

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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: intranasal 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

###### Name

Hossein Khoshrang

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3355 0028

###### Email address

khoshrang@gums.ac.ir

##### 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 hydrochloride 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

Razi hospital, Sardar e Jangal Street

#### City

Rasht

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice chancellor of Research of Guilan University of Medical Sciences

#### Full name of responsible person

Shadman Nemati

#### Street address

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

#### City

Rasht

#### 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

#### Name of organization / entity

Guilan University of Medical Sciences

#### Full name of responsible person

Hossein Khoshrang

#### Position

associate professor of Anesthesiology

#### Other areas of specialty/work

#### Street address

Sardar Jangal Street, Razi hospital

#### City

Rasht

#### Postal code

41488

#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

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Guilan University of Medical Sciences

#### Full name of responsible person

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#### Position

Associate Professor of Anesthesiology

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## Person responsible for updating data

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#### Full name of responsible person

Hedye Nemati

#### Position

Medical laboratory Sciences Technician/ Bachelor's Degree

#### Other areas of specialty/work

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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*