam produced by Caspian company, Iran.

Category

Prevention

2

Description
Intervention 2: Intranasal Ketamin 5mg/kg are administered.Vial ketamin with 50mg/cc Ketamin hydrocchloride produced by TRITTAU company, Germany
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital of Rasht
Full name of responsible person
Hossein Khoshrang
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Research of Guilan University of Medical Sciences
Full name of responsible person
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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
Vice chancellor of Research of Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty