

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of two method of intravenous sedation in control of uncooperative children for dental treatment

Protocol summary

Summary

Appointment and comparison effect of two methods of intravenous sedation include midazolam- ketamine with midazolam- fentanyl in uncooperative children for dental treatment. The patients were disported to the two groups randomized. First group received IV injection of 0.05 mg/kg midazolam and 0.5 mg/kg ketamin every 2 minutes and second group received IV injection of 0.05 mg/kg midazolam and 0.5 microgr/kg fentanyl every 2 minutes. During the operation in both group will given 0.25 mg midazolam if it need, and evaluate the rate of the efficacy of two drug group in control of children during and after of operation. Evaluate the side effect of drug include agitation, fear of the injection, nausea and vomiting too. Evaluated, recorded and analysis the sedation score and work condition by Dental Sedation Teachers Group (DSTG) system every 10 minutes during the operation. After the end of the operation patients looking after the standard observation in recovery and after catch the releasing condition is released by appropriate instruction. The patient is getting under observation by anesthetic proficient during the operation and vital sign, saturation rate of oxygen is getting under observation by pulse oxymetry device. The dentist is doing the local anesthesia injection include lidocain 2% and epinephrin 1/80000 in the location of the operation. The patient study and endorse the testimonial form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303144224N22**

Registration date: **2014-04-28, 1393/02/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-28, 1393/02/08

Registrant information

Name

Nasser Kaviani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Khorasgan Branch

Expected recruitment start date

2013-12-06, 1392/09/15

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two method of intravenous sedation in control of uncooperative children for dental treatment

Public title

Comparison of two method of intravenous sedation in control of uncooperative children for dental treatment

Purpose

Treatment

Inclusion/Exclusion criteria

children ASA I,II; age between 4-9 years old; have satisfaction for study; need dental treatment with

intravenous sedation; don't have psychological problem; don't have insufficient of renal and liver, and COPD and asthma and epilepsy and insufficient of aura; don't have bad history after dental treatment; don't have allergy to the used medicine.

Age

From **4 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

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

Islamic Azad University khorasgan branch,college of dentistry

Street address

Islamic Azad University Khorasgan branch(Isfahan), Arghavanieh, Jey st, Isfahan, Iran

City

Isfahan

Postal code

81551-39998

Approval date

2013-12-02, 1392/09/11

Ethics committee reference number

493007

Health conditions studied

1

Description of health condition studied

child control with dental afride

ICD-10 code

F93.1

ICD-10 code description

Phobic anxiety disorder of child

Primary outcomes

1

Description

sedation score

Timepoint

10 and 20 and 30 and 40 minutes during operation

Method of measurement

observation and completion of questionnaire

Secondary outcomes

1

Description

work condition

Timepoint

10 and 20 and 30 and 40 minutes during operation

Method of measurement

observation and completion of questionnaire

Intervention groups

1

Description

Prescription drug first group: 0.05 mg/kg midazolam and 0.5 mg/kg ketamin intravenously every 2 minutes from each other befor dental treatment

Category

Treatment - Drugs

2

Description

second group: 0.05 mg/kg midazolam and 0.5 microgr/kg fentanyl intravenously every 2 minutes from each other befor dental treatment. During the operation in both group will given 0.25 mg midazolam if it need,

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating Room of Dental Faculty of University of Medical Sciences

Full name of responsible person

Dr Naser Kaviani

Street address

Dental school, University of Medical Sciences, Darvazeh shiraz,Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research ministry of Islamic Azad University of Khorasgan

Full name of responsible person

Dr vahid esfahanian

Street address

Islamic Azad University Khorasgan branch(Isfahan), Arghavanieh, Jey st, Isfahan, Iran

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research ministry of Islamic Azad University of Khorasgan

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**

Islamic Azad University Khorasgan Branch, College of Dentistry

Full name of responsible person

Sanaz Ashrafi

Position

Student of dentistry

Other areas of specialty/work**Street address**

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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