

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A Clinical Trial to Compare Oral Midazolam and Oral Promethazine Effect as Premedication on Sedation among Uncooperative Children undergoing dental procedures

#### Protocol summary

##### Summary

Aim: Comparing oral midazolam and oral promethazine premedication on child's cooperation before ketamin/Midazolam IV administration in pediatric dentistry. Material and Method: This unicenter cross-over randomized double blind clinical trial is carried out on 6 children aged 2-6 years referred to the fellowship unit of dental school due to their fear and multiple dental needs. Patients' selection is based on the following main inclusion criteria: being ASA I or II classification and scored 1 in Frankl Behavior scale and exclusion criteria: no systemic contraindications for sedation; nasal obstruction; respiratory infection; mouth opening limitation; macroglossia; tonsillar hypertrophy. Each patient is scheduled for two subsequent visits to receive one of the two premedications before IV sedation. Each patient will be considered as his/her control (self-control) and patients will randomly be assigns to either intervention group 1 (oral Midazolam as premed in 1st visit and oral Promethazine in 2nd visit) and intervention group 2 (oral Promethazine as the premed in 1st visit and oral Midazolam in 2nd visit) through random number table. Being 6 hours NPO is instructed before sedation. IV Ketamin/Midazolam will be administered half an hour after premedication and following dental treatment will be done. Vital signs will be controlled every 15 minutes as a base before drug administration. Patient's cooperation for IV sedation is measured using HOUP scale. Drugs side effects including nausea and vomiting, dizziness and sleepiness will be recorded at the end of sedation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016120516106N3**

Registration date: **2017-10-29, 1396/08/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-29, 1396/08/07

##### Registrant information

###### Name

Ghassem Ansari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2225 5958

###### Email address

drgansari@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Dental Research Center, Research Institute of Dental Sciences, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2013-12-31, 1392/10/10

##### Expected recruitment end date

2014-12-31, 1393/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A Clinical Trial to Compare Oral Midazolam and Oral Promethazine Effect as Premedication on Sedation

among Uncooperative Children undergoing dental procedures

IR.SBMU.RIDS.REC.21

## Public title

Oral Midazolam Vs Oral Promethazine Premedication Effect on Dental Sedation

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: uncooperative children aged 2-6 years; completely negative Frankle behavioral scale; ASA I or II for systemic health; two teeth requiring the same treatment in two separate sessions Exclusion Criteria: any systemic disease with contraindication for sedation or premedication ;nasal obstruction;respiratory infection; mouth opening limitation; macroglossia; tonsillar hypertrophy

## 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: 26

## 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 in Biomedical Research, Research Institute of Dental Sciences, Shahid Beheshti Univ

##### Street address

Ethics committee Office, 5th floor, Research Institute for Dental Sciences, Dental school, Shahid Beheshti University of Medical Sciences, Daneshjoo blvd, Evin

##### City

Tehran

##### Postal code

1983663113

#### Approval date

2014-09-23, 1393/07/01

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

dental anxiety and management

#### ICD-10 code

F00-F99

#### ICD-10 code description

Mental and behavioural disorders

## Primary outcomes

### 1

#### Description

Patient's Cooperation for Sedation

#### Timepoint

At the IV Administration step

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Nausea and vomiting

#### Timepoint

After the end of treatment and sedation

#### Method of measurement

Questionair

### 2

#### Description

Sleepiness

#### Timepoint

After the end of treatment and sedation

#### Method of measurement

Questionair

### 3

#### Description

Dizziness

#### Timepoint

After the end of treatment and sedation

#### Method of measurement

Questionair

## Intervention groups

### 1

#### Description

Intervention group 1 :In 1st session oral Midazolam suspension premedication (0.5mg/kg) is administered half an hour before IV Ketamin (2mg/kg) and IV

Midazolam (0.5 mg/kg). Then in 2nd session oral Promethazine (1 mg/kg) is administered half an hour before IV Ketamin (2mg/kg) and IV Midazolam (0.5 mg/kg) administration.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2 : In 1st session oral Promethazine suspension premedication (0.5mg/kg) is administered half an hour before IV Ketamin (2mg/kg) and IV Midazolam (0.5 mg/kg). Then in 2nd session oral Midazolam (1 mg/kg) is administered half an hour before IV Ketamin (2mg/kg) and IV Midazolam (0.5 mg/kg) administration.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ghassem Ansari

**Street address**

Department of Pediatric Dentistry, Shahid Beheshti Medical University, Daneshjoo Blvd, Evin, Chamran Highway

**City**

Tehran

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

Vice Chancellor of Research, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Office of Vice Chancellor of Research, 5th Floor, Shahid Beheshti University of Medical Sciences, Daneshjoo blvd, Evin, Chamran Highway

**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 of 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 University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Position**

Professor

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

### Contact

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## 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*