Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 1received 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

Facualty of Dentistry, Shahid Beheshti University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iranian Center of Dental Sciences, School of Dentistry, Shahid Beheshti University of Mdical 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 2sessions similar treatment Exclusion criteria: severe obesity, Tonsilar 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/م ت

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
Houpt 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

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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