Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

A comparison of the sedative effect of oral Midazolam versus nazal Ketamine combined with Nitrous Oxide in pediatric EUA

Protocol summary

Study aim
A comparison of the sedative effect of oral Midazolam versus nazal Ketamine combined with Nitrous Oxide in pediatric EUA

Design
A clinical trial with a control group, with parallel groups, three-way Blinded, randomized, phase 2 on 30 patients. for randomization Excel software was used.

Settings and conduct
This is a three-blind randomized clinical trial on 30 candidate patients will undergo eye evaluation in Faiz operating room at Isfahan city ; After the approval of the ethics committee of the university and obtaining the consent of the patients, the patients will be randomly assigned into 2 groups, in each group the intended intervention is applied and the patient's clinical symptoms are recorded .which records the patient's symptoms, the analyzers which collect the data in they analyze the length of the study and also inform the patients about the type of intervention It has not been applied in any group and therefore they are all blind.

Participants/Inclusion and exclusion criteria
Entry requirements: Candidate patients for eye evaluation in Eye Faiz operating room, age between 2 to 6 years, informed consent of the child's family to participate in the study Exclusion criteria: lack of informed consent of the family during the study, complications due to drug use

Intervention groups
In the intervention group A: 10 minutes before anesthesia, patients receive mg/kg of ketamine intranasally at the same time as nitrous oxide gas administration. In intervention group B:patients receive mcg/kg of oral midazolam At the same time as nitrous oxide gas administration

Main outcome variables
SP02, PR, Recovery time, Sedation score based on the Ramsey sedation scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N51**
Registration date: **2023-06-02, 1402/03/12**
Registration timing: **prospective**

Last update: **2023-06-02, 1402/03/12**
Update count: **0**

Registration date
2023-06-02, 1402/03/12

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparison of the sedative effect of oral Midazolam versus nazal Ketamine combined with Nitrous Oxide in pediatric EUA

Public title
Check the effect of ketamine and Midazolam in EUD

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Children candidates for eye evaluation under anesthesia(EUA) Age between 2 and 6 years Informed consent of the child's family to participate in the study

Exclusion criteria:
Lack of informed consent of the family during the study Complications caused by drug use

Age
From **2 years** old to **6 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by the simple method in which each patient will be assigned a code using a random number table (Random allocation software) and Patients fall into one of two groups depending on whether these codes are even or odd. This continues until the number of patients in both groups reaches the required number.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This is a three-way blind clinical trial; in such a way that The clinical caregiver who is responsible for the care and treatment of the participant in the study is blinded. The analysts who analyze the data collected during the study are also blinded. They do not know the type of intervention applied in each group and are blind. Even though the guardians of the patients are included in the study, they do not know about it They do not have the type of intervention applied and are blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address
Hezar jerib

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8174673461

Approval date
2023-03-04, 1401/12/13

Ethics committee reference number
IR.MUI.MED.REC.1401.431

Health conditions studied

1

Description of health condition studied
Examination UnderAnaesthetic (EUA)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The amount of sedation

Timepoint
Every 5 minutes

Method of measurement
Visual Analogue Scale

2

Description
Blood oxygen saturation

Timepoint
Every 5 minutes

Method of measurement
Pulse oximetry

3

Description
Pulse Rate

Timepoint
Every 5 minutes

Method of measurement
Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first group, one milligram of midazolam is given through the nose and prescribed only once
Category
Treatment - Drugs

2

Description
Intervention group: The second group of ketamine is given 0.5 mg/kg through the nose and it is prescribed only once .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fiez Hospital
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Behzad Nazemoaya
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available