

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 to 18 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

Isfahan

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

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Isfahan

Province

Isfahan

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8195163381

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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.

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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

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Department of Anesthesiology; Al-Zahra Hospital;
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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

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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

Isfahan

Postal code

8174675731

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