

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Compare of Endotracheal Intubation and I-gel or LMA Insertion on Intraocular Pressure and Hemodynamic Response and Post op Nausea and Vomiting in Pediatric Patients Who Receive Propofol and Remifentanyl during Strabismus Surgery.

Protocol summary

Summary

Objective: To determine the effect of endotracheal intubation or I-gel or LMA on intraocular pressure and hemodynamic response and postoperative nausea and vomiting in children who relieved propofol and remifentanyl during surgery for strabismus Study design: randomized single blind clinical trial. Inclusion criteria: 3 to 8 years old; undergoing strabismus surgery; at least 6 hours NPO before surgery. Exclusion criteria: Glaucoma; a history of previous intraocular surgery; heart disease; lung disease ; diabetes; body mass index more than 35; limited mouth opening, mouth and larynx anatomical and pathological defects; possibility of regurgitation; airway obstruction. Method: 90 patients randomly divided into three groups of 30 endotracheal intubation and I-gel and LMA group. Sedation is with oral administration of midazolam 0.33 mg /kg , while anesthesia induced by 1 mg/ kg propofol, 1 µg/kg remifentanyl and 0.4 mg atracurium. Intraocular pressure by an eye specialist is measured by using the Tono pen device. At the same time hemodynamic variables: systolic blood pressures, diastolic blood pressure and heart rate are recorded. 3 minutes after induction endotracheal intubation or insertion of I-gel or LMA will be performed. And at 0, 2 and 5 minutes after intubation intraocular pressure are measured and recorded. After extubation, postoperative nausea and vomiting during recovery time are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040319470N54**

Registration date: **2017-05-13, 1396/02/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-13, 1396/02/23

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare of Endotracheal Intubation and I-gel or LMA Insertion on Intraocular Pressure and Hemodynamic Response and Post op Nausea and Vomiting in Pediatric Patients Who Receive Propofol and Remifentanyl during Strabismus Surgery.

Public title

Compare of Endotracheal Intubation and I-gel or LMA Insertion on Intraocular Pressure and Hemodynamic Response and Post op Nausea and Vomiting in Pediatric Patients Who Receive Propofol and Remifentanyl during Strabismus Surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 3 to 8 years old; undergoing strabismus surgery; at least 6 hours NPO before surgery. Exclusion criteria: Glaucoma; a history of previous intraocular surgery; heart disease; lung disease ; diabetes; body mass index more than 35; limited mouth opening, mouth and larynx anatomical and pathological defects; possibility of regurgitation; airway obstruction.

Age

From **3 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2016-08-22, 1395/06/01

Ethics committee reference number

IR.SUMS.MED.REC.1395.64

Health conditions studied

1

Description of health condition studied

Strabismus

ICD-10 code

H50

ICD-10 code description

Other strabismus

Primary outcomes

1

Description

Intra ocular pressure

Timepoint

every 0, 2, 5 minutes after inserion of airway decices

Method of measurement

tono pen

Secondary outcomes

1

Description

blood pressure

Timepoint

at 0,2 and 5 minutes after insrtion of airway devices

Method of measurement

Sphygmomanometer

2

Description

Heart rate

Timepoint

at 0,2 and 5 minutes after insrtion of airway devices

Method of measurement

pulsoximeter

3

Description

Nausea and Vomiting

Timepoint

at 0,2 and 5 minutes after insrtion of airway devices

Method of measurement

obsevation

Intervention groups

1

Description

Intervention group 1: endotracheal tube used for airway management.

Category

Prevention

2

Description

Interventions group two: I-gel used for airway management.

Category

Prevention

3

Description

Interventions group three: LMA used for airway management.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Hamed Zarei

Street address

Khalili Hospital, Khalili Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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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

Vice Chancellor for Research, Shiraz 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

Shiraz University of Medical Sciences

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Position

anesthesiology resident/physician

Other areas of specialty/work

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MS in English teaching, BS in anesthesia/English Consultant

Other areas of specialty/work

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Web page address**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