

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Assessing and comparing of Midazolam/Propofol and Ketamin/Propofol intravenous sedation in anxiety children for dental treatment

#### Protocol summary

##### Summary

Objectives: Fear and anxiety of some children in dentistry lead to problem that they don't have successful treatment. Because of the necessity of dental treatment in anxiety and uncooperative children in this study we want to compare sedation of different drugs and use them in children sedation center. Design: This is double blind randomized, clinical trial study. Setting and conduct and Participants including major eligibility criteria: 32 anxiety children of ages 6-8 that referring to sedation center, treatment needs only on left side of upper jaw evaluated in 2 groups. Intervention: Intravenous conscious sedation in first group with Midazolam/Propofol and in second group with Ketamin/Propofol is injected. Main outcome measures (variables): Sedation score of patient in 4 different times, during dental treatment and operating conditions at the end of the treatment, according to dental sedation teacher group (DSTG) is measured. Data analyzed with SPSS, Mann-Whitney, Wilcoxon and Friedman tests.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203124224N19**

Registration date: **2013-05-04, 1392/02/14**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-05-04, 1392/02/14

##### Registrant information

###### Name

Nasser Kaviani

###### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2858

##### Email address

kaviani@dnt.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Research of Isfahan university of medical sciences, Isfahan dental school, Hezar Jarib street, Isfahan, Iran.

##### Expected recruitment start date

2013-05-22, 1392/03/01

##### Expected recruitment end date

2013-08-22, 1392/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing and comparing of Midazolam/Propofol and Ketamin/Propofol intravenous sedation in anxiety children for dental treatment

##### Public title

Assessing and comparing of 2 different intravenous sedation drugs in anxiety children for dental treatment

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion Criteria: Children ages 6-8; Uncooperative; Negative in Frankel grading; No specific disease; ASA I; No need to extraction; Treatment needs only on left side of upper jaw; No contraindication of sedation. Exclusion criteria: Emergency event during study; Dental treatment more than 45 minutes.

## Age

From **6 years** old to **8 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: **32**

## 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 Isfahan university of medical science

##### Street address

Dental school, University of medical sciences, Hezar Jerib st, Isfahan

##### City

Isfahan

##### Postal code

#### Approval date

2012-12-09, 1391/09/19

#### Ethics committee reference number

391306

## Health conditions studied

### 1

#### Description of health condition studied

Dental Anxiety

#### ICD-10 code

F-40

#### ICD-10 code description

Phobic anxiety disorders

## Primary outcomes

### 1

#### Description

Sedation grade

#### Timepoint

In 4 different times during dental treatment

#### Method of measurement

According to DSTG score

## Secondary outcomes

### 1

#### Description

Operating conditions

#### Timepoint

One time at the end of the dental treatment

#### Method of measurement

DSTG score

## Intervention groups

### 1

#### Description

Admistartion1 drug regime to1 patients groups: 1-Midazolam/Propofol(Midazolam 0.01mg/kg only one time at the beginning of the dental treatment throughout IV injection and after 5 minutes Propofol drug 0.05mg/kg with infusion pump system throughout IV injection during the whole dental treatment up to 45 minutes)

#### Category

Treatment - Drugs

### 2

#### Description

Admistartion1 drug regime to1 patients groups: 1-Ketamin/Propofol(Ketamin 0.05mg/kg only one time at the beginning of the dental treatment throughout IV injection and after 5 minutes Propofol drug 0.05mg/kg with infusion pump system throughout IV injection during the whole dental treatment up to 45 minutes)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental school of Isfahan university of medical science

##### Full name of responsible person

dr. Mina Shahtoosi

##### Street address

Pediatric center, Isfahan dental school, Isfahan university of medical science

##### City

Isfahan

## Sponsors / Funding sources

## 1

### **Sponsor**

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

Vice chancellor for Research of Isfahan university of medical sciences

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

Mr Tavangar

#### **Street address**

Dentistry school, Hezar Jarib street, Isfahan

#### **City**

Isfahan

### **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 of Isfahan 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 school, Isfahan university of medical science

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

Mina Shahtoosi

#### **Position**

Post graduate student of pediatric dentistry

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

#### **Street address**

Dentistry school, Hezar Jarib street, Isfahan

#### **City**

Isfahan

#### **Postal code**

#### **Phone**

+98 31 1792 2891

#### **Fax**

#### **Email**

kaviani@dnt.mui.ac.ir

#### **Web page address**

## **Person responsible for scientific inquiries**

### **Contact**

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

Dental school of Isfahan university of medical science

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

Mina Shahtoosi

### **Position**

Post graduate student of pediatric dentistry

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## **Person responsible for updating data**

### **Contact**

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

Dental school of Isfahan university of medical science

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Mina Shahtoosi

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#### **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*