

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The comparison of premedication effect of intra-nasal dexmedetomidine and intra-nasal midazolam in sedation, anxiety level and ease of separation from parents in children 2-8 years of age admitted for elective surgery in academic hospitals of Rasht in 2013

Protocol summary

Summary

The aim of this study is to compare premedication effect of intra-nasal dexmedetomidine and midazolam in anxiety level of children 2-8 years of age admitted for elective surgery. This is a prospective study on 100 children between 2-8 years old with ASA class I, II admitted for elective surgery in Razi and Alzahra hospitals of Rasht, Iran in 2013. All children fasted for 8 hours before being transferred to the operating room (OR). Thirty minutes before transferring to OR in the presence of parents at randomized blocks children divided in two groups (D and M). In group D: Dexmedetomidine intranasal 1µg/kg and in group M: Midazolam intranasal 0.2 mg/kg is administered. Relaxation and anxiety levels of children during transferring to OR, facilitate the separation of children from their parents, tolerance of children during placement of IV access is evaluated. At the end of surgery, the time of entrance to the child's recovery until discharge is measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121611766N1**

Registration date: **2013-02-17, 1391/11/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-17, 1391/11/29

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 for research, Guilan University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of premedication effect of intra-nasal dexmedetomidine and intra-nasal midazolam in sedation, anxiety level and ease of separation from parents in children 2-8 years of age admitted for elective surgery in academic hospitals of Rasht in 2013

Public title

The comparison of premedication effect of intra-nasal dexmedetomidine and midazolam in anxiety level of children 2-8 years of age admitted for elective surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: children 2-8 years of age; ASA class I,II and candidate for elective surgery. Exclusion criteria:rejection by the patient's parents; rejection drugs by children; children have allergies to any medications,history of drugs affecting the central nervous system; disease involving the central nervous system; emergent surgery and duration of surgery under 1 hour or up to 2.5 hours.

Age

From **2 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Guilan University of Medical Sciences Ethics Committee

Street address

Namjou Street

City

Rasht

Postal code

4144665385

Approval date

2012-08-06, 1391/05/16

Ethics committee reference number

1910101706

Health conditions studied

1

Description of health condition studied

Children anxitey before general anesthesia

ICD-10 code

F93.2

ICD-10 code description

social anxiety disorder of childhood

Primary outcomes

1

Description

Sedation of children before surgery

Timepoint

During transfer to the operating room

Method of measurement

Ramsay 6 point scale

2

Description

Facilitate the separation of children from parents

Timepoint

During transfer to the operating room

Method of measurement

Feld 3 point scale

3

Description

Reduction of anxiety in children before surgery

Timepoint

During transfer to the operating room

Method of measurement

4 point standard scale

Secondary outcomes

1

Description

Recovery duration

Timepoint

Enter to recovery and exit

Method of measurement

Timer

Intervention groups

1

Description

Dexmedetomidine intranasal 1µg/kg with normal saline

Category

Prevention

2

Description

Midazolam intranasal 0.2 mg/kg with normal saline

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Street address

Sardar e Jangal Ave.

City

Rasht

2

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Street address

Namjoo St.

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology Research Centre

Full name of responsible person

Dr. Siavash Falahatkar

Street address

Razi hospital

City

Rasht

Grant name

10506

Grant code / Reference number

32

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Urology Research Centre

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

Urology Research Center

Full name of responsible person

Dr. Neda Ebrahimpour

Position

MD /Resident

Other areas of specialty/work

Street address

Urology Research Center, Razi Hospital

City

Rasht

Postal code

41448-95655

Phone

+98 13 1552 5259

Fax

Email

urc1384@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urology Research Center

Full name of responsible person

Dr. Hossein Khoshrang

Position

Assistant Proffesor of Guilan University of Medical Sciences

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Urology Research Center

Full name of responsible person

Samaneh Esmaeili

Position

Bachlor/ Accountant of Urology Research Center

Other areas of specialty/work

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Razi Hospital

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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