Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

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

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 refereed 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)

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Recruitment status

Recruitment complete

Funding source

Grant from research commitee 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 pediatriientsc dental pat

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 Chnanceller of Resarch and Technology
City
Rasht
Postal code
Approval date
2014-02-22, 1392/12/03
Ethics committee reference number
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

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 acceptence
Timepoint
At the time of drug administeration
Method of measurement
Observation(Hass method)

2

Description
Adverse effects including
Timepoint
Mucosal irritation, coughing, sneezing, nausia, vomitting
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
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chnceller of research and technology
Full name of responsible person
Dr Rasoul Tabari
Street address
Rasht, Gaz square, West Shahid Beheshti Blvd, Opposit e Sepah Bank,Vice chnceller of research and technology
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
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katayoun salem
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Person responsible for updating data

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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