

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

A comparative trial on hemodynamic changes caused by anesthesia with propofol-remifentanyl and isoflurane-remifentanyl during cleft palate repair surgery in children under 3 years old

Protocol summary

2018-07-27, 1397/05/05

Study aim

This study aimed to compare hemodynamic changes during cleft palate repair in patients anesthetized with isoflurane-remifentanyl and propofol-remifentanyl.

Design

Clinical trial , phase 2 , patients under 3 years old , who are candidated for cleft palate repair surgery , will be allocated to 2 groups of receiving isoflurane-remifentanyl or propofol-remifentanyl, by simple randomized method .

Settings and conduct

In this randomized, double blind study, 100 patients under 3 years old candidated for cleft palate repair surgery will be allocated to two groups of 50 patients to receive either isoflurane-remifentanyl or propofol-remifentanyl for maintaining anesthesia.

Participants/Inclusion and exclusion criteria

Children under 3 years old candidated for cleft palate repair surgery; without any congenital cardiac or pulmonary diseases

Intervention groups

patients anesthetized with isoflurane-remifentanyl and propofol-remifentanyl.

Main outcome variables

Blood pressure Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180520039739N1**

Registration date: **2018-07-27, 1397/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

Registrant information

Name

Mohammadreza Habibzadeh siahroodkolaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3532 0551

Email address

M.habibzadeh@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-06, 1397/04/15

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative trial on hemodynamic changes caused by anesthesia with propofol-remifentanyl and isoflurane-remifentanyl during cleft palate repair surgery in children under 3 years old

Public title

A comparative trial on hemodynamic changes caused by anesthesia with propofol-remifentanyl and isoflurane-remifentanyl

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age < 3 years old American Society of Anesthesiologists (ASA) Class I

Exclusion criteria:

Congenital cardiac or pulmonary diseases

Age

To 3 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization(random number table)

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients and their parents are not aware of the kind of used anesthetic drugs

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan university of medical sciences

Street address

Esfahan university of medical sciences , Hezarjerib Ave.

City

Esfahan

Province

Isfahan

Postal code

ندارد

Approval date

2017-01-09, 1395/10/20

Ethics committee reference number

1395.3.95215

Health conditions studied

1

Description of health condition studied

Anesthesia in cleft palate

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood pressure

Timepoint

q 15 min

Method of measurement

Manometer

2

Description

Heart rate

Timepoint

q 15 min

Method of measurement

Heart monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: propofol and remifentanyl (0/5 microg/kg/min)

Category

Treatment - Drugs

2

Description

Intervention group: isoflurane 1% and remifentanyl(0/5 microg/kg/min)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hosein hospital

Full name of responsible person

Mohammadreza Habibzadeh

Street address

Emam Khomeini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
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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
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Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available