

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the Effects of Midazolam and Hydroxyzine premedication on side effects of Ketamine Intravenous Sedation in Pediatric Dentistry

Protocol summary

Summary

This double blind clinical trial aims to compare the effect of premedication with hydroxyzine and midazolam on side effects of sedation with intravenous ketamine administration in pediatric dentistry. Twenty 2-6 year-old children are selected among those presenting to dental school clinic using convenience sampling and are randomly divided into two groups (n=10). The parents are briefed about the procedure and written informed consent is obtained from them. The inclusion criteria are ASI class I, two to six years of age, definitely negative or negative Frankl behavioral rating scale and requiring at least two treatment sessions. The exclusion criteria are colds, tonsillar hypertrophy and obesity. In the first session, group one receives 1mg/kg hydroxyzine (protocol A) and group two receives 0.5mg midazolam syrup combined with 0.25mg atropine (protocol B). In the second session, this order is reversed and group one receives protocol B while group two receives protocol A. Upon noticing the signs/symptoms of sedation, patients receive a combination of 0.5mg/kg midazolam and 5mg/kg ketamine intravenously. Dental treatment is commenced 20-30 minutes after drug administration and local anesthesia is induced using 2% lidocaine with 1:80,000 epinephrine. Depth of sedation and children's behavior are assessed by a blind examiner using Houpt sedation rating scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602291882N8**
Registration date: **2016-10-24, 1395/08/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-24, 1395/08/03

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Faculty of Dentistry, Shahid Beheshti University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

All costs of the project is paid by Dental Research Center, Research Institute of Dental Sciences, Dental School, Shahid Beheshti University of Medical Sciences Tehran, Iran.

Expected recruitment start date

2014-10-02, 1393/07/10

Expected recruitment end date

2015-03-16, 1393/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Midazolam and Hydroxyzine premedication on side effects of Ketamine Intravenous Sedation in Pediatric Dentistry

Public title

Effect of Midazolam and Hydroxyzine premedication on

reduction of side effects of Ketamine sedation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy 2-6 years old children:
Uncooperative negative and definitely ranked as Frankel scale: having at least two sessions dental treatment
Exclusion criteria: Cold and allergy:Tonsils hypertrophy more than 50%: severe obesity

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: **20**

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 of Shahid Beheshti University of
Medical Sciences,Tehran, Iran

Street address

Shahi Beheshti Dental School, Daneshjo Blvd, Evin

City

Tehran

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

21

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

Primary outcomes

1

Description

Drowsiness

Timepoint

1 hour, 2 hours after sedation and 6 hours after discharge

Method of measurement

Parents observation and report

2

Description

Nausea

Timepoint

1 hour, 2 hours after sedation and 6 hours after discharge

Method of measurement

Parents observation and report

3

Description

Dizziness

Timepoint

1 hour, 2 hours after sedation and 6 hours after discharge

Method of measurement

Parents observation and report

4

Description

Vomit

Timepoint

1 hour, 2 hours after sedation and 6 hours after discharge

Method of measurement

Parents observation and report

Secondary outcomes

1

Description

Conscious sedation

Timepoint

Every 15 minutes

Method of measurement

Houpt scale

2

Description

SpO2

Timepoint

Every 15 minutes

Method of measurement

pulse oxymeter

3**Description**

Heart Rate

Timepoint

Every 15 minutes

Method of measurement

pulse oxymeter

Intervention groups**1****Description**Syrup of Hydroxyzine(Kharazmi Phrmaceutic Co., Iran)
1mg/kg as oral and premedication.**Category**

Treatment - Drugs

2**Description**Midazolam syrup(Dales Pharmaceutic, England) 0.5
mg/kg+ Atropine(Caspian Pharmaceutic,Iran) 0.25
mg/kg, as oral and premedication.**Category**

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**Dental School, Shahid Beheshti University of Medical
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Dr. Masoud Fallahinejad Ghajari

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

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Full name of responsible person

Dr. S. Mohammad Reza Safavi

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Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

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**

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Full name of responsible person

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

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Postal code**Phone****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