

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the IV sedation effect of ketamine/propofol and ketamine/midazolam in dental treatments of 2-6 years old uncooperative children

Protocol summary

Study aim

Intravenous sedation effect of Ketamine/Propofol and Ketamine/Midazolam on Non-Cooperative Pediatric Dental Patient 2-6 Years Old

Design

Randomized clinical trial, triple blindness, cross control group. Twenty 2-6 years old children divide into two intervention and control groups with flipping a coin. Trial phase is 3.

Settings and conduct

Children are randomly assigned to one of two groups of cases and controls. 30 minutes before starting treatment 0.3Mg / kg midazolam is given orally to the patient as premedication. Group A: first session 2 mg/kg ketamine and 2 mg/kg Propofol and group B: first session 2 mg/kg Ketamine and 0.2 mg/kg midazolam by intravenous injection They receive treatment from the beginning. In both groups, the order of medication in the second session is reversed. The drugs are given to the patient by the person who is unaware of the dose of the drug and the patient is not aware of the composition of the drug. The pulse oximeter probe is also placed on the child's finger to record the amount of changes in blood oxygen(SpO2) and pulse rate(PR) obtained in the form of each patient. Dental treatment begins with local anesthesia of 2% lidocaine and 1/100,000 epinephrine. Rate of crying, drowsiness and movement; at the time of anesthesia injection and 15 minutes and 30 minutes from the start of work with the Houpt scale is evaluated and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Uncooperative 2-6 year old children, need 2 sessions similar treatment. Exclusion criteria: Suffering systemic diseases, common cold.

Intervention groups

Ketamine 2mg/kg+ Propofol 2mg/kg and Ketamine 2mg/kg+ Midazolam 0.2 mg/kg

Main outcome variables

Success of dental treatment according to Houpt Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090506001882N10**

Registration date: **2021-03-08, 1399/12/18**

Registration timing: **prospective**

Last update: **2021-03-08, 1399/12/18**

Update count: **0**

Registration date

2021-03-08, 1399/12/18

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Faculty of Dentistry, Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the IV sedation effect of ketamine/propofol and ketamine/ midazolam in dental treatments of 2-6 years old uncooperative children

Public title

Sedative effect of ketamine / propofol and ketamine / midazolam on non-cooperating children in pediatric dentistry

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Be in the negative group be Frankel's behavioral classification. Requires at least 2 similar treatment sessions. Be in the ASAI group. Be 2 to 6 years old.

Exclusion criteria:

Suffering Systemic Disease.. Colds during in treatment session. Non-prescription medication including allergies and treatment needs different from protocol.

Age

From **2 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is conducted using Coin toss with patient placed in one of the two groups of A or B on that basis.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug combination is given to the patient by the anesthesiologist. Patient and researcher and evaluator do not know the dose of the drug.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Institute of Dental Sciences, Shahid

Beheshti University of Medical Sciences

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5th Floor, Dental School, Blvd. Daneshjoo, Evin, Tehran, Iran.

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Approval date

2021-03-01, 1399/12/11

Ethics committee reference number

IR.SBMU.DRC.REC.1399.127

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

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

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

Conscious sedation

Timepoint

Every 15 minutes

Method of measurement

Houpt scale

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

SpO2

Timepoint

Every 15 minutes

Method of measurement

Pulse oximeter

2**Description**

Heart rate

Timepoint

Every 15 minutes

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group: Intravenous injection of 2mg/kg Ketamine(50mg/cc, Rotexmedica Co., Germany)+2mg/kg Propofol(10mg/cc Fresenius C.,Austria)

Category

Treatment - Drugs

2

Description

Intervention group: Intravenous injection of 2mg/kg Ketamine (50mg/cc, Rotexmedica Co., Germany)+0.2mg/kg Midazolam(5mg/cc,Darupakhsh Co., Iran)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences, Dental School

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoud Fallahinejad Ghajari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available