

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### comparison of sedative effect of intranasal Dexmedetomidine, Midazolam and Ketamine in outpatient pediatric surgeries

#### Protocol summary

##### Summary

Children -parents dissociation and entrance to the operating room are accompanied with anxiety which causes unwished intra and postoperative complications. Postoperative agitation, pain, nausea and vomiting are other problems that reducing and controlling them, is one of the aims of an anesthesiologist. The purpose of this study is to compare the effect of intranasal dexmedetomidine, midazolam and ketamine on preoperative sedation and postoperative nausea, vomiting and pain and as a result, decreasing the hospital cost, shorter recovery stay and early return of children to daily activity.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013081614372N1**

Registration date: **2014-02-11, 1392/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-11, 1392/11/22

##### Registrant information

##### Name

Simin Azemati

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4270

##### Email address

azemati@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences, vice chancellor of research

##### Expected recruitment start date

2013-07-23, 1392/05/01

##### Expected recruitment end date

2013-12-21, 1392/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparison of sedative effect of intranasal Dexmedetomidine, Midazolam and Ketamine in outpatient pediatric surgeries

##### Public title

comparison of sedative effect of Dexmedetomidine, Midazolam and Ketamine in outpatient pediatric surgeries

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: children aged between 2-7 year; ASA classification I-II; unilateral inguinal herniorrhaphy  
Exclusion criteria: Hx. of hypersensitivity to drugs of the study (Midazolam; Ketamine and Dexmedetomidine); liver failure; renal failure; upper respiratory tract infection; cardiac arrhythmia; congenital heart disease; neurologic disease

##### Age

From **2 years** old to **7 years** old

##### Gender

Both

##### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 90

### 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 Shiraz University of Medical Sciences

##### Street address

Vice Chancellor for research ; Shiraz University of Medical Sciences ,Zand street

##### City

SHIRAZ

##### Postal code

#### Approval date

2013-09-15, 1392/06/24

#### Ethics committee reference number

CT-P-92-5311

## Health conditions studied

### 1

#### Description of health condition studied

Restlessness and agitation

#### ICD-10 code

R45

#### ICD-10 code description

Symptoms and signs involving emotional state

## Primary outcomes

### 1

#### Description

anxiety

#### Timepoint

Every 10 min after separation of parents

#### Method of measurement

Observation( Four point scale)

### 2

#### Description

Pain

#### Timepoint

Every 15min in PACU

#### Method of measurement

Observation( Modified objective pain scale)

### 3

#### Description

Nausea & vomiting

#### Timepoint

Recovery time

#### Method of measurement

observation

### 4

#### Description

Sedation

#### Timepoint

Every 10 minutes

#### Method of measurement

Obsevation( Modified observer's assessment alertness sedation)

## Secondary outcomes

### 1

#### Description

Sedation scale in PACU

#### Timepoint

Every 15 min

#### Method of measurement

Observation( Modified observer's assessment alertness sedation)

## Intervention groups

### 1

#### Description

intra nasal midazolam 0.2 mg/kg ,45-60 minutes before induction

#### Category

Treatment - Drugs

### 2

#### Description

Intranasal ketamine 8mg/kg ,45-60 minutes before induction

#### Category

Treatment - Drugs

### 3

#### Description

Intranasal dexmedetomidine 1.5 mic /kg ,45-60 minutes before induction

**Category**

Treatment - Drugs

empty

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Nemazi hospital

**Full name of responsible person**

Maryam Keihani

**Street address**

Zand street

**City**

Shiraz

2**Recruitment center****Name of recruitment center**

Ghadir hospital

**Full name of responsible person**

Maryam Keihani

**Street address**

Koran Square

**City**

Shiraz

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**Shiraz University of Medical Sciences. Research  
chancellor**Full name of responsible person**

Dr. Gholam Reza Hatam

**Street address**Research chancellor, Shiraz University of Medical  
Sciences. Zand street**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**Shiraz University of Medical Sciences. Research  
chancellor**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****Person responsible for general inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Keihani

**Position**

Anesthesiology resident

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street**City**

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inquiries****Contact****Name of organization / entity**Department of anesthesia, Shiraz anesthesiology and  
critical care research center, Shiraz University**Full name of responsible person**

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**Position**

Associate professor of anesthesiology

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,mbkhosravi44@gmail.com**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Medical Faculty

**Full name of responsible person**

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**Fax****Email****Web page address****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*