Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of hemodynamic changes between propofol–remifentanil and isoflurane anesthesia for repair of cleft palate in infants

Protocol summary

Summary

The objective of the present study is to compare hemodynamic changes between propofol– remifentanil and isoflurane anesthesia for repair of cleft palate in infants. A total of 126 infants, aged 4–24 months, ASA class I or II, candidates for surgery of cleft palate repair, will be prospectively enrolled in the study. After preoperative examination infants will be randomized to one of the two groups to receive either a propofol–remifentanil or a isoflurane anesthesia. Group 1 will receive propofol (100-150mcg/kg/min) and remifentanil (0.2-0.5mcg/kg) as the maintenance. Group 2 will receive isoflurane (1.2%-1.5%). Both groups will receive oxygen/nitrous oxide 50%/50% for maintenance of anesthesia. Bispectral index (BIS) will be used after induction of anesthesia. The level of anesthesia will be maintained at 50±10 limit. Morphine (0.1mg/kg) will be administered 15-30 minute before termination of the surgery in group 1. Heart rate, arterial blood pressure, fentanyl dosage, endtidal concentrations of O2, and CO2 will be recorded every10 min from the beginning of the surgery until the end of anesthesia and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103106022N1**
Registration date: **2011-05-07, 1390/02/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-05-07, 1390/02/17

Registrant information

Name
Reza Taheri
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic changes between propofol–remifentanil and isoflurane anesthesia for repair of cleft palate in infants

Public title

Comparison of hemodynamic changes between propofol–remifentanil and isoflurane anesthesia for repair of cleft palate in infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 4-24 months, ASA class I or II, undergoing cleft palate surgery Exclusion criteria: predisposition for malignant hyperthermia, cerebral

disease, history of apnea, any syndromic disorder

Age
To **2 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Daneshgah Ave,

City
Tabriz

Postal code

Approval date
2010-10-07, 1389/07/15

Ethics committee reference number
5/4/5149

Health conditions studied

1

Description of health condition studied
Anesthesia

ICD-10 code
Y48.0

ICD-10 code description
Anaesthetics and therapeutic gases

Primary outcomes

1

Description
Hemodinamic differences

Timepoint
every 10 minutes during anesthesia

Method of measurement
electrocardiogram and blood pressure measurment for evaluation of heart rate and blood pressure

Secondary outcomes

1

Description
pain and agitation

Timepoint
every 10 minutes during anesthesia

Method of measurement
Flacc score

Intervention groups

1

Description
Intervention group will receive remifentnil (0.2-0.5mcg/kg/min) and propofol (100-150mcg/kg/min), during 4-5 hours anesthesia

Category
Treatment - Drugs

2

Description
Control group will receive 1.2-1.5% MAC isoflurane through the ventilator, during 4 hours anesthesia

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Children hospital of Tabriz

Full name of responsible person
Reza Taheri

Street address

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Alireza Ostad Rahimi

Street address
Tabriz University of Medical Sciences, Tabriz

City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty