Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of oral Midazolam with oral Zolpidem on the anxiety of children undergoing eye evaluation under general anesthesia

Protocol summary

Study aim
Comparison of efficacy of oral Midazolam and oral Zolpidem on children's anxiety before surgery

Design
A double-blind, randomized clinical trial with community-based and pragmatic control group and parallel group design

Settings and conduct
In this double-blind randomized clinical trial, the children undergoing eye examination under general anesthesia at Rasool Akram Hospital, Tehran, Iran will enter to study.The selected patients will be randomly assigned to receive either midazolam 0.25 mg/kg oral 30 minutes before surgery or zolpidem 0.25 mg/kg oral 30 minutes before surgery. The randomization is done by a computer program and children will be blind to medications. The anxiety is measured using an observational device called the Modified Yale Preoperative Anxiety Scale which will be filled out by an anesthesiologist who is blind to the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male or female patients aged between 3 to 9; being in class 1 and 2 according to the American Association of Anesthesiologists; eye evaluation under general anesthesia. Exclusion criteria: Contraindication to pre-operative sedation; known allergy or sensitivity to drugs; patient's weight below the fifth or above 95th percentile on the CDC-developed growth chart; Children with metabolic, endocrine, cardiopulmonary or hepatic diseases

Intervention groups
Control group: At first anxiety score is measured half an hour before entering the operating room, and .25 mg/kg of midazolam is given orally. Then the anxiety score is measured at the time of entering the operating room and seeing the anesthetic mask. Intervention group: At first, the anxiety score is measured half an hour before entering the operating room and .25 mg/kg of zolpidem is given orally then the anxiety score is measured at the time of entering the operating room and seeing the anesthetic mask .

Main outcome variables
Child anxiety score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141127020112N7**
Registration date: **2018-10-19, 1397/07/27**
Registration timing: **retrospective**

Last update: **2018-10-19, 1397/07/27**
Update count: **0**

Registration date
2018-10-19, 1397/07/27

Registrant information

Name
Pooya Derakhshan

Name of organization / entity
Birjand Univesity of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-27, 1397/05/05

Expected recruitment end date
2018-08-27, 1397/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral Midazolam with oral Zolpidem on the anxiety of children undergoing eye evaluation under general anesthesia

Public title

Effect of Zolpidem and Midazolam on anxiety of children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pediatric patients ages 2-9 years ASA class I-II undergoing eye evaluation under general anesthesia

Exclusion criteria:

contraindication to preoperative sedation, known allergy or sensitivity to the study medications parents' unwillingness on the children's participation in the study Patients with weights below the 5th percentile or above the 95th percentile according to the current published CDC growth chart Children with metabolic, endocrine, cardiac, pulmonary or hepatic diseases

Age

From **2 years** old to **9 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into 2 groups. Randomization is done by a computer program and the host does not know. For random assignment, the rand-between command in Excel software is used. Individuals with an even code are assigned to the Midazolam group and individuals with the odd code are assigned to the Zolpidem group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both medicines given to patients ,are dissolved in same juice and kept in the same containers. The parents of patients and the collectors of the data, do not know the type of drug administered to the child.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to Milad tower, Hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2017-10-14, 1396/07/22

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411174011

Health conditions studied

1

Description of health condition studied

Anxiety in children before surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score

Timepoint

Measuring the anxiety level at the beginning of the study (before the intervention) and thirty minutes after taking the drug

Method of measurement

Modified Yale preoperative anxiety scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 0.25 mg/kg of midazolam ; oral use; 30 minutes before surgery.

Category
Treatment - Drugs

2

Description
Intervention group 2: 0.25 mg/kg of zolpidem; oral; 30 minutes before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Medical complex
Full name of responsible person
Pooya Derakhshan
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Sponsors / Funding sources

1

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Email
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Web page address
http://vcr.iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Pooya derakhshan
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after making people unidentifiable

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will be available to researchers working in academia and, and those in the industry can also take action.

Under which criteria data/document could be used

Uses that lead to better interaction between the physician and the surgeon with the patient And reducing parental stress and worries

From where data/document is obtainable

Pooya_derakhshan@bums.ac.ir Anesthesiology department, Hazrat rasool complex,Sattar khan Ave.Postal code:Pooya_derakhshan@bums.ac.ir

What processes are involved for a request to access data/document

After six months from the publication of the article, qualified people can immediately receive the data by mentioning the reasons for the need for the data.

Comments