Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of sedative effect of intravenous Ketamin/Fentanyl with Midazolam/Fentanyl on 2-6 years old uncooperative pediatric dental patients

Protocol summary

Study aim

Sedative level of IV administration of Fentanyl/Ketamine cocktail with IV administration of Fentanyl/Midazolam cocktail in uncooperative pediatric patients

Design

Randomized controlled double blind clinical trial, Phase 3 on 30 patients Group I: get FAM in 1st visit and FAK in 2nd, Group II: get FAK in 1st visit and FAM in Sample sized is adopted from earlier similar studies.

Settings and conduct

Informed consent was obtained from parents while ethics approval was sought from the Ethics committee of the university. Children of 2 to 6 years were selected from those referred to the Dental School Shahid Beheshti University of Medical Sciences. Cases are schedules for treatment at Hospital Dentistry fellowship Clinic of this school. Patients are randomly divided into two groups, Group I: will receive FAK at 1st sedation session and FAM at 2nd while Group II: receives FAM at 1st and FAK at 2nd sedation session. Operator and evaluators are blind to the injective drug contents.

Participants/Inclusion and exclusion criteria

inclusion criteria: uncooperative pediatric patients of 2 to 6 years of age (definitely negative in Frankl scale) confirmed by two pedodontists needing two treatment sessions with administration of local anesthesia. Only patients in ASA are included. exclusion criteria: patients with systemic disease, common cold, any contraindication of drug use or sedation, Allergy.

Intervention groups

Intervention group: FAM is administered at a session Control group: FAK is administered at other session

Main outcome variables

determination of the effect of FAK in sedating these children determination of effect of FAM in sedating these children determining the potential changes in BP, RR, SPO2, PR in each session.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140106016106N7**
Registration date: **2020-11-30, 1399/09/10**
Registration timing: **retrospective**

Last update: **2020-11-30, 1399/09/10**
Update count: **0**

Registration date

2020-11-30, 1399/09/10

Registrant information

Name

Ghassem Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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drgansari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-08, 1398/01/19

Expected recruitment end date

2020-12-17, 1399/09/27

Actual recruitment start date

2019-04-08, 1398/01/19

Actual recruitment end date

2020-03-31, 1399/01/12

Trial completion date

2020-05-03, 1399/02/14

Scientific title
Comparison of sedative effect of intravenous Ketamin/Fentanyl with Midazolam/Fentanyl on 2-6 years old uncooperative pediatric dental patients

Public title
Evaluation of sedative effect of ketamine/fentanyl and midazolam/fentanyl on dental uncooperative children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 2 to 6 years Patients needing at least 2 similar dental treatment sessions ،treating each tooth requires local Anesthesia. pediatric patients in ASA I Uncooperative child definitely negative (in Frankl scale)

Exclusion criteria:
Patients with any Systemic disease Patients having common cold at treating session any contraindication for the use of drugs any contraindication for the use of sedation Drug Allergy

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: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Child aged 2-6 years with two similar dental treatment needs in one jaw. Both sexes will be accepted for inclusion.
Actual sample size reached: **25**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Carious primary molars with pulpal involvement in both sides of a jaw are selected with similar size cavities needing similar treatments and consuming relatively close times.

Randomization (investigator's opinion)
Randomized

Randomization description
In order to Assess the sequence effect on patient's behavior, all participats will randomly be assigned into one of the two groups, with group I receiving experimental drug combination (Fentanyl Atropin Midazolam) at the first visit and Control drug combination (Ketamine Atropine Fentanyl) at the second visit while the second group will receive the Control drug combination (Ketamine Atropine Fentanyl) at the first visit and experimental drug combination (Fentanyl Atropin Midazolam) at the second visit in opposite order. A table of randomization of numbers will be used for allocation of samples for the two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Preparation of experimental and control drugs into previously coded syringes are performed by the anesthesiologist in charge. In this line the operator (researcher) and the two judging evaluators do not have any clue of the content of the syringes.

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

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Tehran

Province
Tehran

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1983963113

Approval date
2020-02-15, 1398/11/26

Ethics committee reference number
IR.SBMU.DRC.REC.1398.220

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 Fentanyl1-2 µg/kg micrograms , Midazolam 0.2 mg/kg , Atropine 0.1 mg/kg IV in one of the two randomize assigned and scheduled visits using an IV line while all vital signs are checked and recorded at start and in every 15 minute intervals.
Category
Treatment - Drugs

2

Description
Control group: Receiving the drug combination of Fentanyle1 to 2 µg/kg , Midazolam 0.2 mg/kg , Atropine 0.1 mg/kg in one of the two randomly assigned scheduled visits by randomization table using an IV line while all vital signs are checked and recorded at start and in every 15 minute intervals during treatment.
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Dr Ghassem Ansari
Position
Professor
Latest degree
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Person responsible for updating data

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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
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 Ketamine 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