Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effect of propofol/ketorolac/Apotel with propofol / Fentanyl IV sedation in dental treatments of 2-6 years old uncooperative children

Protocol summary

Study aim

Comparing of Propofol/Ketorolac/Apotel with Propofol/Fentanyl IV Sedation in Dental Treatments of 2-6 Years Old Uncooperative Children.

Design

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

Settings and conduct

Children are randomly placed in one of two study(A) and control(B) groups. Thirty minutes before the start of treatment, oral midazolam(0.5 mg/kg) is given to the child as a premedication in all sessions. In group A, in the first session, intravenous Propofol/Ketorolac/Apotel (1mg/kg, 0.5mg/kg and 20mg/kg respectively) and in the second session intravenous Propofol/ Fentanyl(1mg/kg and 1µg/kg respectively) combination is administered by the anesthesiologist. In group B, the order of drug administration is reversed to that of group A. The patient, the therapist and the evaluator do not know the type of sedative drug. Then the dental treatment is performed with 2% lidocaine anesthesia injection. Throughout each session, SpO2 oxygen saturation and heart rate are recorded during the intravenous injection of drugs, after anesthesia injection, every 15 minutes during treatment and during discharge. The degree of sedation is done by evaluating the amount and quality of sedation based on the Houpt criteria, parameters SPO2 and Heart Rate. Side effects of drugs including nausea, vomiting, behavioral changes in recovery and 24 hours after treatment are reviewed and compared.

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

2mg/kg Propofol+ 0.5mg/kg Ketorolac+ 20mg/kg Apotel and 1mg/kg Propofol+1µg/kg Fentanyl

Main outcome variables

Success of dental treatment according to Houpt Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090506001882N11**
Registration date: **2023-01-22, 1401/11/02**
Registration timing: **prospective**

Last update: **2023-01-22, 1401/11/02**
Update count: **0**

Registration date

2023-01-22, 1401/11/02

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Facualty 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

2023-02-04, 1401/11/15

Expected recruitment end date

2023-06-12, 1402/03/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of propofol/ketorolac/Apotel with propofol / Fentanyl IV sedation in dental treatments of 2-6 years old uncooperative children

Public title

Evaluation of propofol / ketorolac / Apotel sedation with intravenous propofol / fentanyl in dental treatment of uncooperating children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be in the negative group of 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: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done by flip a Coin, tap or line and the patients stay on of the groups A or B.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug combination is given to the patient by the anesthesia technician. 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

Ethics Organization Committee in Biomedical Researches, Institute of Dental Research

Street address

Shahid Beheshti University, Daneshjoo Blv., Evin

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1983963113

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.SBMU.DRC.REC.1401.027

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 1mg/kg Propofol(10mg/cc Fresenius Co., Austria)/0.5mg/kg Ketorolac( )/20mg/kg APOTEL( )
Category
Treatment - Drugs

2

Description
Intervention group: Intravenous injection of 1mg/kg Propofol(10mg/cc Fresenius Co., Austria)/1µ/kg Fentanyl( )
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti University of Medical Siences, Dental School
Full name of responsible person
Dr. Masoud Fallahinejad Ghajari
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Sponsors / Funding sources

1

Sponsor
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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
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Position
Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

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