

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intranasal midazolam and dexmedetomidin premedication effect on 2-6 years old uncooperative children behavior in dentistry

Protocol summary

Summary

The aim of this study is comparison effect of intranasal midazolam and dexmedetomidine on 2-6 years old children behavior in pediatric dentistry. This cross-over double blind randomized controlled trial is carried on twenty 2-6 years old children referred to dental school based on inclusion criteria: Healthy according ASA1 classification; uncooperative negative and definitely negative as frankl scale; having at least 2 sessions dental work and exclusion criteria: Cold; tonsils hypertrophy; severe obesity. After obtaining written informing consent, written and orally instructions before conscious sedation, at first meeting the first group receives 0.2 mg/kg Midazolam intranasal(Regimen A) and the second group receives 1 µg/kg Dexmedetomidine intranasal(Regimen B). In the second session, the first group receive regimen B and the second group B receives regimen A. After 20 minutes premedication every patient receives 0.1 mg/kg Midazolam and 1-2 mg/kg Ketamine and 0.25 mg Atropine intravenously. Dental treatment starts with lidocaine 2% with adrenaline 1/80000 anesthesia by a pedodontist who is blind to type of regimen. Sedation level and the child's behavior based on Houpt scale evaluates by a member of teamwork who does not aware of the type of regimen. Arterial blood oxygen saturation (SpO2), heart rate (HR) and blood pressure before administration, starting, every 15 minutes during the work, after work and discharge patients records in related form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601281882N7**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Faculty of Dentistry, Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 3010

Email address

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Recruitment status

Recruitment complete

Funding source

All costs of the project is paid by Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences Tehran, Iran.

Expected recruitment start date

2016-02-13, 1394/11/24

Expected recruitment end date

2016-08-10, 1395/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intranasal midazolam and dexmedetomidin premedication effect on 2-6 years old uncooperative children behavior in dentistry

Public title

Premedication effect of intranasal midazolam and dexmedetomidine on children behavior

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy 2-6 years old children:
Uncooperative negative and definitely ranked as Frankel scale: having at least two sessions dental treatment
Exclusion criteria: Cold and allergy:Tonsils hypertrophy more than 50%: severe obesity

Age

From **2 years** old to **6 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 of Shahid Beheshti University of
Medical Sciences,Tehran, Iran

Street address

Shahid Beheshti Dental University of Medical
Sciences, Daneshjo Blvd, Evin

City

Tehran

Postal code

Approval date

2015-12-22, 1394/10/01

Ethics committee reference number

IR.SBMU.RIDS.REC.1394.73

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

Primary outcomes

1

Description

Conscious sedation

Timepoint

Every 15 minutes

Method of measurement

Houpt scale

Secondary outcomes

1

Description

SpO2

Timepoint

Every 15 minutes

Method of measurement

pulse ooxymeter

Intervention groups

1

Description

Dexmedotimidine 1µg/kg, intranasal

Category

Treatment - Drugs

2

Description

Midazolam 0.2 mg/kg, intranasal

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Dental School

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

Street address

Evin, Daneshjo Blvd, Shahi Beheshti Dental School

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Evin, Daneshjo Blvd, Shahid Beheshti university of
Medical Sciences

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, Shahid Beheshti University
of Medical Sciences

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**

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Web page address

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