

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Conscious sedation effect of oral chloral hydrate-hydroxyzine versus midazolam-hydroxyzine in uncooperative 2-6 year old children undergoing dental treatment

#### Protocol summary

##### Summary

The objective of the present study was to investigate the Sedation effect of anxiolytic drugs on uncooperative children's behavior during dental treatment. In this double blind, randomized clinical trial, 16 uncooperative children, aged 2-6 years old, were randomly assigned into the following 2 groups. The patients in the group 1 received 50mg/kg chloral hydrate + 1mg/kg hydroxyzine and in the group 2 received regimen B including 0.5 mg/kg midazolam + regimen A including 1mg/kg hydroxyzine in the first visit. In the second visit the patients in the first group received regimen B and vice versa. The patient monitored visually. The level of sedation, determined by Houpt's criteria for overall behavior, pulse rate, and arterial blood oxygen saturation was measured and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903071882N2**

Registration date: **2011-05-02, 1390/02/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-05-02, 1390/02/12

##### 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

Iranian Center of Dental Sciences, School of Dentistry, Shahid Beheshti University of Medical Sciences,

##### Expected recruitment start date

2010-04-30, 1389/02/10

##### Expected recruitment end date

2010-09-01, 1389/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Conscious sedation effect of oral chloral hydrate-hydroxyzine versus midazolam-hydroxyzine in uncooperative 2-6 year old children undergoing dental treatment

##### Public title

The Sedation Effect of Anxiolytic drugs on uncooperative children's behavior during dental treatment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Healthy child (ASA I-II), uncooperative child, at least 2 sessions similar treatment Exclusion criteria: severe obesity, Tonsillar hypertrophy (more than 50%), presence of common cold

**Age**

From **2 years** old to **6 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **16**

**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**

Dental Research Center of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti School of dentistry, Daneshjoo Boulevard, Evin

**City**

Tehran

**Postal code**

1983963113

**Approval date**

2010-12-21, 1389/09/30

**Ethics committee reference number**

5550/پ/17/25/ت م

**Health conditions studied****1****Description of health condition studied**

Fear and Anxiety

**ICD-10 code**

F00, F99

**ICD-10 code description**

Organic, including symptomatic, mental disorders

**Primary outcomes****1****Description**

Conscious Sedation

**Timepoint**

Every 15 minutes

**Method of measurement**

Haupt criteria

**Secondary outcomes****1****Description**

Arterial blood saturation

**Timepoint**

Every 15 minutes

**Method of measurement**

Pulse Oxymeter

**2****Description**

Pulse Rate

**Timepoint**

Every 15 minutes

**Method of measurement**

Pulse Oxymeter

**Intervention groups****1****Description**

Midazolm 0.5mg/kg + Hydroxyzine 1mg/kg Expected time for sedation: 20-30 minutes Treatment time: 30 minutes

**Category**

Treatment - Drugs

**2****Description**

Chloral Hydrate 50mg/kg + hydroxyzine 1mg/kg Expected time for sedation: 30-45 minutes Treatment time: 30 minutes

**Category**

Treatment - Drugs

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

Mofid Children Hospital, Shahid Beheshti Dental School

**Full name of responsible person**

Dr. Masoud Fallahinejad Ghajari

**Street address****City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Dental Research Center

**Full name of responsible person**

Dr. Mohammad Reza Safavi

**Street address**

Shahid Beheshti Dental School, Daneshjoo Boulevard,  
Evin

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Dental Research Center

**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**

Dr. Vahid Golpayegani M

**Position**

Pedodontist/Associate Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Position**

Pedodontist/Associate Professor

**Other areas of specialty/work**

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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*