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 to10 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 recieved 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)

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+98 87 3356 5863

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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 to10 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: Propophol drug Group B: Fentanyl drug BABA ABBA BBAA AABB BABA ABAB BAAB ABBA In the first 4 patients, the first and third persons recieve fentanyl and the second and fourth patients recieve propofol. In the next four, the first two recieve fentanyl drugs and the third and fourth patients recieve 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 sofisticate the drug used (in an accidental manner) in an aluminum foil and give it to a clinical caregiver for injectin to the patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Kurdestan University of Medical Sciences
Street address
Pasdaran St, Kurdestan 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
Pasdaran Blvd، in front of Tamin Ejtemaii hospital
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6617983476
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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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Pasdaran Bulvd, Kurdestan University of Medical Science
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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 fallowing 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