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 participats will randomly assigned to one of the two groups with group I receive experimental drug combination (Fentanyl Atropin 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 Scienses
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://wwwdrgansari.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 Fentanyle 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 cotrolling 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 chancelor for research at Shahid Beheshti University of Medical Sciences
Comments