

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison the sedative effect of intranasal administration of midazolam and Dexmedetomidine in uncooperative 4 to 6 years of age pediatric dental patients

Protocol summary

Summary

The aim of this study is to compare the effectiveness of two sedative agents including Intranasal Midazolam and Dexmedetomidine among uncooperative pediatric dental patients. The double blind randomized study will be conducted in parallel groups. The study participants include one hundred healthy (ASA I) uncooperative 4 to 6 years of age dental patients who are referred to specialized clinic of Pediatric Dentistry of Guilan Dental School who are and behavior are classified Negative or Definitely Negative (scores 1 and 2) according to Frankl Behavioral Scale. Those children with a history of allergic reactions to any of above mentioned agents or any other sedatives, as well as history of sleep apnea, delayed growth or mental retardation, any previous adverse reaction to sedation or general anesthesia, and those children who refuse to accept the drug administration, and who have a history of upper respiratory infection or nasal secretion during the past two weeks will be excluded from study. The participants are randomly assigned in to one of two experimental groups to receive either midazolam 0.2 mg/kg or Dexmedetomidine 1µg/kg. Sedation status will be evaluated using Houpt Sedation Rating Scale from aspects of Sleep, Crying, Movement and Overall sedation status. Vital signs including Oxygen saturation (SpO2), Heart Rate, Blood Pressure, and Respiratory Rate are recorded before drug administration and then the child will be transferred to dental chair after 15 minutes. The Vital signs will be recorded again at beginning of the treatment and then every 15 minutes until the end of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409141861N5**

Registration date: **2014-09-23, 1393/07/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-23, 1393/07/01

Registrant information

Name

Katayoun Salem

Name of organization / entity

Tehran Azad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 0966

Email address

nastaranegar@gmail.com

Recruitment status

Recruitment complete

Funding source

Grant from research committee of Guilan University of Medical Sciences

Expected recruitment start date

2014-10-02, 1393/07/10

Expected recruitment end date

2015-04-30, 1394/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the sedative effect of intranasal

administration of midazolam and Dexmedetomidine in uncooperative 4 to 6 years of age pediatric dental patients

3920422813

Health conditions studied

1

Description of health condition studied

Sedation

ICD-10 code

F-93.1

ICD-10 code description

Phobic anxiety disorder of childhood

Primary outcomes

1

Description

Overall behavior

Timepoint

At the end of treatment session

Method of measurement

Houpt Sedation Rating Scale

2

Description

Sleep

Timepoint

During treatment

Method of measurement

Houpt Sedation Rating Scale

3

Description

Movement

Timepoint

During treatment

Method of measurement

Houpt Sedation Rating Scale

4

Description

crying

Timepoint

During treatment

Method of measurement

Houpt Sedation Rating Scale

5

Description

Dental fear

Timepoint

At the end of treatment session

Method of measurement

Questinnaire

Public title

Comparison of intranasal midazolam and Dexmedetomidine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Uncooperative pediatric dental patients; age 4 to 6 years; negative or definitely negatively Behavioral; healthy (ASA I); need at least one dental appointment including injection and pulp treatment. Exclusion criteria: History of allergy to either administered agents or other sedatives; sleep apnea; delayed in growth; mental retardation; allergic reaction to other sedatives or general anesthesia; nonacceptance of drug administration; upper respiratory infection or nasal secretions during the past two weeks.

Age

From **14 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Guilan University of Medical Sciences

Street address

Rasht, Gaz Square, West shahid Beheshti Blvd, Vice Chancellor of Research and Technology

City

Rasht

Postal code

Approval date

2014-02-22, 1392/12/03

Ethics committee reference number

6

Description

Behavior problems

Timepoint

Before treatment

Method of measurement

SDQ Questionnaire

7

Description

Arterial blood oxygen saturation (SpO₂)

Timepoint

Before drug administration, at the beginning of treatment, and then every 15 minutes until the end of treatment

Method of measurement

Pulse oximeter

8

Description

Heart rate

Timepoint

Before drug administration, at the beginning of treatment, and then every 15 minutes until the end of treatment

Method of measurement

Pulse oximeter

9

Description

Respiratory Rate

Timepoint

Before drug administration, at the beginning of treatment, and then every 15 minutes until the end of treatment

Method of measurement

Counting the number of chest movements by examiner

10

Description

Systolic and diastolic Blood Pressure

Timepoint

Before drug administration, at the beginning of treatment, and then every 15 minutes until the end of treatment

Method of measurement

Digital pressure measurement device

Secondary outcomes

1

Description

Intra-nasal drug acceptance

Timepoint

At the time of drug administration

Method of measurement

Observation(Hass method)

2

Description

Adverse effects including

Timepoint

Mucosal irritation, coughing, sneezing, nausea, vomiting

Method of measurement

Observation

Intervention groups

1

Description

Control: Midazolam 0.2 mg/kg, 15 minutes before dental treatment. The drug will be calculated by insulin syringe and sprayed without dilution in each nostril in 5 to 10 seconds intervals in semi supine position.

Category

Treatment - Drugs

2

Description

Intervention: Dexmedetomidine 1µg/kg 15 minutes before treatment. The drug will be calculated by insulin syringe and sprayed without dilution in each nostril in 5 to 10 seconds intervals in semi supine position.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinic of Guilan Dental School

Full name of responsible person

Katayoun Salem

Street address

Rasht. Imam blvd. opposite Pardis Hotel

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chnceller of research and technology

Full name of responsible person

Dr Rasoul Tabari

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City

Rasht

Grant name

طرح‌های پژوهشی

Grant code / Reference number

3920422813

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chnceller of research and technology

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**

Guilan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

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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*