

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effects of oral Midazolam premedication on recall preoperative process in General Anaesthesia in children dentistry

#### Protocol summary

##### Summary

To decrease dental work recall in children and minimize the emotional trauma under general anaesthesia, which used an effective premedication may facilitate a smoother induction of GA. The aim of this study is to determine efficacy dental work recall in children. In this prospective clinical trial, 60 uncooperative children are selected from those referring for dental work under general anaesthesia. Healthy children (ASAI, ASAII) and aged 4 to 10 years with refused treatment; these children are extremely uncooperative and anxious. Children are excluded from the study, if they are respiratory unstable, have any hypoxia, arrhythmia or pain in recovery room. Patients are divided into case and control groups. The case group receives orally 0.5 mg/kg of injectable midazolam mixed with juice, 20 minutes before separation from parents. If the child is not allowed venepuncture before induction of GA, inhalational anaesthetic used by combination oxygen, N<sub>2</sub>O, isoflurane are used. Standard and same monitoring and maintenance of anaesthesia during operation for all children are done. In recovery room maintaining are performed for all patients. According to the (PADS) scale system and standard protocol. After that, ask about the recall of events from child.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201101054224N9**  
Registration date: **2011-08-23, 1390/06/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-08-23, 1390/06/01

#### 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, Isfahan University of Medical Sciences

#### Expected recruitment start date

2010-09-23, 1389/07/01

#### Expected recruitment end date

2011-09-20, 1390/06/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation the effects of oral Midazolam premedication on recall preoperative process in General Anaesthesia in children dentistry

#### Public title

Evaluation the effects of oral Midazolam premedication on recall preoperative process under General Anaesthesia in children dentistry

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion Criteria: Systemic Condition: ASAI, ASAII;  
Uncooperative children dentistry operation candidate for

general anaesthesia; Exclusion Criteria: Exist of Hypoxia; Arrhythmia; Pain in recovery room; Agitation; Nausea

### Age

From **4 years** old to **10 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan university of Medical Sciences ethical committee

##### Street address

Isfahan Dental College, Isfahan Medical University, Hezar Jireeb Street

##### City

Isfahan

##### Postal code

##### Approval date

2010-10-18, 1389/07/26

##### Ethics committee reference number

390017

## Health conditions studied

### 1

#### Description of health condition studied

Post operative recall

#### ICD-10 code

F93.8

#### ICD-10 code description

Other childhood emotional disorders

## Primary outcomes

### 1

#### Description

Recall of process and events

#### Timepoint

Before medication, after anaesthesia

#### Method of measurement

Filling questionnaire

## Secondary outcomes

### 1

#### Description

Anaesthetic technique

#### Timepoint

After medication

#### Method of measurement

Objective

## Intervention groups

### 1

#### Description

Drug prescription, orally 0.5 mg/kg inject able midazolam mix with juice

#### Category

Prevention

### 2

#### Description

Placebo Prescription

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Dental College

##### Full name of responsible person

Sara Nazari

##### Street address

Shohadaye sofe street

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

##### Full name of responsible person

Aminallah Tavangar

##### Street address

Shohadaye sofe street

**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, 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**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Isfahan Dental College- Isfahan Medical University

**Full name of responsible person**

Dr Naser Kaviani

**Position**

Doctor of Anesthesia

**Other areas of specialty/work**

**Street address**

Shohadaye Sofeh Street

**City**

Isfahan

**Postal code**

IRAN

**Phone**

00983117922858 -009803116687080

**Fax**

**Email**

kaviani@dnt.mui.ac.ir

**Web page address**

www.dentalfear\_blogfa.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Isfahan Dental College- Isfahan Medical University

**Full name of responsible person**

Nasser kaviani

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

Shohadaye Sofeh Street

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1792 2858

**Fax**

**Email**

kaviani@dnt.mui.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*