

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of sedative effect of syrup of midazolam and injectable midazolam (as oral) on behavior of 3-6 years old uncooperative children in dentistry

#### Protocol summary

##### Summary

The aim of this study is comparison of sedative effect of the syrup midazolam and injectable midazolam as oral on 3-6 years old uncooperative children under dental treatment. This double blind cross over clinical trial is done on 20 children 3-6 years old referred to dental school. The samples according to inclusion criteria: healthy children as ASA1 classification; uncooperative negative and definitely negative as Frankle scale and exclusion criteria: cold; allergy and tonsil hypertrophy are divided into two groups randomly. After obtaining informed written consent, orally and written instructions before conscious sedation, at first meeting the one group receive combination of 0.5 mg/kg syrup midazolam +1 mg/kg hydroxyzine (regimen A) and the other group receive combination of 0.5 mg/kg injectable midazolam with fruit juice as oral+ 1 mg/kg hydroxyzine (regimen B). In the second session, the first group receive regimen B and the second group B receives regimen A. Dental treatment starts by a pedodontist who is blind to type of regimen 20-30 minutes after drug administration and lidocaine 2% with adrenaline 1/100000 anesthesia. 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) and heart rate (HR) by finger pulse oxymeter 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: **IRCT201406171882N5**

Registration date: **2016-02-25, 1394/12/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-02-25, 1394/12/06

##### 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

Investigator

##### Expected recruitment start date

2013-07-06, 1392/04/15

##### Expected recruitment end date

2014-01-05, 1392/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of sedative effect of syrup of midazolam and injectable midazolam (as oral) on behavior of 3-6 years old uncooperative children in dentistry

##### Public title

Effectiveness of oral and injectable midazolam on children behavior in dentistry

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Healthy 3-6 years old children as ASA1 classification! Uncooperative negative and definitely negative according to Frankle scale! Having at least two sessions of dental treatment Exclusion criteria: Cold and allergy! Tonsils hypertrophy more than 50%; Severe obesity

### **Age**

From **3 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**

Randomization is carried with the toss of a coin.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee, Shahid Beheshti University of Medical Sciences

##### **Street address**

Shahid Beheshti Dental School, Daneshjo Blvd, Evin

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2013-09-04, 1392/06/13

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

19

## **Health conditions studied**

### 1

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

Fear and anxiety

### **ICD-10 code**

F00-F01-F0

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

Organic, including symptomatic, mental disorders

## **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**

0.5 mg/kg Syrup of Midazolam(Amsed, England) +1 mg/kg Hydroxyzine(Abureyhan, Iran). Waiting time for sedation 20 to 30 minute. Treatment time: 30 minute

#### **Category**

Treatment - Drugs

### 2

#### **Description**

0.5 mg/kg injectable Midazolam as oral (Darupakhsh, Iran) + 1 mg/kg Hydroxyzine(Abureyhan, Iran). Waiting time: 20-30 minutes. Treatment time:30 minutes

#### **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**

Shahi Beheshti Dental School, Daneshjo Blvd, Evin

**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. Masoud Fallahinejad Ghajari

**Street address**

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**

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**

Dental Research Center, Shahid Beheshti Dental School

**Full name of responsible person**

Dr. Sarira Zomorodian

**Position**

Dental student

**Other areas of specialty/work**

**Street address**

Shahid Beheshti Dental School, Daneshjo Blvd, Evin

**City**

Tehran

**Postal code**

**Phone**

+98 21 2240 3080

**Fax**

**Email**

sarira\_zomorodian@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Dental Research Center, 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**

**Street address**

Shahid Beheshti Dental Schoolt, Daneshjo Blvd, Evin

**City**

Tehran

**Postal code**

**Phone**

+98 21 2240 3080

**Fax**

**Email**

masoudfallah36@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Dental Research Center, 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**

**Street address**

Shahid Beheshti Dental School, Daneshjo Blvd, Evin

**City**

Tehran

**Postal code**

**Phone**

+98 21 2240 3080

**Fax**

**Email**

masoudfallah36@yahoo.com

**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*