Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effects of two different doses of Propofol in treatment of delirium in children from 1 to 6 years during recovery from general anesthesia

Protocol summary

Study aim
Comparison of the effect of two doses of propofol in the treatment of delirium in the recovery of 1-6 years old children under general anesthesia

Design
A clinical trial with two intervention groups, with parallel groups, double blind, randomized

Settings and conduct
This study is a randomized clinical trial based on simple randomized, double-blind randomization which is performed in Imam Hossein Hospital, Isfahan, Iran, from 1396 to 1397.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: Children 1 to 6 years old, candidate for general anesthesia. Exclusion criteria include: any child psychiatric problems

Intervention groups
Patients were separated from their parents after being treated with 0.01 mg / kg of midazolam plus 1 mg / kg of ketamine and taken to the operating room. Fentanyl and 0.5 mg / kg of atracurium are administered and then patients are anesthetized with a dose of 200 mg / kg propofol plus 50% oxygen. After the end of surgery and extubation, patients were recovered and pain scores were recorded every 5 minutes according to FLACC criteria, and fentanyl 1 mg / kg was administered if the score was equal to or greater than 3. Delirium scores are recorded in children every 5 minutes based on the Delirium Immediate Measurement Scale, counting as or greater than 10 as emergency delirium, and in the first group treated with propofol at a dose of 1 mg / kg. The second group is treated with propofol at a dose of 1 mg / kg. Repeat dose if needed

Main outcome variables
The score of delirium based on Rapid Delirium Scale in children

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200119046193N1**
Registration date: **2020-03-06, 1398/12/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-06, 1398/12/16**
Update count: **0**

Registration date
2020-03-06, 1398/12/16

Registrant information

Name
kimia golkar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3668 8817

Email address
kimiagol72@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-09, 1398/11/20

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of two different doses of Propofol in treatment of delirium in children from 1 to 6 years during recovery from general anesthesia

Public title
Effect of Propofol in treatment of Delirium
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children between 1 to 6 years candidated for general Anesthesia
Exclusion criteria:
Any Psychiatric problems Including ADHD and Depression and other behavioral disorders in children
Age
From **1 year** old to **6 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Allocation ,the patients are divided into two groups including 35.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medicines are Delivered and Coded in two doses by the Researcher and the Anesthesiologist dose not know the groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Isfahan University Medical Science
Street address
Building No.4, Isfahan University of Medical Sciences, Hezar jerib Ave
City
Esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2017-12-06, 1396/09/15
Ethics committee reference number
IR.MUI.REC.1396.3.664

Health conditions studied

1

Description of health condition studied
Delirium
ICD-10 code
F05
ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
Delirium score
Timepoint
Every 5 minutes in recovery
Method of measurement
The Pediatric Anesthesia Emergence Delirium Scale (PAED)

2

Description
Sedatin score
Timepoint
Every 5 minutes in recovery
Method of measurement
The University of Michigan Sedation Scale

3

Description
Length of Stay at the Recovery Room
Timepoint
Every 5 minutes in recovery
Method of measurement
Modified Aldrete Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: By random sampling, patients will be divided into two groups of 35 people. Patients were separated from their parents after being treated with

0.01 mg / kg of midazolam plus 1 mg / kg of ketamine and taken to the operating room. Fentanyl and 0.5 mg / kg of atracurium are administered and then patients are anesthetized with a dose of 200 mg / kg propofol plus 50% oxygen. After the end of surgery and extubation, patients were recovered and pain scores were recorded every 5 minutes according to FLACC criteria, and fentanyl 1 mg / kg was administered if the score was equal to or greater than 3. The delirium score is recorded according to the pediatric emergency delirium criteria every 5 minutes after anesthesia, scores equal to or greater than 10 as emergency delirium, and in the first group treated with propofol at a dose of 1 mg / kg. we give. Repeat dose if needed.

Category

Treatment - Drugs

2

Description

Intervention group 2: Similar to the first group except that the group is treated with propofol at a dose of 1 mg / kg and repeated as needed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam hossein hospital

Full name of responsible person
Amir Shafa

Street address
Emam khomeini Ave, Km 10

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Esfahan

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815163381

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh haghjoo javanmard

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7346181746

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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Amir Shafa

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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
information of participants and results of the study
When the data will become available and for how long
1 year after publish of the letter
To whom data/document is available
all of the researchers that are interested to have access to these information
Under which criteria data/document could be used
by sending request
From where data/document is obtainable
the projects admin
What processes are involved for a request to access data/document
by email
Comments