

# 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, 0.02 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 Houtp 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 Eftekhari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2217 5350

##### Email address

leila.eftekhari.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

## 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), 0.02 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 Eftekhari

##### 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

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##### Phone

+98 21 2217 5351

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Leila Eftekhari

##### Street address

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

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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

Leila Eftekhari

##### 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

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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**  
Leila Eftekhar  
**Position**  
fellowship  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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Medical Sciences, Daneshju Blv., Velenjak St.,  
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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**  
Leila Eftekhar  
**Position**  
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**Latest degree**  
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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