

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison the effect of two drugs, propofol and fentanyl in controlling emergence agitation of 2 to 10 years old children following general anesthesia with sevoflurane

Protocol summary

Study aim

Comparison the effect of propofol and fentanyl in controlling agitation following general anesthesia with sevoflurane

Design

A randomized, double-blind, clinical trial with a sample size of 50 patients

Settings and conduct

50 children aged 2 to 10 years old with class 1 or 2 American Society of Anesthesiologists (ASA) who candidate general anesthesia with sevoflurane in Kosar educational hospital of Sanandaj were evaluated. At the end of surgery, in the post anesthetic care unit (PACU), agitated patients was divided into two groups: one group received fentanyl and another group received propofol. Each patient was monitored for their complications and effects of treatment. In this study, participants, clinical caregivers, evaluator and therapist were blinded.

Participants/Inclusion and exclusion criteria

Children aged 2 to 10 years old with a grade 1 or 2 American Society of Anesthesiologists (ASA) under general anesthesia with sevoflurane were enrolled to the study, and children with a history of growth retardation, psychological or neurological illness, abnormal or erritable airway were excluded from the study.

Intervention groups

Intervention group 1: propofol; Control group: fentanyl

Main outcome variables

Agitation score, nausea, vomiting, apnea, disturbance of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181130041804N1**

Registration date: **2019-01-23, 1397/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-23, 1397/11/03**

Update count: **0**

Registration date

2019-01-23, 1397/11/03

Registrant information

Name

Arash Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3356 5863

Email address

arash.amini@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-31, 1397/10/10

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two drugs, propofol and fentanyl in controlling emergence agitation of 2 to 10 years old children following general anesthesia with sevoflurane

Public title

Effect of two drugs, propofol and fentanyl in controlling emergence agitation following anesthesia with sevoflurane gas

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children aged 2 to 10 years old Class one or two of ASA Children under general anesthesia with sevoflurane

Exclusion criteria:

Children with growth retardation Children with psychological diseases Children with neurological disease Children with abnormal airway Irritable children

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation is permuted block randomization using following pattern. Group A: Propofol drug Group B: Fentanyl drug BABA ABBA BBAA AABB BABA ABAB BAAB ABBA In the first 4 patients, the first and third persons receive fentanyl and the second and fourth patients receive propofol. In the next four, the first two receive fentanyl drugs and the third and fourth patients receive the drug propofol. And so to the end of the of samples , the above pattern is used .

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant, the clinical caregiver and data analyser are not aware of the type of drug used, and only the researcher or the person other than above sophisticated the drug used (in an accidental manner) in an aluminum foil and give it to a clinical caregiver for injection to the patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran St, Kurdistan University of Medical Science

City

Sanandaj

Province

Kurdistan

Postal code

66614713446

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.MUK.REC.1397.183

Health conditions studied**1****Description of health condition studied**

agitation due to sevoflurane gas

ICD-10 code

XVIII

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes**1****Description**

Agitation Score

Timepoint

5 ,10 ,15 ,20 minute after the treatment of Agitation

Method of measurement

RASS (Richmond agitation sedation scale)

Secondary outcomes**1****Description**

Vomiting

Timepoint

5,10,15,20 minutes after injection of propofol or fentanyl

Method of measurement

In the form of positive or Negative by watching and reporting the caregiver

2**Description**

Nausea

Timepoint

5,10,15,20 minutes after injection of propofol or fentanyl

Method of measurement

In the form of positive or Negative by watching and

reporting the caregiver

Intervention groups

1

Description

Intervention Group: Receive 0.5mg/kg Propofol drug after agitation

Category

Treatment - Drugs

2

Description

Control Group: Recieve 0.5mcg/kg Fentanyl drug after agitation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational hospital of Kowsar, Sanandaj

Full name of responsible person

Dr Jamal Amjadi

Street address

Pasdarán Blvd. in front of Tamin Ejtemaii hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Qaderi

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Arash Amini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

I can send the following upon request of the researchers: Participants data file, study protocol, clinical study report, the codes used in the analysis, data classification system

When the data will become available and for how long

One year after the print results

To whom data/document is available

Researchers in the University

Under which criteria data/document could be used

Without any condition

From where data/document is obtainable

Apply to my E.mail.adress

What processes are involved for a request to access data/document

One week

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Arash Amini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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