

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of the IV sedation effect of ketamine/propofol and ketamine/midazolam in dental treatments of 2-6 years old uncooperative children

#### Protocol summary

##### Study aim

Intravenous sedation effect of Ketamine/Propofol and Ketamine/Midazolam on Non-Cooperative Pediatric Dental Patient 2-6 Years Old

##### Design

Randomized clinical trial, triple blindness, cross control group. Twenty 2-6 years old children divide into two intervention and control groups with flipping a coin. Trial phase is 3.

##### Settings and conduct

Children are randomly assigned to one of two groups of cases and controls. 30 minutes before starting treatment 0.3Mg / kg midazolam is given orally to the patient as premedication. Group A: first session 2 mg/kg ketamine and 2 mg/kg Propofol and group B: first session 2 mg/kg Ketamine and 0.2 mg/kg midazolam by intravenous injection They receive treatment from the beginning. In both groups, the order of medication in the second session is reversed. The drugs are given to the patient by the person who is unaware of the dose of the drug and the patient is not aware of the composition of the drug. The pulse oximeter probe is also placed on the child's finger to record the amount of changes in blood oxygen(SpO2) and pulse rate(PR) obtained in the form of each patient. Dental treatment begins with local anesthesia of 2% lidocaine and 1/100,000 epinephrine. Rate of crying, drowsiness and movement; at the time of anesthesia injection and 15 minutes and 30 minutes from the start of work with the Houpt scale is evaluated and recorded.

##### Participants/Inclusion and exclusion criteria

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

##### Intervention groups

Ketamine 2mg/kg+ Propofol 2mg/kg and Ketamine 2mg/kg+ Midazolam 0.2 mg/kg

##### Main outcome variables

Success of dental treatment according to Houpt Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090506001882N10**

Registration date: **2021-03-08, 1399/12/18**

Registration timing: **prospective**

Last update: **2021-03-08, 1399/12/18**

Update count: **0**

##### Registration date

2021-03-08, 1399/12/18

##### 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

2021-04-09, 1400/01/20

##### Expected recruitment end date

2021-07-06, 1400/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the IV sedation effect of ketamine/propofol and ketamine/ midazolam in dental treatments of 2-6 years old uncooperative children

## Public title

Sedative effect of ketamine / propofol and ketamine / midazolam on non-cooperating children in 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 ASAI group. Be 2 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 **2 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 conducted using Coin toss with patient placed in one of the two groups of A or B on that basis.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The drug combination is given to the patient by the anesthesiologist. Patient and researcher and evaluator do not know the dose of the drug.

## Placebo

Not used

## Assignment

Crossover

## 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, Blvd. Daneshjoo, Evin, Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۹۸۳۹۶۳۱۱۳

#### Approval date

2021-03-01, 1399/12/11

#### Ethics committee reference number

IR.SBMU.DRC.REC.1399.127

## 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 oximeter

### 2

#### Description

Heart rate

#### Timepoint

Every 15 minutes

#### Method of measurement

Pulse oximeter

## Intervention groups

## 1

### Description

Intervention group: Intravenous injection of 2mg/kg Ketamine(50mg/cc, Rotexmedica Co., Germany)+2mg/kg Propofol(10mg/cc Fresenius C.,Austria)

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Intravenous injection of 2mg/kg Ketamine (50mg/cc, Rotexmedica Co., Germany)+0.2mg/kg Midazolam(5mg/cc,Darupakhsh Co., Iran)

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid Beheshti University of Medical Sciences, Dental School

#### Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

#### Street address

Evin, Daneshjo Blvd, Shahi Beheshti Dental School

#### City

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#### Phone

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## 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

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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

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Dr. Narjes Amiri

#### Position

Fellowship

#### Latest degree

Specialist

#### Other areas of specialty/work

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**Full name of responsible person**

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**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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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