

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A Comparison of 2 Oral Sedation Regimens: Hydroxyzine-Midazolam and Hydroxyzine -Meperidine with oral Hydroxyzine-submucosal Meperidine in Dental Sedation of uncooperative 2-6 years of age children

Protocol summary

Summary

Aim: To compare efficacy and safety of 3 sedation regimens . Study design: Randomized, double blind with controls. Study population: 2-6 years of age uncooperative dental patients, refering to Mofeed Educational hospital and Shaheed Beheshti Dental school. Inclusion criteria: Uncooperative behavior (Frankl 1and 2); Age between 2-6; Health status ASA I. Exclusion criteria: History of allergic reaction to drugs that are using in this study; sleep apnea. Sample size: 78. Interventions: Group A: Hydroxyzine-Midazolam; Group B: Hydroxyzine-Meperidine. both A and B are administered via Oral route. Group C: Oral Hydroxyzine-Submucosal Meperidine. The patient will be monitored for physiologic parameters every 15 minutes for Heart rate, Blood Pressure, Respiratory rate and SPo2 (Oxygen saturation). Behavior will be rated according to HOUPPT scale at the end of appointment, which evaluates the degree of sleep, movement and crying. Outcomes: Safety (physiologic parameters) and Efficacy (HOUPPT scale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101181861N2**
Registration date: **2011-04-30, 1390/02/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-30, 1390/02/10

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

The approved research budget

Expected recruitment start date

2010-05-24, 1389/03/03

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of 2 Oral Sedation Regimens: Hydroxyzine-Midazolam and Hydroxyzine -Meperidine with oral Hydroxyzine-submucosal Meperidine in Dental Sedation of uncooperative 2-6 years of age children

Public title

Comparison of Meperidine versus Midazolam Sedation in Uncooperative children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 2-6 years; Behavior: Negative or completely negative according to Frankl

rating scale; Health status: ASA I; should have at least 3 consecutive similar treatment sessions. Exclusion criteria: history of allergic reactions to Benzodiazepines or any other drug used in the study; Previous complications with general anesthesia in patient or family; Hyper trophic adenoids in a manner that occupied more than 50% of pharyngeal space (Brodsky 2+>); Sleep apnea.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **78**

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

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

Street address

4th floor, Dental School, Daneshjoo Boulevard, Evin

City

Tehran

Postal code

19832

Approval date

2011-03-13, 1389/12/22

Ethics committee reference number

8910/ل.س.م/..

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F93.1

ICD-10 code description

Phobic anxiety disorder of childhood

Primary outcomes

1

Description

Sleepness

Timepoint

Once(at the beginning of the treatment)

Method of measurement

Observation

2

Description

Movement

Timepoint

During the process of treatment

Method of measurement

Observation

3

Description

Crying

Timepoint

During the process of treatment

Method of measurement

Observation

4

Description

Overall behavior

Timepoint

During the process of treatment

Method of measurement

Observation

5

Description

Fear of Dentistry

Timepoint

Before treatment and after the final session

Method of measurement

questionnaire

6

Description

Recovery time

Timepoint

After treatment completion

Method of measurement

Observation

7

Description

Respiratory Rate

Timepoint

At the beginning of the study and then every 15 minutes

Method of measurement

Monitoring

8**Description**

Blood Pressure

Timepoint

At the beginning of the study and then every 15 minutes

Method of measurement

Monitoring

9**Description**

Oxygen Saturation

Timepoint

At the beginning of the study and then every 15 minutes

Method of measurement

Monitoring

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

Adverse reactions

Timepoint

During and after treatment

Method of measurement

Observation

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

InterventionGroup B (Midazolam-Hydroxyzine): in this group, Hydroxyzine is administered with a dose of 1mg/kg at first, after 30 minutes Midazolam (0.5 mg/kg in mixture with the same volume of 10% sugar syrup) will be administered to the patient by cup and under the supervision of anesthesiologist. In the case of uncooperation, the drug will be poured in the lower buccal vestibule by a syringe.Treatment will begin after 30 minutes.

Category

Treatment - Drugs

2**Description**

Intervention group C (Oral Meperidine-Hydroxyzine): in this group both meperidine (2mg/kg) and hydroxyzine (1mg/kg) are administered simultaneously 1 hour before treatment

Category

Treatment - Drugs

3**Description**

Control Group (submucosal injection of meperidine-Hydroxyzine): in this group, Hydroxyzine (1mg/kg) is administered one hour before treatment. After 30 minutes of hydroxyzine administration, meperidine (1mg/kg) will be injected slowly in upper vestibule between canine and first molar (11) at the opposite site of dental. The main treatment will be begun in half an hour.

Category

Treatment - Drugs

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

Shahid Beheshti Dental School

Full name of responsible person

Dr Toomarian

Street address

Daneshjoo Blvd, Evin

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

Dental Research Center, Shahid Beheshti Dental School

Full name of responsible person

DR Lida Toomarian

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Evin, Daneshjoo Blvd

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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

Dental Research Center, Shahid Beheshti Dental School

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

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Position

Secretary of Investigation and Research Department

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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