

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)

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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 centers1**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

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**Shiraz University of Medical Sciences. Research
chancellor**Full name of responsible person**

Dr. Gholam Reza Hatam

Street addressResearch 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 sourceShiraz 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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Position

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

Medical Faculty

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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*