

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessing and comparing of Midazolam/Propofol and Ketamin/Propofol intravenous sedation in anxiety children for dental treatment

Protocol summary

Summary

Objectives: Fear and anxiety of some children in dentistry lead to problem that they don't have successful treatment. Because of the necessity of dental treatment in anxiety and uncooperative children in this study we want to compare sedation of different drugs and use them in children sedation center. Design: This is double blind randomized, clinical trial study. Setting and conduct and Participants including major eligibility criteria: 32 anxiety children of ages 6-8 that referring to sedation center, treatment needs only on left side of upper jaw evaluated in 2 groups. Intervention: Intravenous conscious sedation in first group with Midazolam/Propofol and in second group with Ketamin/Propofol is injected. Main outcome measures (variables): Sedation score of patient in 4 different times, during dental treatment and operating conditions at the end of the treatment, according to dental sedation teacher group (DSTG) is measured. Data analyzed with SPSS, Mann-Whitney, Wilcoxon and Friedman tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203124224N19**

Registration date: **2013-05-04, 1392/02/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-04, 1392/02/14

Registrant information

Name

Nasser Kaviani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

kaviani@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research of Isfahan university of medical sciences, Isfahan dental school, Hezar Jarib street, Isfahan, Iran.

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing and comparing of Midazolam/Propofol and Ketamin/Propofol intravenous sedation in anxiety children for dental treatment

Public title

Assessing and comparing of 2 different intravenous sedation drugs in anxiety children for dental treatment

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion Criteria: Children ages 6-8; Uncooperative; Negative in Frankel grading; No specific disease; ASA I; No need to extraction; Treatment needs only on left side of upper jaw; No contraindication of sedation. Exclusion criteria: Emergency event during study; Dental treatment more than 45 minutes.

Age

From **6 years** old to **8 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **32**

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**

Ethics committee of Isfahan university of medical science

Street address

Dental school, University of medical sciences, Hezar Jerib st, Isfahan

City

Isfahan

Postal code**Approval date**

2012-12-09, 1391/09/19

Ethics committee reference number

391306

Health conditions studied**1****Description of health condition studied**

Dental Anxiety

ICD-10 code

F-40

ICD-10 code description

Phobic anxiety disorders

Primary outcomes**1****Description**

Sedation grade

Timepoint

In 4 different times during dental treatment

Method of measurement

According to DSTG score

Secondary outcomes**1****Description**

Operating conditions

Timepoint

One time at the end of the dental treatment

Method of measurement

DSTG score

Intervention groups**1****Description**

Admistartion1 drug regime to1 patients groups: 1-Midazolam/Propofol(Midazolam 0.01mg/kg only one time at the beginning of the dental treatment throughout IV injection and after 5 minutes Propofol drug 0.05mg/kg with infusion pump system throughout IV injection during the whole dental treatment up to 45 minutes)

Category

Treatment - Drugs

2**Description**

Admistartion1 drug regime to1 patients groups: 1-Ketamin/Propofol(Ketamin 0.05mg/kg only one time at the beginning of the dental treatment throughout IV injection and after 5 minutes Propofol drug 0.05mg/kg with infusion pump system throughout IV injection during the whole dental treatment up to 45 minutes)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental school of Isfahan university of medical science

Full name of responsible person

dr. Mina Shahtoosi

Street address

Pediatric center, Isfahan dental school, Isfahan university of medical science

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research of Isfahan university of medical sciences

Full name of responsible person

Mr Tavangar

Street address

Dentistry school, Hezar Jarib street, Isfahan

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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

Vice chancellor for Research of Isfahan university of medical 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

Dental school, Isfahan university of medical science

Full name of responsible person

Mina Shahtoosi

Position

Post graduate student of pediatric dentistry

Other areas of specialty/work

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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