Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Intranasal midazolam/ketamine sedation of 3-6 year old uncooperative dental patients

Protocol summary

Summary

In this double blind randomized controlled trial, 20 uncooperative 3-6 year old children with scorers 1,2 Frankle and ASA 1,2 health condition that need at least 2 treatment session after taking written informed consent divide into 2 groups randomly.Group 1 take combination of 10mg/kg ketamine+ 0.5mg/kg midazolam as intranasal and group 2 take the same combination as oral in fist session.Both groups receive the alternate treatment protocol at their second session.The rate of sedation and behavior assessing do by Houpt criteria and pulse oxymeter beginning, 15 and 30 minutes respectively. Also the parent consent, practitioner, side effects of sedation, recovery time ,drowsiness at home assess. Collected data were analyzed using Wilcoxon and paired-t test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305101882N3**
Registration date: **2014-06-26, 1393/04/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-26, 1393/04/05

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Facualty of Dentistry, Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

All costs of research will be provided by shahid Beheshti University of Medical Sciences, Dental Science Research Center .

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-06-26, 1392/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intranasal midazolam/ketamine sedation of 3-6 year old uncooperative dental patients

Public title

sedative effect of intranasal ketamine/midazolam on 3-6 year old children behavior in pediatric dentistry

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Frankle 1,2 uncooperative child 2-ASA 1,2 healthy child 3-Needs to at least 2 treatment session Exclusion criteria: 1- Nasal obturation 2-Respratory infection 3-Tonsile hypertrophy 4-Macroglosia

Age

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

Gender

Both

Phase
0
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
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Dental School, Buliv. Daneshjoo, Evin
City
Tehran
Postal code
Approval date
2012-07-09, 1391/04/19
Ethics committee reference number
17th session

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F98-F90
ICD-10 code description
F13

Primary outcomes

1

Description
Sleeping
Timepoint
After effect of drug, 15 and 30 minutes
Method of measurement
Observation and Houpt Scale

2

Description
Crying
Timepoint
After effect of drug, 15 and 30 minutes
Method of measurement
Observation and Houpt Scale

3

Description
Movement
Timepoint
After effect of drug, 15 and 30 minutes
Method of measurement
Observation and Houpt Scale

4

Description
Overall Behavior
Timepoint
After effect of drug, 15 and 30 minutes
Method of measurement
Observation and Houpt Scale

Secondary outcomes

1

Description
Heart Rate
Timepoint
Befor treatment, after effect of drug, 15and 30 minutes
Method of measurement
Pulse oxymeter

2

Description
Spo2
Timepoint
Befor treatment, after effect of drug, 15and 30 minutes
Method of measurement
Pulse oxymeter

Intervention groups

1

Description
First visit Case group: Intranasal 10mg/kg ketamine+ 0.5mg/kg midazolam Control group: Oral 10mg/kg ketamine+ 0.5mg/kg midazolam
Category
Treatment - Drugs

2

Description
Second visit Control group: Intranasal 10mg/kg ketamine+ 0.5mg/kg midazolam Case group: Oral

10mg/kg ketamine+ 0.5mg/kg midazolam

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

Dental school, Daneshjoo BUlivrd., Evin

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Research Center,Research Institute of Dental sciences

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

Street address

Dental school, Daneshjoo BUlivrd., Evin

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dental Research Center,Research Institute of Dental 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

Research Dental Center

Full name of responsible person

Dr.AA Soleymani

Position

Pedodontist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Pedodontist/Associated Professor

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Person responsible for updating data

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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