Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Effect of Fentanyl addition to Ketamin, Midazolam mixture in intravenous sedation of 2 to 6 years old uncooperative children

Protocol summary

Study aim
Addition of fentanyl to Ketamin-Midazolam-based intravenous sedation for 2-6 years old uncooperative dental patients

Design
Randomized cross over triple blind clinical trial

Settings and conduct
32 children referred to the pedodontics department of Shahid Beheshti University of Medical Sciences at the dental school between the ages of 2 and 6 years with the criteria mentioned for clinical trial will be selected. The medications are prepared by an anesthetist and administered by an anesthetic technician without notice of clinician and of the selected drug type. A randomized computerized list for allocation of patients is used in two groups of 1 or 2 drug regimens to eliminate the Carry over effect. Blood pressure cuff, pulsed oximeter, chest lid probes are used. Oxygen and Nitrous Oxide administered through a nasal cannula at a total rate of 3 liters per minute.

Participants/Inclusion and exclusion criteria
2 to 6 years old non-cooperative children (definitely negative at Frankl's scale) that at least two pediatric dentist have evaluated their lack of co-operation; patients do not have any systemic disease, contraindication in drug usage, mouth opening limitation, macroglossia and tonsilar hypertrophy . patients need at least 2 same treatment session with local anesthetics.patient do not have any respiratory infection and nasal obstruction in treatment session.

Intervention groups
Intervention group 1: In 1st session intravenous sedation with Ketamin, Midazolam. In 2nd session intravenous sedation with Fentanyl, Ketamin and Midazolam.
Intervention group 2: In 1st session intravenous sedation with Fentanyl, Ketamin, Midazolam. In 2nd session intravenous sedation with Ketamin and Midazolam.

Main outcome variables
O2 saturation; Heart rate; Respiratory rate; Blood pressure; Sleepiness, motion, cry and overall behavior according to Houpt sedation scale.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140106016106N5**
Registration date: **2018-08-05, 1397/05/14**
Registration timing: **retrospective**

Last update: **2018-08-05, 1397/05/14**
Update count: **0**

Registration date
2018-08-05, 1397/05/14

Registrant information
Name
Ghassem Ansari
Name of organization / entity
Country
Iran (Islamic Republic of)
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drgansari@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2018-02-24, 1396/12/05

Actual recruitment start date
2017-09-23, 1396/07/01

Actual recruitment end date
2018-04-25, 1397/02/05

Trial completion date
empty

Scientific title
Effect of Fentanyl addition to Ketamin, Midazolam mixture in intravenous sedation of 2 to 6 years old uncooperative children

Public title
"Sedation with Fentanyl & Ketamin in pediatric dentistry"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
2 to 6 year old non-cooperative children (definitely negative at Frankl's scale) that at least two pediatric dentist have evaluated their lack of co-operation At least 2 same treatment sessions with local anesthetics are required The patient is in the ASA I group.

Exclusion criteria:
Patients with systemic diseases Any contraindication in drug use Any contraindication in sedation

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each patient randomly receives intravenously Midazolam and Ketamine in a session and in other session Fentanyl, Ketamine and Midazolam.
Actual sample size reached: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Random numbers

Blinding (investigator's opinion)
Triple blinded

Blinding description
The patient's parents are acquainted with the research method and informed consent is obtained.
Patient,clinician and person that records behavioral effects.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Biomedical Research, Research Institute of Dental Sciences

Street address
Office of Ethics, Research Institute for Dental Sciences, 5th floor,Dental school, Shahid Beheshti University of Medical Sciences, Student blvd, Evin

City
Tehran

Province
Tehran

Postal code
1983663113

Approval date
2017-08-07, 1396/05/16

Ethics committee reference number
IR.SBMU.RIDS.REC.1396.469

Health conditions studied

1

Description of health condition studied
Intravenous sedation in dentistry

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
O2 Saturation of blood

Timepoint
Recording O2 saturation at the baseline, anesthesia injection, 15 and 30 minutes after the start of treatment and at discharge of the patient

Method of measurement
Alborz Saadat hospital monitoring device

2

Description
Heart rate

Timepoint
Recording Heart rate at the baseline, anesthesia injection, 15 and 30 minutes after the start of treatment and at discharge of the patient

Method of measurement
Alborz Saadat hospital monitoring device

3

Description
Blood pressure

Timepoint
Recording Blood pressure at the baseline, anesthesia

injection, 15 and 30 minutes after the start of treatment and at discharge of the patient

Method of measurement

Alborz Saadat hospital monitoring device

4

Description

Respiratory rate

Timepoint

Recording respiratory rate at the baseline, anesthesia injection, 15 and 30 minutes after the start of treatment and at discharge of the patient

Method of measurement

Alborz Saadat hospital monitoring device

5

Description

Sleepiness scale

Timepoint

Anesthesia injection, 15 and 30 minutes after the start of treatment

Method of measurement

Houpt sedation scale

6

Description

Crying scale

Timepoint

Anesthesia injection, 15 and 30 minutes after the start of treatment

Method of measurement

Houpt sedation scale

7

Description

Motion scale

Timepoint

Anesthesia injection, 15 and 30 minutes after the start of treatment

Method of measurement

Houpt sedation scale

8

Description

Overall behavior

Timepoint

Anesthesia injection, 15 and 30 minutes after the start of treatment

Method of measurement

Houpt sedation scale

Secondary outcomes

1

Description

Parents' opinion about sedation session

Timepoint

24 hours after treatment

Method of measurement

Questionaire

2

Description

Clinician opinion about treatment session

Timepoint

At the end of treatment session

Method of measurement

Questionaire

Intervention groups

1

Description

Intervention group 1: In 1st session oral Midazolam suspension premedication (0.5 mg/kg) is administered half an hour before IV Ketamin (up to 2 mg/kg), 1 mg Midazolam and 0.1 mg Atropin injection. Then in 2nd session oral Midazolam suspension premedication (0.5 mg/kg) is administered half an hour before IV Fentanyl (up to 1 mcg/kg), Midazolam 1 mg, Atropin 0.1 mg, Ketamin (up to 2 mg/kg) injection.

Category

Treatment - Drugs

2

Description

Intervention group 2: in 1st session oral Midazolam suspension premedication (0.5 mg/kg) is administered half an hour before IV Fentanyl (up to 1 mcg/kg), Midazolam 1 mg, Atropin 0.1 mg and Ketamin (up to2mg/kg) injection. Then in 2nd session oral Midazolam suspension premedication (0.5 mg/kg) is administered half an hour before IV Ketamin (up to 2 mg/kg), 1 mg Midazolam and 0.1 mg Atropin injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Ghassem Ansari

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Dental School, Student's Blvd, Evin

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drgansari@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Office of Vice chancellor of research, 5th floor, Shahid Beheshti University of Medical Sciences, Daneshjoo blvd, Evin, Chamran Highway, Tehran

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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

Ghassem Ansari

Position

PhD, Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ghassem Ansari

Position

PhD, Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Position

PhD, Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Drug dose used and data results
When the data will become available and for how long
Accessibility 6 month after issuing results
To whom data/document is available
Researchers in medical or dental universities
Under which criteria data/document could be used
Statistical analysis and the use of data with the exact mention of the source is indispensable.
From where data/document is obtainable
Aii Rashidian, DDS, MS Email: A_rashidian@dentaliau.ac.ir Address: 1945883919, 8 unit, n 492, Pasdaran Ave., Tehran
What processes are involved for a request to access data/document
3 month after admission of request
Comments