

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

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Email address

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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 nasal 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

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Isfahan

Postal code

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

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan University of Medical Sciences

Full name of responsible person

Mohamad Mahdi Haidar

Position

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Latest degree

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Position

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Person responsible for updating data

Contact

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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