

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of sevoflurane with and without propofol for laryneal mask airway insertion in children; a double-blinded clinical trial

Protocol summary

Study aim

The aim of this study was to compare the effect of sevoflurane with and without propofol for laryneal mask airway insertion in children.

Design

A clinical trial with parallel, double-blind, randomized by randomizer website, phase 3 was performed on 36 patients in both equal groups.

Settings and conduct

Phase 3 clinical trial with two parallel groups was performed on 36 patients referred to Shahid Motahari Hospital in Urmia. Patients were enrolled in two equal groups (sevoflurane with propofol group = 18 people and sevoflurane without propofol group = 18 people). In this study, patients and clinical assessor as well as statistical analyzers were unaware of group assignment. Randomization was done by randomizer website.

Participants/Inclusion and exclusion criteria

Inclusion criteria were age between 2 to 8 years old, American Society of Anesthesiologists (ASA) I and II and abdominal and lower limb surgeries. Exclusion criteria were dissatisfaction of parents to participate in the study, the possibility of surgery with spinal anesthesia.

Intervention groups

Intervention group: In this group, sevoflurane with propofol was used before inserting laryngeal mask in children. Control group: In this group, sevoflurane without propofol was used before inserting laryngeal mask in children.

Main outcome variables

Time to reach the desired relaxation for laryngeal mask insertion, heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201207049639N5**

Registration date: **2021-01-09, 1399/10/20**

Registration timing: **retrospective**

Last update: **2021-01-09, 1399/10/20**

Update count: **0**

Registration date

2021-01-09, 1399/10/20

Registrant information

Name

Hadi Houshyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

hooshyar.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-22, 1399/04/02

Expected recruitment end date

2020-11-29, 1399/09/09

Actual recruitment start date

2020-06-24, 1399/04/04

Actual recruitment end date

2020-11-30, 1399/09/10

Trial completion date

2020-11-30, 1399/09/10

Scientific title

Comparison of sevoflurane with and without propofol for laryneal mask airway insertion in children; a double-blinded clinical trial

Public title

Effect of sevoflurane and propofol for laryneal mask

airway insertion

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 2 to 8 years old American Society of Anesthesiologists (ASA) I and II Abdominal and lower limb surgeries
Exclusion criteria:
 Dissatisfaction of parents to participate in the study
 Possibility of surgery with spinal anesthesia

Age
From **2 years** old to **8 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
 Target sample size: **36**
 Actual sample size reached: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
 Candidate children for abdominal and lower limb surgery were randomly divided into two groups receiving sevoflurane with and without propofol using <https://www.randomizer.at/>.

Blinding (investigator's opinion)
Double blinded

Blinding description
 Patients were unaware of their placement in the intervention groups and the statistical analyzer received the data in code, not the actual grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Resalat Street, Jihad Ave., Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2019-06-19, 1398/03/29

Ethics committee reference number

IR.UMSU.REC.1398.107

Health conditions studied

1

Description of health condition studied

Laryneal mask airway insertion in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Time to reach the desired relaxation for laryngeal mask insertion

Timepoint

Due to the nature of the variable under study, which is time, only once from the time of administration of sevoflurane to the desired relaxation was considered

Method of measurement

Timer by second

Secondary outcomes

1

Description

Heart rate

Timepoint

Once during laryngeal mask insertion

Method of measurement

Pulsoximeter

Intervention groups

1

Description

Intervention group: Patients in the intervention group underwent induction of anesthesia with 8% sevoflurane with oxygen and N2O in equal proportions. The criterion of anesthesia was the disappearance of the eyelid reflex. Laryngeal mask was inserted 90 second after anesthesia by skilled person. During this time, the patient received only 8% sevoflurane with oxygen and N2O in equal proportions and 1 mg/kg propofol (Produced by ABIAN Pharmed).

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group underwent induction of anesthesia with 8% sevoflurane with oxygen and N2O in equal proportions. The criterion of anesthesia was the disappearance of the eyelid reflex. Laryngeal mask was inserted 90 second after anesthesia by skilled person. During this time, the patient received only 8% sevoflurane with oxygen and N2O in equal proportions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Motahari Hospital

Full name of responsible person

Dr. Hadi Hooshyar

Street address

Shahid Motahhari hospital; Kashani street, Urmia, Iran.

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Phone

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Email

hooshyar.h@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences; Resalat street; Jihad Blvd; Urmia; Iran.

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mohebbi.i@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hadi Hooshyar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Shahid Motahhari Hospital; Kashani street; Urmia; Iran.

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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 can be provided without patients' names

When the data will become available and for how long

A year after completion of the study

To whom data/document is available

Faculty researchers

Under which criteria data/document could be used

Only for research purposes approved by a legal center as
an approved project

From where data/document is obtainable

Email to the scientific responsible of the project who is
Dr. Hoshyar hooshyar.h@umsu.ac.ir

What processes are involved for a request to access data/document

One week after sending the email and checking the
purpose of the request

Comments