

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

Isfahan

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

City

Esfahan

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Isfahan

Postal code

815163381

Phone

+98 31 3386 6566

Email

emamhossein_hospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh haghjoo javanmard

Street address

Hezarjarib Ave

City

Esfahan

Province

Isfahan

Postal code

7346181746

Phone

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Email

sh_haghjoo@med.mui.ac.ir

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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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

Person responsible for updating data

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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