Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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Iran (Islamic Republic of)
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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 minestiry ofIslamic 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
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Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research minestiry ofIslamic 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

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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