

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of the sedative effects of Intra-Venous Propofol / Fentanyl combination Vs. Ketamine / Midazolam combination for uncooperative 2-6 year old children undergoing dental procedures.

Protocol summary

Study aim

Comparative evaluation of the sedation efficacy, effects and safety of intra-Venous infusion of Propofol / Fentanyl combination versus Ketamine / Midazolam combinations in a group of uncooperative 2-6 year old children undergoing dental procedures.

Design

Double blind , randomized, cross over clinical trial carried out on 24 patients

Settings and conduct

This study will be performed on uncooperative children referred to the pediatric dentistry fellowship department of Shahid Beheshti dental faculty who need two similar dental procedures. They will be divided into groups AB and BA randomly. In group AB, in the first treatment session, drugs regimen A (Propofol/Fentanyl) and in the second treatment session, drugs regimen B (Ketamine/Midazolam) will be used for sedation. In group BA, the use of sedative drugs, will be reversed. All physiologic and behavioral parameters will be recorded during various stages of treatment by a trained assistant. The choice of drug regimen, medication of drugs and control of the patient 's vital signs will be done by an anesthesiologist without the knowledge of the treating dentist and the parents

Participants/Inclusion and exclusion criteria

Inclusion criteria: A- Uncooperative 2-6 years old children B- Patient in ASA I C- Patient requires at least two similar dental procedures with local anesthesia Exclusion criteria: A-Patient with systemic disorder or allergic/asthmatic history B-Patient with a cold or airway obstruction during dental procedure C-Patient with medical advice to stop the sedative drugs

Intervention groups

Propofol/Fentanyl versus Ketamine/Midazolam will be used to behavioral control of uncooperative children undergoing dental procedures

Main outcome variables

Determining an effective and appropriate drug regimen with minimal side effects between Propofol/Fentanyl and Ketamine/Midazolam for sedation in dental procedures of uncooperative children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211123053154N1**

Registration date: **2022-04-03, 1401/01/14**

Registration timing: **retrospective**

Last update: **2022-04-03, 1401/01/14**

Update count: **0**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Mohammad Esmaeilzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4496 9962

Email address

dr.m.esmaeilzadeh@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the sedative effects of Intra-Venous Propofol / Fentanyl combination Vs. Ketamine / Midazolam combination for uncooperative 2-6 year old children undergoing dental procedures.

Public title

Comparative evaluation of the sedative effects of Intra-Venous Propofol / Fentanyl combination Vs. Ketamine / Midazolam combination for uncooperative children undergoing dental procedures.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Uncooperative 2-6 years old children Patient is in ASA I Patient requires at least two similar dental procedures with local anesthesia

Exclusion criteria:

Patient with systemic disorder or allergic/asthmatic history Patient with a cold or airway obstruction during dental procedure Patient with medical advice to stop the sedative drugs

AgeFrom **2 years** old to **6 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be divided in two groups AB and BA, in which the AB group prescribed drug A and then drug B. The order of drug administration in group BA will be reversed

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and the therapist are not aware of sedative medication regimen during dental procedures. The anesthesiologist and the care team will only be aware about that

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

Unit 5, NO.2, The first dead end, Shahid Sharifi Ave, Abazar Blvd, Ayatollah Kashani Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1471735576

Approval date

2021-03-07, 1399/12/17

Ethics committee reference number

IR.SBMU.DRC.REC.1399.131

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

Dental treatment of uncooperative children under sedation conditions

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

the level of child's cooperation

Timepoint

Before dental treatment, during dental treatment and after dental treatment

Method of measurement

Observation and based on Houpt Behavioral Scale

2**Description**

Heart Rate

Timepoint

Before dental treatment, during dental treatment and after dental treatment

Method of measurement

Pulse oximeter device made by the Alborz company

3**Description**

Atrial oxygen saturation or Spo2

Timepoint

Before dental treatment, during dental treatment and after dental treatment

Method of measurement

Pulse oximeter device made by the Alborz company

Secondary outcomes

empty

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

In group AB, combination of Fentanyl (dose: 1µgr/kg) and Propofol (dose: 2 mg/kg) will be injected in the intervention phase and the first session of dental treatment for sedation induction. Propofol injection will continue (dose: 150µgr/kg/H) for sedation maintenance

Category

Treatment - Drugs

2**Description**

In group BA, combination of Ketamine (dose: 2mgr/kg) and Midazolam (dose: 0.2 mg/kg) will be injected in the intervention phase and the first session of dental treatment for sedation induction.

Category

Treatment - Drugs

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

Pediatric dentistry Fellowship Department of Shahid Beheshti Dental Faculty

Full name of responsible person

Mohammad Esmaeilzadeh

Street address

Unit 5, No2, The first dead end, Shahid Sharifi Ave, Abazar Blvd, Ayatollah Kashani Highway, Tehran

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dr.m.esmaeilzadeh@sbmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

Street address

School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd, Daneshgah Square, Evin, Shahid Chamran Highway

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1983963113

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+98 21 2203 2387

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Zarghi@sbmu.ac.ir

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

40

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

Mohammad Esmaeilzadeh

Position

Assistance professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Esmaeilzadeh

Position

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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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

Observance of ethical standards

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only data on drug outcome will be provided and the patients' personal information will be strictly confidential

When the data will become available and for how long

Immediately after the end of the research and presentation of the result or through the publication of an article

To whom data/document is available

Researchers working in academic and scientific institutes

Under which criteria data/document could be used

Researchers working in academic and scientific institutes and presenting valid C.Vs

From where data/document is obtainable

Applicants can obtain access to the data by submitting a request to the moderator 's email or phone number in due time. Moderator : Mohammad Esmaeilzadeh Email: dr.m.esmaeilzadeh@sbm.ac.ir phone number: 0098 912 3467984

What processes are involved for a request to access data/document

After submitting the applicant 's request via the mentioned email or phone number and Provide a valid C.V stating that she/he is working in reputable domestic or foreign scientific research institutes, the applicant will be able to access the information of this research within one week after submitting the request, if she/he has the requisite conditions.

Comments