

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparing the sedative effect of oral Midazolam/Hydroxyzine vs Chloral hydrate/Hydroxyzine 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 behavior following 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)

Phone

+98 21 2225 5958

Email address

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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/Hydroxyzine 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

Immediately 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 of 1st 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 the drug administration time to the discharge stage.

Category

Treatment - Drugs

2

Description

Oral suspension of Midazolam(0.5 mg/kg) along side Hydroxyzine elixir (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

Street address

Dental School, Student's Blvd

City

Tehran

2

Recruitment center

Name of recruitment center

Shahid Beheshti Medical University

Full name of responsible person

Ghassem Ansari

Street address

Dental School, Students Blvd, Evin

City

Tehran

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

Full name of responsible person

Ghassem Ansari

Position

PhD, Professor

Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti Medical University

Full name of responsible person

Ghassem Ansari

Position