

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### A comparative evaluation of sedative effect of intravenous ketamine/midazolam with ketamine/dexmedetomidine combination in 2-6 years old uncooperative pediatric dental patient

#### Protocol summary

##### Study aim

Comparing the sedation effects of intravenous ketamine-midazolam and intravenous ketamine-dexmedetomidine combination in the dental treatment of non-cooperative children aged 2 to 6 years.

##### Design

Cross-over, double-blind, randomized clinical trial on 24 patients

##### Settings and conduct

This double-blind study will be conducted on 24 non-cooperative children referred to the pediatric dental fellowship department of the dental school who need at least two similar dental treatments. The patients will be randomly divided into two treatment groups, AB and BA. In group AB, drug regimen A (intravenous ketamine-midazolam) will be used in the first treatment session, and drug regimen B (intravenous ketamine-dexmedetomidine) will be used in the second session for sedation. In the BA group, the order of prescribing sedatives will be the opposite. All behavioral and physiological parameters of the patient will be recorded by the trained assistant during the different stages of the treatment.

##### Participants/Inclusion and exclusion criteria

Entry criteria: non-cooperative children aged 2-6 years (completely negative based on Frankel scale classification) The patient should be in ASA I group The patient needs to perform at least 2 sessions of similar dental work and needs injections. Exit criteria: Do not have a systemic disease. Do not be in ASA1, ASA2 groups. Do not have contraindications to receive sedatives. During sedation, they should not have symptoms of cold or respiratory tract obstruction.

##### Intervention groups

In order to control the pharmacological behavior of non-cooperative children during dental treatments, two medicinal groups of intravenous ketamine-midazolam

and intravenous ketamine-dexmedetomidine will be used in comparison.

##### Main outcome variables

Success of dental treatment according to the Houpt criterion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230629058616N1**

Registration date: **2023-07-25, 1402/05/03**

Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**

Update count: **0**

##### Registration date

2023-07-25, 1402/05/03

##### Registrant information

##### Name

Masoud Seyedahadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4422 1555

##### Email address

drmasoud@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-06, 1402/05/15

##### Expected recruitment end date

2023-10-07, 1402/07/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative evaluation of sedative effect of intravenous ketamine/midazolam with ketamine/dexmedetomidine combination in 2-6 years old uncooperative pediatric dental patient

**Public title**

Evaluation of sedative effect of ketamine/midazolam with ketamine/dexmedetomidine in dental uncooperative children

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Non-cooperative children aged 2-6 years (completely negative based on the Frankel scale rating) The patient should be in ASA I group. The patient needs to perform at least 2 sessions of similar dental work and needs injection.

**Exclusion criteria:**

Do not have a systemic disease. Do not be in ASA1, ASA2 groups. Do not have contraindications to receive sedatives. During sedation, they should not have symptoms of cold or respiratory tract obstruction

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Children selected to perform this clinical trial are randomly divided into two equal groups, in the first group (A) in one treatment session with the combination of intravenous ketamine/dexmedetomidine and in the next session with the combination of intravenous ketamine/midazolam under sedation. and in the second group (B) the order of prescribing the medicinal combination will be reversed. Two dental treatment sessions should be designed in such a way that they are similar and comparable in terms of the type and duration of treatment. The combination of studied drugs is also prepared by the anesthesiologist and prescribed to the patient during the treatment and according to the protocol.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patients and the therapist are not aware of sedative medication regimen during dental procedures. The anesthesiologist and the care team will only be aware about that

**Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti Dental School, Daneshjoo Blvd, Shahriyari sq, Evin, Chamran Highway, Tehran-Iran

**City**

tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2023-06-10, 1402/03/20

**Ethics committee reference number**

IR.SBMU.DRC.REC.1402.010

**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**

The level of child's cooperation

**Timepoint**

Before dental treatment, during dental treatment and after dental treatment

**Method of measurement**

Observation and based on Houpt Behavioral Scale

## 2

### **Description**

Heart Rate

### **Timepoint**

Before dental treatment, during dental treatment and after dental treatment

### **Method of measurement**

Pulse oximeter device

## 3

### **Description**

Atrial oxygen saturation or Spo2

### **Timepoint**

Before dental treatment, during dental treatment and after dental treatment

### **Method of measurement**

Pulse oximeter device

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In group AB, combination of Dexmedetomidine (dose: 1µgr/kg) and ketamine (dose: 2 mg/kg) will be injected in the intervention phase and the first session of dental treatment for sedation induction. Propofol injection will continue (dose: 150µgr/kg/H) for sedation maintenance

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: In group BA, combination of Ketamine (dose: 2mgr/kg) and Midazolam (dose: 0.2 mg/kg) will be injected in the intervention phase and the first session of dental treatment for sedation induction.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Dr Seyed Masoud Seyed Ahadi

##### **Street address**

School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd, Daneshgah Square, Evin, Shahid Chamran Highway

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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 Masoud Fallahi Nezhad

##### **Street address**

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masoudfallah36@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

No

#### **Title of funding source**

Research Assistant of Shahid Beheshti University of Medical Sciences

#### **Proportion provided by this source**

50

#### **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**

Seyed Masoud Seyed Ahadi

##### **Position**

Hospital dentistry fellowship

##### **Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Position**

hospital dentistry fellowship student

**Latest degree**

Specialist

**Other areas of specialty/work**

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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