Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the Sedative Effects of Intramuscular vs Intravenous of Ketamine, Midazolam and Atropine Cocktail in 2–6-Year-Old Uncooperative Dental Patients

Protocol summary

Study aim

Comparison of intramuscular and intravenous sedation effects of ketamine, midazolam and atropine in 2-6 year old non-cooperative children in dentistry

Design

Phase 3 Cross-over double-blinded clinical trial on 32 children, the samples will be divided by simple randomization method. The randomization unit will be individual and the samples will be assigned to two groups using the individual randomization table.

Settings and conduct

Two similar treatment sessions will be done in the fellowship department of Shahid Beheshti Dental School. Medicines will be prepared and prescribed by an anesthesiologist. Drugs used in the intramuscular group include 6 mg/kg of ketamine (500 mg/10 ml, EXIR, Iran), 0.05 mg/kg of midazolam (0.5 mg/ml, EXIR, Iran) and 0.02 mg/kg of atropine (0.5 mg/ml, Darou pakhsh, Iran) and in the intravenous group will include 2 mg/kg of ketamine, 0.0.2 mg/kg of midazolam and 0.02 mg/kg of atropine. Participants, researcher, clinical caregiver and data analyst will be blinded to the study.

Participants/Inclusion and exclusion criteria

Uncooperative 2–6-year-old children with definitely negative or negative Frankl scores, who required at least 2 similar dental treatment visits.The subjects were ASA I.Children with nasal obstruction, respiratory infections, limitations in neck movement, macroglossia, tonsil hypertrophy, micrognathia, or limitations in mouth opening were excluded.

Intervention groups

Children will be randomly placed in two groups I and II. In group I, the combination of ketamine, midazolam, and atropine will be administered intramuscularly in the first session and intravenously in the second session, and in group II, the drug administration method will be the opposite in the first and second sessions.

Main outcome variables

The amount of sedation and behavioral evaluation based on the Houpt criterion; physiological parameters; side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180401039166N1**
Registration date: **2025-01-31, 1403/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-31, 1403/11/12**
Update count: **0**

Registration date

2025-01-31, 1403/11/12

Registrant information

Name

Leila Eftekhar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2217 5350

Email address

leila.eftekhar.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-04, 1403/10/15

Expected recruitment end date

2025-05-05, 1404/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Sedative Effects of Intramuscular vs Intravenous of Ketamine, Midazolam and Atropine Cocktail in 2–6-Year-Old Uncooperative Dental Patients

Public title

Comparison of Intramuscular vs Intravenous Sedation in Dental Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Uncooperative 2–6-year-old children with definitely negative or negative Frankl scores, who were referred to the Pediatric Dentistry Fellowship Clinic at the Dental School of Shahid Beheshti University of Medical Sciences, Tehran, Iran, and required at least 2 similar dental treatment visits.The subjects were included if they were classified as ASA I, according to the American Society of Anesthesiology (ASA).

Exclusion criteria:

Children with nasal obstruction, respiratory infections, limitations in neck movement, macroglossia, tonsil hypertrophy, micrognathia, or limitations in mouth opening were excluded.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **32**

More than 1 sample in each individual

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

Two similar dental treatment sessions per participant

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be divided into two groups of intramuscular and intravenous sedation by simple randomization method. The randomization unit will be independent individuals and the samples will be assigned into two groups using the individual randomization table.

Blinding (investigator's opinion)

Double blinded

Blinding description

1. Participants: Parents will know about participating in the study and performing treatment with intramuscular or intravenous sedation in two sessions, but they will be blinded to the type of sedation in each session. 2. Researcher and clinical caregiver: is responsible for performing dental treatment and is blinded to the sedation method (intramuscular or intravenous) used by the anesthesiologist. 3. Data Analyst: Data will be analyzed by a statistician who is unaware of the sedation method.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research School of Dental Sciences - Shahid Beheshti University of Medical Sciences

Street address

School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshju Blv., Velenjak St., Chamran Highway, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2024-07-09, 1403/04/19

Ethics committee reference number

https://ethics.research.ac.ir/IR.SBMU.DRC.REC.1403.068

Health conditions studied

1

Description of health condition studied

Intramuscular and intravenous sedation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The level of sedation and behavioral evaluation based on the Houpt criterion

Timepoint

T0: the beginning of work; T1: after anesthesia injection; T2: 15 minutes after starting work, T3: 30 minutes after starting work and T4: end of work

Method of measurement

Houpt Scale

Secondary outcomes

1

Description
Physiological parameters
Timepoint
T0: the beginning of work; T1: after anesthesia injection; T2: 15 minutes after starting work, T3: 30 minutes after starting work and T4: end of work
Method of measurement
Data table

Intervention groups

1

Description
Intervention group: Intramuscular injection:Drugs used in the intramuscular group include the combination of 6 mg/kg of ketamine (500 mg/10 ml, EXIR, Iran), 0.05 mg/kg of midazolam (0.5 mg/ml, EXIR, Iran) and 0.02 mg/kg of atropine (0.5 mg/ml, Daroupakhsh, Iran)
Category
Treatment - Drugs

2

Description
Intervention group: Intravenous injection: In the intravenous group, it will include 2 mg/kg of ketamine(500 mg/10 ml, EXIR, Iran), 0.0.2 mg/kg of midazolam(0.5 mg/ml, EXIR, Iran) and 0.02 mg/kg of atropine(0.5 mg/ml, Daroupakhsh, Iran).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Leila Eftekhar
Street address
School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshju Blv., Velenjak St., Chamran Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2217 5351
Email
leila.eftekhar.a@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Leila Eftekhar
Street address
School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshju Blv., Velenjak St., Chamran Highway, Tehran, Iran,
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2217 5351
Email
leila.eftekhar.a@gmail.com
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
Leila Eftekhar
Position
fellowship
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshju Blv., Velenjak St., Chamran Highway, Tehran, Iran
City

Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2217 5351

Email
leila.eftekhar.a@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Leila Eftekhar

Position
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School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshju Blv., Velenjak St., Chamran Highway, Tehran, Iran

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Province
Tehran

Postal code
1983969411

Phone
+98 21 2217 5351

Email
leila.eftekhar.a@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Leila Eftekhar

Position
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School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshju Blv., Velenjak St., Chamran Highway, Tehran, Iran

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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
In order to protect the privacy and medical information of patients

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Part of the documents will be shared, for example study protocol, statistical analysis, informed consent form, and clinical study report.

When the data will become available and for how long
Data access period is 6 months after the publication of the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
In order to achieve new results that were not investigated in the study.

From where data/document is obtainable
The Scientific reviewer of the study via e-mail address

What processes are involved for a request to access data/document
After the applicant's request and application review, if approved, the documents will be provided to the applicant within 2 months.

Comments