

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

Faculty of Dentistry, Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 3010

Email address

masfalnegh@sbmu.ac.ir

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- Respiratory 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

Street address

Dental school, Daneshjoo BUlivrd., Evin

City

Tehran

Postal code

1983963113

Phone

+98 21 2241 3897

Fax

Email

asoleimani@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Dental Center, Institute Research Dental Sciences

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

Position

Pedodontist/Associated Professor

Other areas of specialty/work

Street address

Dental school, Daneshjoo BUlivrd., Evin

City

Tehran

Postal code

Phone

+98 21 2240 3080

Fax

Email

masoudfallah36@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti Dental School

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

Position

Pedodontist/Associate Professor

Other areas of specialty/work

Street address

Dental school, Daneshjoo BUlivrd., Evin

City

Tehran

Postal code

Phone

+98 21 2240 3080

Fax

Email

masoudfallah36@yahoo.com

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