

# 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 (ASA I 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

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**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**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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**Phone**

22413897 -021

**Email**

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**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

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**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**

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**Fax****Email**

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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**

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**