

# 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)

##### Phone

+98 21 2240 3010

##### Email address

masfalnegh@sbmu.ac.ir

##### 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

##### City

Tehran

##### Province

Tehran

##### 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**

Evin, Daneshjo Blvd, Shahi Beheshti Dental School

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2241 3897

**Email**

masfalnegh@sbmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Zarghi

**Street address**

Evin, Daneshjo Blvd, Shahid Beheshti university of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۳۹۹۶۳۱۱۳

**Phone**

+98 21 2243 9780

**Email**

zarghi@sbmu.ac.ir

**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

**Street address**

Evin, Daneshjo Blvd, Shahid Beheshti university of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۳۹۶۳۱۱۳

**Phone**

+98 21 2240 3080

**Email**

masfalnegh@sbmu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mostafa Mohaveri

**Position**

Fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Evin, Daneshjo Blvd, Shahid Beheshti university of  
Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۳۹۶۳۱۱۳

**Phone**

+98 21 2240 3050

**Email**

mohaveri@gmail.com

## Person responsible for updating data

**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

**Street address**

Evin, Daneshjo Blvd, Shahid Beheshti university of  
Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۳۹۶۳۱۱۳

**Phone**

+98 21 2240 3080

**Email**

masfalnagh@sbmu.ac.ir

## 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