Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

Comparative study of the effect of propofol and ketofol on restlessness after anesthesia in children aged 18-6 months under cleft palate surgery

Protocol summary

Study aim
Determination of the effect of propofol and ketofol on restlessness after anesthesia in children aged 18-6 months under cleft palate surgery

Design
A randomized, Triple-blinding clinical trial, with the parallel groups, Phase 2-3 on 86 patients

Settings and conduct
In this randomized three-blind randomized clinical trial study, 86 children who are candidates for cleft palate surgery presented at Imam Hossein Hospital in Isfahan will be included in the study and will be randomly divided into 2 groups. One group will receive propofol and the other group will receive ketofol. Delirium score, pain score, and hemodynamic parameters of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
The children aged 6 to 18 months, candidates for cleft palate surgery, classified as ASA I and II are included after obtaining the child's parent's satisfaction to participate in the study. Exclusion criteria include underlying diseases such as mitochondrial metabolism disorder and fat metabolism disorder, a history of convulsion, and growth retardation.

Intervention groups
All patients go to the operating room after premedication with 0.01 mg/kg midazolam and induction of anesthesia is performed by injecting 2 mg/kg propofol, 2 µg / kg fentanyl, and 0.5 mg/kg atracurium. Then, the patients of the first intervention group are anesthetized with 100 µg/kg/min of propofol with 50% oxygen and 50% air. The second intervention group is anesthetized with a combination of propofol at a dose of 75 µg/kg/min and ketamine at a dose of 25 µg/kg/min with 50% oxygen and 50% air.

Main outcome variables
Delirium; Pain; Pressure; Heart rate; Percentage of oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N22**
Registration date: **2021-01-20, 1399/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-20, 1399/11/01**
Update count: **0**

Registration date
2021-01-20, 1399/11/01

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparative study of the effect of propofol and ketofol on restlessness after anesthesia in children aged 18-6 months under cleft palate surgery

Public title
The effect of propofol and ketofol on restlessness after anesthesia in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 6 to18 months Candidate for cleft palate surgery Classified as ASA I and II based on American Society of Anesthesiologists Classification Consent to participate in the study
Exclusion criteria:
Underlying diseases such as mitochondrial metabolic disorders and fat metabolism disorders History of convulsion Growth and development retardation
Age
From **6 months** old to **18 months** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 86 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, propofol and ketofol, are prepared by the pharmacist and placed in coded packages, and delivered daily to an anesthesiologist, who prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2020-11-29, 1399/09/09
Ethics committee reference number
IR.MUI.MED.REC.1399.765

Health conditions studied

1

Description of health condition studied
Cleft palate
ICD-10 code
Q35.9
ICD-10 code description
Cleft palate, unspecified

Primary outcomes

1

Description
Delirium score
Timepoint
Immediately upon entering the recovery ward and 15, 30 and 45 minutes later in the recovery
Method of measurement
Pediatric Anesthesia Emergence Delirium Scale (PAED)

2

Description
Pain score
Timepoint
15, 30 and 45 minutes later in the recovery
Method of measurement
Behavioral scale derived from the Face, Leg, Activity, Cry, Consolability (FLACC)

3

Description
Blood Pressure
Timepoint
Immediately after surgery, in the minutes of 15, 30, and 45 during surgery and immediately, 15, 30, and 45

minutes after recovery

Method of measurement

Monitoring device

4

Description

Heart rate

Timepoint

Immediately after surgery, in the minutes of 15, 30, and 45 during surgery and immediately, 15, 30, and 45 minutes after recovery

Method of measurement

Monitoring device

5

Description

Percentage of oxygen saturation

Timepoint

Immediately after surgery, in the minutes of 15, 30 and 45 during surgery and immediately, 15, 30 and 45 minutes after recovery

Method of measurement

Monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Anesthesia induction is performed for patients by injecting 2 mg/kg propofol(Caspian Tamin Pharmaceutical), 2 µg/kg fentanyl(Caspian Tamin Pharmaceutical), and 0.5 mg/kg atracurium(Caspian Tamin Pharmaceutical). The propofol (Caspian Tamin Pharmaceutical) maintenance anesthesia is administered to the patient at 100 µg/kg/min with 50% oxygen.

Category

Treatment - Drugs

2

Description

Second intervention group: Anesthesia induction is performed for patients by injecting 2 mg/kg propofol(Caspian tamin Pharmaceutical), 2 µg/kg fentanyl(Caspian Tamin Pharmaceutical), and 0.5 mg/kg atracurium(Caspian Tamin Pharmaceutical). The maintenance anesthesia including a combination of propofol (Caspian Tamin Pharmaceutical) at a dose of 75 µg/kg/min and ketamine (Rotex Medica Pharmaceutical) at a dose of 25 µg/kg/min with 50% oxygen, is administered to the patient.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital in Isfahan

Full name of responsible person

Amir Shafa

Street address

Imam Khomeini street

City

Isfahan

Province

Isfehan

Postal code

8195163381

Phone

+98 31 3386 6266

Email

shafa_amir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Department of Anesthesiology; Al-Zahra Hospital; Sofeh boulevard

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
shafa_amir@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Amir Shafa

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Department of Anesthesiology; Al-Zahra Hospital; Sofeh boulevard

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
shafa_amir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Fatemeh Ghorbani

Position
Non-faculty physician

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Department of Anesthesiology; Al-Zahra Hospital; Sofeh boulevard

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
fatemeghorbani2014@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not 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
No - There is not 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