

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparison of intranasal midazolam and dexmedetomidin premedication effect on 2-6 years old uncooperative children behavior in dentistry

#### Protocol summary

##### Summary

The aim of this study is comparison effect of intranasal midazolam and dexmedetomidine on 2-6 years old children behavior in pediatric dentistry. This cross-over double blind randomized controlled trial is carried on twenty 2-6 years old children referred to dental school based on inclusion criteria: Healthy according ASA1 classification; uncooperative negative and definitely negative as frankl scale; having at least 2 sessions dental work and exclusion criteria: Cold; tonsils hypertrophy; severe obesity. After obtaining written informing consent, written and orally instructions before conscious sedation, at first meeting the first group receives 0.2 mg/kg Midazolam intranasal(Regimen A) and the second group receives 1 µg/kg Dexmedetomidine intranasal(Regimen B). In the second session, the first group receive regimen B and the second group B receives regimen A. After 20 minutes premedication every patient receives 0.1 mg/kg Midazolam and 1-2 mg/kg Ketamine and 0.25 mg Atropine intravenously. Dental treatment starts with lidocaine 2% with adrenaline 1/80000 anesthesia by a pedodontist who is blind to type of regimen. Sedation level and the child's behavior based on Houpt scale evaluates by a member of teamwork who does not aware of the type of regimen. Arterial blood oxygen saturation (SpO2), heart rate (HR) and blood pressure before administration, starting, every 15 minutes during the work, after work and discharge patients records in related form.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201601281882N7**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-03-13, 1394/12/23

##### 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

masfalnagh@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

All costs of the project is paid by Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences Tehran, Iran.

##### Expected recruitment start date

2016-02-13, 1394/11/24

##### Expected recruitment end date

2016-08-10, 1395/05/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of intranasal midazolam and dexmedetomidin premedication effect on 2-6 years old uncooperative children behavior in dentistry

##### Public title

Premedication effect of intranasal midazolam and dexmedetomidine on children behavior

## 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

Parallel

## 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

Shahid Beheshti Dental University of Medical Sciences, Daneshjo Blvd, Evin

##### City

Tehran

##### Postal code

#### Approval date

2015-12-22, 1394/10/01

#### Ethics committee reference number

IR.SBMU.RIDS.REC.1394.73

## 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

Conscious sedation

#### Timepoint

Every 15 minutes

#### Method of measurement

Houpt scale

## Secondary outcomes

### 1

#### Description

SpO2

#### Timepoint

Every 15 minutes

#### Method of measurement

pulse ooxymeter

## Intervention groups

### 1

#### Description

Dexmedetomidine 1µg/kg, intranasal

#### Category

Treatment - Drugs

### 2

#### Description

Midazolam 0.2 mg/kg, intranasal

#### 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

## Sponsors / Funding sources

## 1

### **Sponsor**

#### **Name of organization / entity**

Vice chancellor for research, 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

### **Grant name**

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

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

Yes

### **Title of funding source**

Vice chancellor for research, 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**

Shahid Beheshti Dental School

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

Lily Shafie

#### **Position**

Assistant Professor

#### **Other areas of specialty/work**

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## **Person responsible for scientific inquiries**

### **Contact**

#### **Name of organization / entity**

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

Dr. Masoud Fallahinejad Ghajari

#### **Position**

Associate Professor, Department of Pediatric  
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#### **Other areas of specialty/work**

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#### **Web page address**

## **Person responsible for updating data**

### **Contact**

#### **Name of organization / entity**

Shahid Beheshti Dental School

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

Dr. Masoud Fallahinejad Ghajari

#### **Position**

Associate Professor, Department of Pediatric  
Dentistry

#### **Other areas of specialty/work**

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#### **Phone**

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#### **Fax**

#### **Email**

masfalnegh@sbmu.ac.ir

#### **Web page address**

## **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*