

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

A comparative evaluation of sedative effect of intravenous ketamine/midazolam with ketamine/dexmedetomidine combination in 2-6 years old uncooperative pediatric dental patient

Protocol summary

Study aim

Comparing the sedation effects of intravenous ketamine-midazolam and intravenous ketamine-dexmedetomidine combination in the dental treatment of non-cooperative children aged 2 to 6 years.

Design

Cross-over, double-blind, randomized clinical trial on 24 patients

Settings and conduct

This double-blind study will be conducted on 24 non-cooperative children referred to the pediatric dental fellowship department of the dental school who need at least two similar dental treatments. The patients will be randomly divided into two treatment groups, AB and BA. In group AB, drug regimen A (intravenous ketamine-midazolam) will be used in the first treatment session, and drug regimen B (intravenous ketamine-dexmedetomidine) will be used in the second session for sedation. In the BA group, the order of prescribing sedatives will be the opposite. All behavioral and physiological parameters of the patient will be recorded by the trained assistant during the different stages of the treatment.

Participants/Inclusion and exclusion criteria

Entry criteria: non-cooperative children aged 2-6 years (completely negative based on Frankel scale classification) The patient should be in ASA I group The patient needs to perform at least 2 sessions of similar dental work and needs injections. Exit criteria: Do not have a systemic disease. Do not be in ASA1, ASA2 groups. Do not have contraindications to receive sedatives. During sedation, they should not have symptoms of cold or respiratory tract obstruction.

Intervention groups

In order to control the pharmacological behavior of non-cooperative children during dental treatments, two medicinal groups of intravenous ketamine-midazolam

and intravenous ketamine-dexmedetomidine will be used in comparison.

Main outcome variables

Success of dental treatment according to the Houpt criterion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230629058616N1**

Registration date: **2023-07-25, 1402/05/03**

Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**

Update count: **0**

Registration date

2023-07-25, 1402/05/03

Registrant information

Name

Masoud Seyedahadi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative evaluation of sedative effect of intravenous ketamine/midazolam with ketamine/dexmedetomidine combination in 2-6 years old uncooperative pediatric dental patient

Public title

Evaluation of sedative effect of ketamine/midazolam with ketamine/dexmedetomidine in dental uncooperative children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Non-cooperative children aged 2-6 years (completely negative based on the Frankel scale rating) The patient should be in ASA I group. The patient needs to perform at least 2 sessions of similar dental work and needs injection.

Exclusion criteria:

Do not have a systemic disease. Do not be in ASA1, ASA2 groups. Do not have contraindications to receive sedatives. During sedation, they should not have symptoms of cold or respiratory tract obstruction

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Children selected to perform this clinical trial are randomly divided into two equal groups, in the first group (A) in one treatment session with the combination of intravenous ketamine/dexmedetomidine and in the next session with the combination of intravenous ketamine/midazolam under sedation. and in the second group (B) the order of prescribing the medicinal combination will be reversed. Two dental treatment sessions should be designed in such a way that they are similar and comparable in terms of the type and duration of treatment. The combination of studied drugs is also prepared by the anesthesiologist and prescribed to the patient during the treatment and according to the protocol.

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

Shahid Beheshti Dental School, Daneshjoo Blvd, Shahriyari sq, Evin, Chamran Highway, Tehran-Iran

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tehran

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Postal code

1983969411

Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.SBMU.DRC.REC.1402.010

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**

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

3

Description

Atrial oxygen saturation or Spo2

Timepoint

Before dental treatment, during dental treatment and after dental treatment

Method of measurement

Pulse oximeter device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group AB, combination of Dexmedetomidine (dose: 1µgr/kg) and ketamine (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

Control group: 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Seyed Masoud Seyed Ahadi

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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?

No

Title of funding source

Research Assistant of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

Seyed Masoud Seyed Ahadi

Position

Hospital dentistry fellowship

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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