

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 scheduled 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

+98 21 2225 5958

Email address

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

City

Tehran

Province

Tehran

Postal code

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 Fentanyl 1-2 µg/kg micrograms , Midazolam 0.2 mg/kg , Atropine 0.1 mg/kg IV in one of the two randomized 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 Fentanyl 1 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

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

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

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

Email

drgansari@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Sara Shafiee

Position

Fellowship resident

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Unit 20, #1 Kamraniyeh Bldg, West Lavasani cross, Kamraniyeh Cross

City

Tehran

Province

Tehran

Postal code

1998653141

Phone

+98 21 2265 1556

Email

shafieeinsta@gmail.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 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