Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the sedative effect of etomidate and propofol in dental treatment of children.

Protocol summary

Study aim
The aim of this study is to compare 2 combinations of etomidate/fentanyl and propofol/fentanyl by intravenous injection in sedation of uncooperative children during dental treatments.

Design
This study was designed as a randomized, crossover and clinical evaluation. Study population: There are 20 children aged 3 to 6 who refer to the hospital fellowship department of Shahid Beheshti Faculty of Dentistry.

Settings and conduct
The present study was carried out in non-cooperative children (Frankel 1 and 2), healthy (ASAI 2-6 years old, referring to the hospital fellowship department of Shahid Beheshti Faculty of Dentistry

Participants/Inclusion and exclusion criteria
Inclusion criteria: A. Non-cooperative children aged 2-10 (completely negative and negative based on Frankel scale grading) (36) B. The patient should be in ASA I group. C. The patient needs to perform at least 2 sessions of similar dental work with local anesthesia. exclusion criteria A. Suffering from systemic diseases or having a history of asthma and allergies B. Catching a cold and blocking the respiratory tract during dental treatment C. Existence of any medical advice and orders prohibiting the use of drugs used to induce sedation (existence of any adrenal, liver, kidney failure, drug sensitivities or airway obstruction, etc.)

Intervention groups
The first group is the combination of etomidate, fentanyl and the second group is propofol, fentanyl

Main outcome variables
The consumers of this research are anxious and uncooperative children with decayed teeth for whom it is not possible to perform dental treatment normally in the clinic.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230515058193N1**
Registration date: **2024-11-22, 1403/09/02**
Registration timing: **retrospective**

Last update: **2024-11-22, 1403/09/02**
Update count: **0**

Registration date
2024-11-22, 1403/09/02

Registrant information
Name
Sedighe Mozafar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8895 9210
Email address
se.mozafar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-21, 1403/05/31

Expected recruitment end date
2024-10-22, 1403/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the sedative effect of etomidate and propofol in dental treatment of children.

Public title
Comparative study of sedative effects of intravenous administration of etomidate, fentanyl, midazolam drug combination with propofol, fentanyl, midazolam in children's dental treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy children without any background, syndrome and special conditions Absence of illness at present (cold and presence of nasal and pharyngeal discharge)
Exclusion criteria:
Children with perfect physical health
Age
From **2 years** old to **10 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each participant is examined twice in the study
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling was done in a simple way and classification was done randomly
Blinding (investigator's opinion)
Double blinded
Blinding description
The present study is double-blind and only the anesthesiologist was aware of the process
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid beheshti medical sciences
Street address
Chamran street
City
Tehran
Province
Tehran
Postal code
021-22175350-51
Approval date
2023-01-12, 1401/10/22
Ethics committee reference number
IR.SBMU.DRC.REC.1402.011

Health conditions studied

1

Description of health condition studied
Examining the sedative effect of drugs
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Oxygen saturation
Timepoint
After prescribing the medicine and starting the treatment and every 10 minutes until discharge
Method of measurement
Percent

2

Description
heart beat (RATE)
Timepoint
Before drug administration, after drug administration and starting treatment, and every 10 minutes until discharge
Method of measurement
A number between 60 and 100

Secondary outcomes

1

Description
Anesthetic drugs
Timepoint
When injecting the patient
Method of measurement
MG/KG

Intervention groups

1

Description
In the first group (AB), they underwent sedation in one treatment session with the combination of intravenous drug A: etomidate/fentanyl/midazolam and in the next

session with the combination of intravenous drug B: propofol/fentanyl/midazolam.

Category

Treatment - Drugs

2

Description

Intervention group: The second group (BA) was the opposite of the first group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Fellowship Department of Shahid Beheshti Faculty of Dentistry

Full name of responsible person

Dr.sedighe Mozafar

Street address

Chamran street

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

se.mozafar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.falahinejad

Street address

Chamran street

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2241 3897

Email

se.mozafar@gmail.com

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

80

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.Dedighe Mozafar

Position

Assisstant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Chamran street

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

22413897 -021

Email

se.mozafar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Sedighe Mozafar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Vesal st,Italy st

City

Tehran

Province

Tehran

Postal code

1983963113

Phone
+98 21 8895 9210
Fax
Email
se.mozafar@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Sedighe Mozafar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Vesal st,Italy st
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 8895 9210
Fax
Email
se.mozafar@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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
A clinical study report will be provided
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
It will be available for researchers working in academic and scientific institutions
Under which criteria data/document could be used
People who use documents to apply for reviews of other people examined in the study, get a positive response to receive the documents
From where data/document is obtainable
o receive documents, to the email address send a message to se.mozafar@gmail.com.
What processes are involved for a request to access data/document
Documents will be sent within two weeks after sending the message.
Comments