

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of the Effects of Midazolam and Hydroxyzine premedication on side effects of Ketamine Intravenous Sedation in Pediatric Dentistry

#### Protocol summary

##### Summary

This double blind clinical trial aims to compare the effect of premedication with hydroxyzine and midazolam on side effects of sedation with intravenous ketamine administration in pediatric dentistry. Twenty 2-6 year-old children are selected among those presenting to dental school clinic using convenience sampling and are randomly divided into two groups (n=10). The parents are briefed about the procedure and written informed consent is obtained from them. The inclusion criteria are ASI class I, two to six years of age, definitely negative or negative Frankl behavioral rating scale and requiring at least two treatment sessions. The exclusion criteria are colds, tonsillar hypertrophy and obesity. In the first session, group one receives 1mg/kg hydroxyzine (protocol A) and group two receives 0.5mg midazolam syrup combined with 0.25mg atropine (protocol B). In the second session, this order is reversed and group one receives protocol B while group two receives protocol A. Upon noticing the signs/symptoms of sedation, patients receive a combination of 0.5mg/kg midazolam and 5mg/kg ketamine intravenously. Dental treatment is commenced 20-30 minutes after drug administration and local anesthesia is induced using 2% lidocaine with 1:80,000 epinephrine. Depth of sedation and children's behavior are assessed by a blind examiner using Houpt sedation rating scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201602291882N8**  
Registration date: **2016-10-24, 1395/08/03**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-10-24, 1395/08/03

##### 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

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##### Recruitment status

###### Recruitment complete

##### Funding source

All costs of the project is paid by Dental Research Center, Research Institute of Dental Sciences, Dental School, Shahid Beheshti University of Medical Sciences Tehran, Iran.

##### Expected recruitment start date

2014-10-02, 1393/07/10

##### Expected recruitment end date

2015-03-16, 1393/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effects of Midazolam and Hydroxyzine premedication on side effects of Ketamine Intravenous Sedation in Pediatric Dentistry

##### Public title

Effect of Midazolam and Hydroxyzine premedication on

reduction of side effects of Ketamine sedation

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Healthy 2-6 years old children:  
Uncooperative negative and definitely ranked as Frankel scale: having at least two sessions dental treatment  
Exclusion criteria: Cold and allergy:Tonsils hypertrophy more than 50%: severe obesity

#### **Age**

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

#### **Gender**

Both

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **20**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **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,Tehran, Iran

###### **Street address**

Shahi Beheshti Dental School, Daneshjo Blvd, Evin

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2014-09-23, 1393/07/01

##### **Ethics committee reference number**

21

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Anxiety

##### **ICD-10 code**

F06.4

#### **ICD-10 code description**

Organic anxiety disorder

### **Primary outcomes**

#### **1**

##### **Description**

Drowsiness

##### **Timepoint**

1 hour, 2 hours after sedation and 6 hours after discharge

##### **Method of measurement**

Parents observation and report

#### **2**

##### **Description**

Nausea

##### **Timepoint**

1 hour, 2 hours after sedation and 6 hours after discharge

##### **Method of measurement**

Parents observation and report

#### **3**

##### **Description**

Dizziness

##### **Timepoint**

1 hour, 2 hours after sedation and 6 hours after discharge

##### **Method of measurement**

Parents observation and report

#### **4**

##### **Description**

Vomit

##### **Timepoint**

1 hour, 2 hours after sedation and 6 hours after discharge

##### **Method of measurement**

Parents observation and report

### **Secondary outcomes**

#### **1**

##### **Description**

Conscious sedation

##### **Timepoint**

Every 15 minutes

##### **Method of measurement**

Houpt scale

#### **2**

##### **Description**

SpO2

##### **Timepoint**

Every 15 minutes

**Method of measurement**

pulse oxymeter

**3****Description**

Heart Rate

**Timepoint**

Every 15 minutes

**Method of measurement**

pulse oxymeter

**Intervention groups****1****Description**Syrup of Hydroxyzine( Kharazmi Phrmaceutic Co., Iran)  
1mg/kg as oral and premedication.**Category**

Treatment - Drugs

**2****Description**Midazolam syrup(Dales Pharmaceutic, England) 0.5  
mg/kg+ Atropine(Caspian Pharmaceutic,Iran) 0.25  
mg/kg, as oral and premedication.**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**Dental School, Shahid Beheshti University of Medical  
Sciences,Tehran, Iran**Full name of responsible person**

Dr. Masoud Fallahinejad Ghajari

**Street address**

Shahi Beheshti Dental School, Daneshjo Blvd, Evin

**City**

Tehran

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. S. Mohammad Reza Safavi

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Shahid Beheshti Dental School, Daneshjo Blvd, Evin.

**City**

Tehran

**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***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**Dental Research Center, Shahid Beheshti Dental  
School**Full name of responsible person**

Dr. Anahita Bozorgmanesh

**Position**

Pedodontist

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**Full name of responsible person**

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**City**

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**Postal code****Phone****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*