Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison the effect of intranasal midazolam versus different doses of intranasal ketamine in reducing preoperative pediatric anxiety

Protocol summary

Summary

Objective: To compare the effect of intranasal midazolam versus different doses of intranasal ketamine in reducing preoperative pediatric anxiety. Methodology: The participants of this double blind clinical trial study consisted of 120 children. Their age range was between 2-8 years. They were in ASA class I of anesthesia and were chosen for elective surgery in Qods hospital in Qazvin, Iran. The patients were randomly divided in four equal groups. Intervention: For reducing patients' anxiety, in the first group midazolam 0.2mg/kg, in the second group ketamine 0.5 mg/kg, in the third group ketamine 3 mg/kg and in the fourth one normal saline 1drop/kg were administered intranasally. Fifteen minutes after drug administration, severity of anxiety had been assessed with modified Yale preoperative anxiety score (m-Yale PAS) and level of sedation had been evaluated by Ramsay sedation scale in operative room before intravenous catheterization. All data were transferred to the SPSS-10 software and analyzed statistically with Anova, Kroscal Valis and Mann-Whitney tests. P-Value less than 0.05 was considered meaningful. Primary outcome measure: Anxiety Primary outcome time point : Fifteen minutes after drug usage(before IV line insertion) Primary outcome method of measurement: M-Yale PAS chart and Ramsay Sedation Scale chart Inclusion: Elective surgery ;ASA class1 ;Age between 2-8 years exclusion criteria :ASA class 2or higher ;Childs using antihistaminic, anticonvulsive, analgesic or sedative agents ;Childs with nasopharyngeal dysfunction, upper respiratory tract infection, epistaxis or allergic rhinitis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104236254N1**
Registration date: **2011-09-07, 1390/06/16**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-09-07, 1390/06/16

Registrant information

Name
Nematolah Adeli
Name of organization / entity
Qazvin , University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 28 1333 7006
Email address
neadeli@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice -chancellor for research, Qazvin university of medical sciences

Expected recruitment start date

2010-05-23, 1389/03/02

Expected recruitment end date

2010-08-27, 1389/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intranasal midazolam versus different doses of intranasal ketamine in reducing preoperative pediatric anxiety

Public title

Comparison the effect of intranasal midazolam versus different doses of intranasal ketamine in reducing

preoperative pediatric anxiety

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Elective surgery ;ASA class 1; Age between 2-8 years Exclusion criteria : ASA class 2 or higher ;Children using antihistaminic, anticonvulsive ,analgesic or sedative agents ;Children with nasopharyngeal disorder, upper respiratory tract infection ,epistaxis or allergic rhinitis.

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee, Qazvin university of medical sciences

Street address
Shahid Bahonar, Blvd

City
Qazvin

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
4262/20/28

Health conditions studied

1

Description of health condition studied
Behavioural and emotional disorders with onset usually occurring in childhood and adolescence

ICD-10 code
F93.1

ICD-10 code description
Phobic anxiety disorder of childhood

Primary outcomes

1

Description
Anxiety

Timepoint
Fftheen minutes after drug usage(before IV line insertion)

Method of measurement
M-Yale PAS

Secondary outcomes

empty

Intervention groups

1

Description
Control : Group3 received 1 drop/kg normal salin

Category
Prevention

2

Description
Intervention: patients in group one received0.2 mg/kg midazolam

Category
Prevention

3

Description
Intervention: group 2 received0.5 mg/kg ketamine

Category
Prevention

4

Description
Intervention: group 4received3 mg/kg ketamine

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghods Hospital

Full name of responsible person
Dr Nematollah Adeli

Street address

Plate 20 , Ghods Blvd , Qazvin City

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research of Qazvin University of Medical Science

Full name of responsible person

Dr Saeed Assefzadeh

Street address

Post code431102589 , Plate 3, Shahid Bahonar Blvd , Qazvin City

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for research of Qazvin University of Medical Science

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

Qazvin, University of Medical Science and health services

Full name of responsible person

Nematollah Adeli

Position

Resident

Other areas of specialty/work

Street address

Post Code 4321102589 , Plate 3 , Shahid Bahonar Blvd , Qazvin City

City

Qazvin

Postal code

4321102589

Phone

+98 28 1223 6381

Fax

Email

neadeli@qums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin, University of Medical Sciences and Health Services

Full name of responsible person

Seyed Abbas Hosseini Jahromi

Position

Assistant professor in anesthesia

Other areas of specialty/work

Street address

Post code 4321102589 , Plate 3 , Shahid Bahonar Blvd, Qazvin City

City

Qazvin

Postal code

4321102589

Phone

+98 28 1223 6381

Fax

+98 28 1333 7006

Email

papaya812002@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Qazvin , University of Medical Sciences and Health Services

Full name of responsible person

Nematollah Adeli

Position

Resident

Other areas of specialty/work

Street address

Postcode 4321102589, Plate 3 , Shahid Bahonar Blvd, Qazvin City

City

Qazvin

Postal code

4321102589

Phone

+98 28 1333 6001

Fax

+98 28 1333 7006

Email

neadeli@qums.ac.ir

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