

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial of comparison of intranasal midazolam and inhalation sedation (N2O/O2) on 3 to 6 year-old children`s behavior under dental treatments

Protocol summary

Summary

Title: A clinical trial of comparison of intranasal midazolam and inhalation sedation (N2O/O2) on 3 to 6 year-old children`s behavior under dental treatments
Objectives: Evaluation of the effect of intranasal midazolam and inhalation sedation (N2O/O2) on 3 to 6 year-old children`s behavior under dental treatments.
Design: Randomized cross over clinical trial
Setting and conduct: 14 samples were randomly sedated once by the combination of intranasal midazolam with nasal drops of 2% lidocaine hydrochloride without inhalation sedation(A) and once with the combination of inhalation sedation(N2O/O2) with intranasal lidocaine/midazolam (B) in the next session on the same patient . Houpt scoring system was used to evaluate patient`s behavior and depth of the sedation. To compare the redundancy of the items with regards to cross-over design of the study, wilcoxon-Signe Rank test was used. Participants: 14 patients aged 3 to 6 years old
Variables eligibility criteria: No nasal obstruction; respiratory infection; limitation of neck movement; macroglosia; tonsil hypertension; micrognathia and limitation of mouth opening; ASA=1; at least two sessions needed including pulpotomy or filling of primary upper or lower molar; uncooperative children
Interventions: Administeration of intranasal midazolam and inhalation sedation(N2O/O2)
Main outcome measures: Children`s behaviour under dental treatments

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111930971N1**
Registration date: **2017-09-27, 1396/07/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-27, 1396/07/05

Registrant information

Name

Nahid Askarizadeh

Name of organization / entity

Dental branch, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21225645713

Email address

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-06-27, 1391/04/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of comparison of intranasal midazolam and inhalation sedation (N2O/O2) on 3 to 6 year-old children`s behavior under dental treatments

Public title

Effect of sedation on children`s behaviour

Purpose

Treatment

Inclusion/Exclusion criteria

No nasal obstruction; respiratory infection; limitation of neck movement; macroglosia; tonsil hypertension; micrognathia and limitation of mouth opening; ASA=1; at least two sessions needed including pulpotomy or filling of primary upper or lower molar; uncooperative children

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee , Dental branch, Islamic Azad University, Tehran

Street address

Dental branch, Islamic Azad University, No 4, 10th Neyestan alley, Pasdaran ave, Tehran

City

Tehran

Postal code

Approval date

2011-10-02, 1390/07/10

Ethics committee reference number

692

Health conditions studied

1

Description of health condition studied

behaviour

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

behaviour

Timepoint

The same day

Method of measurement

Houpt scoring system

Secondary outcomes

1

Description

Depth of sedation

Timepoint

Same day

Method of measurement

Houpt scoring system

Intervention groups

1

Description

Administration of 0.5 mg/kg infusion midazolam via intranasal route in addition to inhalation sedation to the intervention group

Category

Behavior

2

Description

Administration of 0.5 mg/kg infusion midazolam via intranasal route to the control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental branch, Islamic Azad University

Full name of responsible person

Dr Nahid Askarizadeh

Street address

No 4, 10th Neyestan, Pasdaran St, Dental branch, Islamic Azad University, Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Dental branch, Islamic Azad University

Full name of responsible person

Dr Nahid Askarizadeh

Street address

No 4, 10th Neyestan, Pasdaran St, Dental branch, Islamic Azad University

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Dental branch, Islamic Azad 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**

Dental branch, Islamic Azad University

Full name of responsible person

Dr Nahid Askarizadeh

Position

Associate Professor

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Yasaman Rezvani

Position

Faculty member of pediatric ward

Other areas of specialty/work**Street address**

Shahid Beheshti University of Medical Sciences, Pediatric ward, Velenjak avenue

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Web page address**Person responsible for updating data****Contact****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