

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Title Comparison of Nasal Midazolam and Ketamine Effects in Different Doses on Relaxation of Non-Cooperative pediatric Dental patient 3-6 Years Old

Protocol summary

Study aim

Comparison of Nasal Midazolam and Ketamine Effects in Different Doses on Relaxation of Non-Cooperative pediatric Dental patient 3-6 Years Old

Design

Randomized clinical trial, triple blindness, cross control group. Twenty 3-6 years old children divide into two intervention and control groups with flipping a coin.

Settings and conduct

Children are randomly assigned to one of two groups of controls and cases. Group A: The first session, they received 4mg/kg midazolam with 4mg/kg ketamine and group B: The first session, midazolam received 0.5mg/kg with 3mg/kg ketamine 15 to 20 minutes before the start of treatment. In both groups, the order of drug administration is reversed in two sessions. The drugs are given to the patient by a person who does not know the dose of the drug and the patient is not aware of the drug composition. 15 to 20 minutes before treatment, the drug is emptied through a syringe into the nose of children. After observing the symptoms sedation, the child is transferred to the dental chair. The pulse oximeter probe is also placed on the child's finger to record the amount of changes in blood oxygen and pulse rate obtained in the form of each patient. Dental treatment begins with the use of local anesthesia 2% lidocaine with epinephrine 1/100000. The amount of crying, drowsiness, and movement; At the time of IV, anesthesia and 10 and 20 minutes of onset are assessed and recorded based on the Houpt rating scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Uncooperative 3-6 year old children, need 2 sessions similar treatment. Inclusion criteria: Suffering systemic diseases, common cold.

Intervention groups

0.4 mg/kg midazolam+ 4 mg/kg ketamine 0.5 mg/kg midazolam+ 3 mg/kg ketamine

Main outcome variables

Success of dental treatment according to Houpt Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090506001882N9**

Registration date: **2020-10-10, 1399/07/19**

Registration timing: **retrospective**

Last update: **2020-10-10, 1399/07/19**

Update count: **0**

Registration date

2020-10-10, 1399/07/19

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Faculty of Dentistry, Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2240 3010

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Title Comparison of Nasal Midazolam and Ketamine Effects in Different Doses on Relaxation of Non-Cooperative pediatric Dental patient 3-6 Years Old

Public title
Evaluation of the combined effect of nasal midazolam/ketamine on sedation of 3-6 years non-cooperative pediatric dentistry

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Be in the negative group be Frankel's behavioral classification. Requires at least 2 similar treatment sessions . Be in the ASA1 group. Be 3 to 6 years old.
Exclusion criteria:
Suffering Systemic Disease. Colds during in treatment session. Non-prescription medication including allergies and treatment needs different from protocol

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done by flip a Coin, tap or line and the patients stay on of the groups A or B.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug combination is given to the patient by the anesthesia technician. Patient and researcher and evaluator do not know the dose of the drug.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute of Dental Sciences, Shahid Beheshti University of Medical Sciences

Street address

5th floor,Dental School, Blv Daneshjoo, Evin

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Province

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Postal code

1983963113

Approval date

2020-01-15, 1398/10/25

Ethics committee reference number

IR.SBMU.DRC.REC.1398.212

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Conscious sedation

Timepoint

Every 15 minutes

Method of measurement

Houpt scale

Secondary outcomes

1

Description

SpO2

Timepoint

Every 15 minutes

Method of measurement

pulse oxymeter

Intervention groups

1

Description

The combination of 0.4 mg/kg midazolam (5 mg/cc , Darupakhsh Co., Iran) + 4 mg/kg ketamine (50 mg/ccThe

combination of 4 mg / kg midazolam (5 mg/cc, Darupakhsh Co., Iran) + 4 mg/kg ketamine (50 mg/cc, Rotexmedica Co., Germany) is sprinkled into the patient's nostril.

Category

Treatment - Drugs

2

Description

The combination of 0.5 mg/kg midazolam (5 mg/cc , Darupakhsh Co., Iran) + 3 mg/kg ketamine (50 mg/cc)The combination of 4 mg / kg midazolam (5 mg/cc, Darupakhsh Co., Iran) + 4 mg/kg ketamine (50 mg/cc, Rotexmedica Co., Germany) is sprinkled into the patient's nostril.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Dental School

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoud Fallahinejad Ghajari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Fellowship

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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