

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the effects of propofol/fentanyl and propofol/apotel for IV sedation during the dental treatment of 2-6 years old preoperative pediatric patients

Protocol summary

Study aim

Intravenous sedation effect of apotel/Propofol and Fentanyl/propofol on Non-Cooperative 2-6 Years Old Pediatric Dental Patients

Design

Randomized clinical trial, triple blindness, cross control group. Thirty eight 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 control and case groups. 30 minutes before the start of the treatment 0.5 mg/kg midazolam is given orally to the patient. Group A: 15 mg/kg Apotel and 2 mg/kg propofol in the first session and group F: 1 microgram/kg fentanyl and 2 mg/kg propofol in the first session. In both groups, the order of drug administration is reversed in the second session. Medicines are given to the patient by the anesthesiologist, and the patient, dentist and evaluator are not aware of the composition of the medicine. The pulse oximeter probe is also placed on the child's finger. Dental treatment begins with local anesthesia of lidocaine 2% and epinephrine 1/100,000. The rate of changes in blood oxygen saturation and heart rate, the rate of crying, sleepiness and movement; At the time of venipuncture, local anesthesia injection, 15 minutes and 30 minutes from the start of work, 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

Apotel 15 mg/kg + propofol 2 mg/kg and Fentanyl 1 microgram/kg + propofol 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: **IRCT20221203056700N1**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **prospective**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name

Maryam Shamsaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2237 0439

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of propofol/fentanyl and propofol/apotel for IV sedation during the dental treatment of 2-6 years old preoperative pediatric patients

Public title

effects of propofol/apotel and propofol/fentanyl on dental sedation of 2-6 years old uncooperative children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

2-6 years old children Uncooperative Need to at least two same and symmetric treatment session ASA 1 health status

Exclusion criteria:

The age under 2 and above 6 years Cooperative Lack of similar treatment needs ASA 2 and more

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: **38**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each patient gives apotel in one session and fentanyl in other one.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done using flipping a coin and the patient is placed in one of groups A or F 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 type and 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 Committee of Shahid Beheshti University of Medical Sciences

Street address

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

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Postal code

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Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.SBMU.DRC.REC.1401.032

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

Venipuncture, local anesthesia and Every 15 minutes

Method of measurement

Haupt scale

Secondary outcomes

1

Description

SPO2

Timepoint

Venipuncture, local anesthesia and every 15 minutes

Method of measurement

Pulse oximeter

2

Description

Heart rate

Timepoint

Venipuncture, local anesthesia and every 15 minutes

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group1: intravenous administration of 15 mg/kg apotel (1g/6.7ml) + 2 mg/kg propofol (10mg/cc Fresenius C.,Austria)

Category

Treatment - Drugs

2

Description

Intervention group2: intravenous administration of 1mcg/kg fentanyl (ml10/mg 5/0 , Caspian Tamin/ Iran) + 2 mg/kg propofol (10mg/cc Fresenius C.,Austria)

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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Full name of responsible person

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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