Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the sedative effect of oral Midazolam/Hydroxyzine vs Chloral hydrate/Hydroxizine in behavior control of 6-10 year old uncooperative children.

Protocol summary

Summary

Background & Aim: The use of premedication and sedation has been widely accepted among the international dental community. The aim of this investigation was to determine the sedative effect of oral Midazolam/Hydroxyzine and Chloral hydrate/Hydroxyzine combination in uncooperative children aged 4-10 years. Materials & Methods: A total of 16 uncooperative Children aged 4-6 years were selected from those referred to the department of Pediatric Dentistry at Shahid Beheshti Medical University. Cases with a behavioral score of 2 in Frankel scale system were included with at least two similar dental needs with each case acting as self-control. Informed consent was obtained from parents of all cases. Half of the population were assigned randomly to receive the first regimen while other half received the other regimen. Child's behavior was videotaped using a mounted digital video recorder in all cases in each appointment. Child's reactions were scored using North Carolina Behavior Rating Scale (NCBRS). Patients received 1mg/kg Hydroxyzine and 0.5 mg/kg Midazolam in one visit and 50 mg/kg Chloral Hydrate along with 1mg/kg Hydroxyzine in the other visit. Attempts were made to keep the two treatment sessions timing equal. Collected data were analyzed using Wilcoxon and Paired t-test. Results:There was a clear increase in the level of child's cooperation and behaviorfollowing the use of the drugs. However there was no significant difference when reaction of children was compared after the administration of the two cocktail drugs. There was a slight superiority on the use of Chloral hydrate/Hydroxyzine over the Midazolam/Hydroxyzine combination (75% to 63% improved behavior). Wilcoxon test showed no significant difference between the effect of two drug groups (P= 0.05). Conclusion:There were no significant differences between the two combination drugs however;Chloralhydrate/Hydroxyzine combination appears to have a higher sedative effect with a longer lasting period when compared to Midazolam/Hydroxyzine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010616106N1**
Registration date: **2014-02-05, 1392/11/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-02-05, 1392/11/16

Registrant information

Name

Ghassem Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran Center For Dental Research, Shahid Beheshti Medical University

Expected recruitment start date

2010-10-11, 1389/07/19

Expected recruitment end date

2011-07-20, 1390/04/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the sedative effect of oral Midazolam/Hydroxyzine vs Chloral hydrate/Hydroxizine in behavior control of 6-10 year old uncooperative children.

Public title
Oral Sedation in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: cases with a behavioral score of 2 in Frankel scale system (Uncooperative); those with at least two similar dental needs; ages of 6-10 years old; able to attend two visits scheduled for dental treatments; able to keep 4 hours NPO prior to sedation. Exclusion criteria: clear from any medical condition (out of the ASA I & II); taking any sedative, narcotic or CNS depressant drug; those who have cold or other respiratory obstruction; those having fever of known or unknown origin; unable to observe 4 hours of NPO; unable to accept the drugs administered due to taste or volume.
Age
From **6 years** old to **10 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Each patient was seen in two separate visits in order to allow a comparison on the same patient preventing any influential factor to interfere with the outcome.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti Medical University, Ethic Committee
Street address
Dental School, Students Blvd, Evin
City
Tehran
Postal code
19863
Approval date
2010-11-16, 1389/08/25
Ethics committee reference number
12-168

Health conditions studied

1

Description of health condition studied
Behavior Control at the Dental Clinics
ICD-10 code
F50-F59
ICD-10 code description
Behavioural syndromes associated with physiological disturbances and physical factors

2

Description of health condition studied
Uncooperative behavior in dental clinic
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Assessing the success rate in child management
Timepoint
Exactly after the operation ends
Method of measurement
Behavior Assessment indices

2

Description
Child cooperation for Dental treatment delivery
Timepoint
Immidiately after the treatment end
Method of measurement
Judged by independent pediatric dentist and the operator

Secondary outcomes

1

Description
Potential side effects of the drugs
Timepoint
End of1st year of the study
Method of measurement
Questionnaire and behavioral scales

2

Description
Assessing the success rate in each group
Timepoint
Half way assessments of the collected data
Method of measurement
Employing behavioral rating scales available

Intervention groups

1

Description
Chloral Hydrate (50 mg/kg) /Hydroxyzine (1 mg/kg) both suspension form were given to children of the case group (oral mode), 1/2 hour before treatment start along with full monitoring the vital signs every 15 minutes starting from thew drug administration time to the discharge stage.
Category
Treatment - Drugs

2

Description
Oral suspension of Midazolam(0.5 mg/kg) along side Hydroxyzine elexir (1mg/kg)was administered in Control session 30 minutes prior to the starting point of the dental treatment in one dose. All vital signs were monitored thoroughly and details were recorded for further analysis.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental School, Shahid Beheshti Medical University
Full name of responsible person
Dr Ghassem Ansari
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2

Recruitment center
Name of recruitment center
Shahid Beheshti Medical University
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran Center for Dental Research, Shahid Beheshti Medical University
Full name of responsible person
Dr. Mohammad Reza Safavi
Street address
Research Center, Dental School, Shahid Beheshti Medical University, Evin
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran Center for Dental Research, Shahid Beheshti Medical University
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 Medical University
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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