Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 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 HOUPT scale at the end of appointment, which evaluates the degree of sleep, movement and crying. Outcomes: Safety (physiologic parameters) and Efficacy (HOUPT 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/ا.ک.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 beggining of the study and then every 15 minutes
Method of measurement
Monitoring

8

Description
Blood Pressure
Timepoint
At the beggining of the study and then every 15 minutes
Method of measurement
Monitoring

9

Description
Oxygen Saturation
Timepoint
At the beggining 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 simultaneousnessly 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 vestible 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
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dental Research Center, Shahid Beheshti Dental School
Full name of responsible person
DR Lida Toomarian
Street address
Evin, Daneshjoo Blvd
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, 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
Ms Asgari

Position
Secretory of Investigation and Research Department

Other areas of specialty/work

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Person responsible for scientific inquiries

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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