

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of respiratory complication between intra-tracheal intubation and Laryngeal Mask Airway (LMA) in neonates undergoing general anesthesia for inguinal herniorrhaphy

Protocol summary

Summary

This clinical trial is performed in Isfahan Imam Hossein (PBH) University Hospital from 21.3.2015 to 30.9.2016. Target population consists of 88 neonates who are candidates of unilateral inguinal herniorrhaphy. Exclusion criteria are surgical complication and operation cancelling. Random sampling will be done through Random Allocation II and patients will be allocated in two groups each consisting of 44 neonates. Intra-tracheal intubation will be performed in one group and Laryngeal Mask Airway (LMA) in the other. Anesthesia induction and maintenance will be performed similarly in both groups. Induction is administered by atropine (.02 mg/kg), fentanyl 2µg/kg, atracorium (.5 mg/kg), and sodium Thiopental (5mg/kg). Isoflurane is administered for maintenance. SPO₂, CO₂ and mean arterial pressure (MAP) will be registered every 15 minutes during operation. Respiratory complications (laryngospasm, bronchospasm and cough) are registered and compared. Data will be analyzed by SPSS 22 through t-test and repeated measure ANOVA.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070126866N2**
Registration date: **2016-07-11, 1395/04/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-11, 1395/04/21

Registrant information

Name

Amir Shafa

Name of organization / entity

Isfahan University of Medical Sciences, Imam hossein Hospital

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-09-30, 1395/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of respiratory complication between intra-tracheal intubation and Laryngeal Mask Airway (LMA) in neonates undergoing general anesthesia for inguinal herniorrhaphy

Public title

respiratory complication in intra-tracheal intubation and Laryngeal Mask (LMA) in neonates

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: neonates (age one month and

younger);body weight >3 kg; gestational age >34 weeks; ASA I class; candidate of unilateral inguinal herniorrhaphy exclusion criteria:surgical complication, operation cancelled

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences, ethical committee od deputy of reseach

Street address

gostaresh, hezarjerib ave.

City

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Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

394063

Health conditions studied

1

Description of health condition studied

inguinal hernia

ICD-10 code

K40.9

ICD-10 code description

K40.9 Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description

respiratory complication

Timepoint

every 5 minutes during operation and every 15 minutes in recovery room

Method of measurement

SPO2, ETCO2, hemodynamic changes

Secondary outcomes

1

Description

Heart rate, mean arterial blood pressure (hemodynamic changes)

Timepoint

every 5 minutes during anesthesia and every 15 minutes in the recovery room

Method of measurement

S'adat monitoring device

Intervention groups

1

Description

Laryngeal Mask (LMA)

Category

Treatment - Drugs

2

Description

intra-tracheal intubation

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossin Hospital (PBUH), Isahan

Full name of responsible person

Amir Shafa, MD, anesthesiologist

Street address

Imam hossein Hospital, Imam khomeini ave, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences
Full name of responsible person
 Dr Mehdi Nematbakhsh
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 Isfahan faculty of medicine
City
 Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Isfahan 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

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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