

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparing the sedative effect of IV Ketamine/Midazolam and Fentanyl/Midazolam in uncooperative pediatric dental patients

#### Protocol summary

##### Study aim

comparing the sedative effect of IV Ketamin/Midazolam cocktail with Fentanyl/Midazolam in uncooperative pediatric Dental patients

##### Design

Randomized double blind clinical trial with two treatment groups of case and control (two sessions). A Randomization table was used to group patients allocation.

##### Settings and conduct

Informed consent will be obtained from parents following an ethics approval sought from the Ethics committee of the University . Participants are selected from uncooperative children aged 2 to 6 years referred to Dental School at Shahid Beheshti University. Study is to be performed at Hospital Dentistry fellowship Clinic of this school. Patients are randomly divided into two groups, who will blindly receive IV Ketamine/Atropine/Midazolam at one and Fentanyl/Atropine/Midazolam at other session.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: uncooperative pediatric patients of 2 to 6 years of age (definitely negative in Frankl scale) confirmed as unable to tolerate treatment at chairside by two pedodontists. At least two similar treatment sessions need on one jaw along with local anesthesia. Patients in ASA I will be included. exclusion criteria: patients with systemic disease, common cold at the attending session, any contraindication of drug use or sedation , unavailability of similar teeth needing treatment in the jaw.

##### Intervention groups

intervention group 1: Fentanyl, Atropine and Midazolam are administered in one session intervention group 2: Ketamine, Atropine and Midazolam are administered in the other session

##### Main outcome variables

Sedative effect of IV Fentanyl/Atropin/Midazolam  
Sedative effect of ketamine/Atropin/Midazolam Changes

in Vital signs including blood pressure, oxygen saturation, respiratory rate Sedation score of Houpt during treatment.

#### General information

##### Reason for update

##### Acronym

KFST

##### IRCT registration information

IRCT registration number: **IRCT20140106016106N6**

Registration date: **2020-11-25, 1399/09/05**

Registration timing: **retrospective**

Last update: **2020-11-25, 1399/09/05**

Update count: **0**

##### Registration date

2020-11-25, 1399/09/05

##### Registrant information

##### Name

Ghassem Ansari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2225 5958

##### Email address

drgansari@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-11-10, 1396/08/19

##### Expected recruitment end date

2018-07-09, 1397/04/18

##### Actual recruitment start date

2017-11-10, 1396/08/19

**Actual recruitment end date**

2018-06-09, 1397/03/19

**Trial completion date**

2018-11-21, 1397/08/30

**Scientific title**

Comparing the sedative effect of IV Ketamine/Midazolam and Fentanyl/ Midazolam in uncooperative pediatric dental patients

**Public title**

Comparing sedation effect of IV Ketamine with Fentanyl in pediatric dentistry

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Uncooperative Children aged 2 to 6 years (definitely negative in Frankl scale) Patients needing at least 2 similar dental treatment sessions with local anesthesia. pediatric patients in ASA I

**Exclusion criteria:**

Patients with any Systemic disease, Patients having common cold at treating session any contraindication for the use of drugs or sedation

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**

Target sample size: **38**

More than 1 sample in each individual

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

participating uncooperative Child, aged 2-6 years with two relatively similar dental treatments needs on the same jaw

Actual sample size reached: **25**

More than 1 sample in each individual

Actual sample size in each individual: **2**

two identical similar sized carious teeth in one jaw with the need for local anesthesia for treatment.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to Assess the sequence effect on patient's behavior, all participants will randomly assigned to one of the two groups with group I receive experimental drug combination (Fentanyl Atropine Midazolam) at the first visit and Control drug combination (Ketamine Atropine Midazolam) at the second visit while the second group will receive the same drugs in opposite order. A computerized randomized numbering will be used for allocation for the two groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Appropriate doses of case and Control Drugs are prepared in separate syringes labeled with coding of A or B by anesthesiologist who injects them based on the protocol. The operator (researcher) and the evaluators have no clue of the type and dose of that given drug while treatment is underway and only able to observe the coded drug at every session.

**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**

Dental Research Institute, Dental School, Shahid Beheshti University of Medical Sciences, Students Blvd, Evin, Chamran High Way,

**City**

Tehran

**Province**

Tehran

**Postal code**

19839663113

**Approval date**

2018-10-14, 1397/07/22

**Ethics committee reference number**

IR.SBMU.DRC.REC.1397.032

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

Uncooperative Pediatric Dental patient

**ICD-10 code**

F41.1

**ICD-10 code description**

Generalized anxiety disorder

**Primary outcomes****1****Description**

Induced sufficient sedation for delivering dental treatment

**Timepoint**

baseline, at IV sedation, every 15 min afterwards, at discharge

**Method of measurement**

Recording data in prepared forms in addition to a questionnaire

## Secondary outcomes

### 1

#### Description

Adverse effects of the sedative drugs used

#### Timepoint

at discharge and 24 hours later

#### Method of measurement

Questionnaire and by phone

## Intervention groups

### 1

#### Description

Intervention group: Receiving the drug combination of 2 µg/kg Fentanyl, 0.2 mg/kg Midazolam, 0.1mg/kg Atropine IV at the case session scheduled using an IV line on top of oxygen line connected to patient's nose. while all vital signs are checked and recorded before injection, at start and in every 15 minute intervals.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Receiving the drug combination of 0.3 mg/kg Fentanyl, 0.2 mg/kg Midazolam, 0.1mg/kg Atropine IV at the control session scheduled using an IV line on top of oxygen line connected to patient's nose. while all vital signs are checked and recorded before injection, at start and in every 15 minute intervals.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Pediatric Dentistry, Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Ghassem Ansari

##### Street address

Dental School, Shahid Beheshti University of Medical Sciences, Students Blvd, Evin,

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

##### Phone

+98 21 2217 9421

##### Fax

+98 21 2240 3897

##### Email

drgansari@sbmu.ac.ir

##### Web page address

http://www.drgansari.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Afshin Zarghi

##### Street address

3rd Floor, Next to Taleghani Hospital, Evin, Chamran High Way

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717434

##### Phone

+98 21 2243 9780

##### Fax

+98 21 2243 9781

##### Email

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

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

Dr Ghassem Ansari

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Dentistry

**Street address**

Department of Pediatric Dentistry, Dental School,  
Shahid Beheshti University of Medical Sciences,  
Students Blvd, Evin,

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2217 9421

**Email**

drgansari@sbmu.ac.ir

**Web page address**

<http://www.drgansari.com>

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Ghassem Ansari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Dentistry

**Street address**

Dept of Pediatric Dentistry, Dental School, Shahid  
Beheshti University of Medical Sciences, Students  
Blvd, Evin, Chamran High Way

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2217 9421

**Fax**

+98 21 2225 5537

**Email**

drgansari@sbmu.ac.ir

**Web page address**

<http://www.drgansari.com>

## Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Mahsa Mansouri

**Position**

Fellowship resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Unit 17, Nasim Bldg, 4th Alley, East Sarv, Saadat  
Abad

**City**

Tehran

**Province**

Tehran

**Postal code**

1998653141

**Phone**

+98 21 2237 6198

**Email**

mahsa\_0o66@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

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

**Title and more details about the data/document**

Raw Data for Fentanyl Project

**When the data will become available and for how long**

A year and half after publication

**To whom data/document is available**

Future Fellowship Residents

**Under which criteria data/document could be used**

Taking a view as well as controlling the accuracy

**From where data/document is obtainable**

Dr Ghassem Ansari

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

Presenting a request to the Vice chancellor for research  
at Shahid Beheshti University of Medical Sciences

**Comments**