Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparative study of using laryngeal mask (LMA) with and without muscle relaxant in anesthesia of children one to four years old undergoing upper extremity reconstructive surgery in Hazrat Fatemeh Hospital.

Protocol summary

Study aim
Comparative study of using laryngeal mask (LMA) with and without muscle relaxant in anesthesia of children one to four years old undergoing upper extremity reconstructive surgery

Design
This study is a double-blind, randomized, phase 3 clinical trial on 70 patients and block randomization method will be used.

Settings and conduct
After proper and standard monitoring, we establish a suitable intravenous injection route from the patient and in two groups of patients, general anesthesia is performed according to the necessary standards (drug injection and anesthesia method). In the first group, neuromuscular relaxant is used as an intervention during induction and the appropriate size of laryngeal mask is selected according to the patient's weight. In the second group, normal saline is used instead of neuromuscular relaxant. According to the patient's weight, the appropriate size of laryngeal mask is selected, then the objectives of the study are compared in two groups. This study is performed in Hazrat Fatemeh Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children one to four years old, anesthesia score ASA 1, 2, upper limb injury Exclusion criteria: Children with the possibility of difficult intubation, Children with upper airway infections, Children with congenital diseases with unusual airway, Children with a history of seizures and neurological diseases, Children at high risk for pulmonary aspiration.

Intervention groups
In one group of patients, neuromuscular relaxant is used as an intervention during induction of anesthesia, and in another group, normal saline is used instead of neuromuscular relaxant.

Main outcome variables
Laryngeal mask placement, intraoperative movement of laryngeal mask, laryngeal mask pressure, laryngeal mask complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110513006465N3**
Registration date: **2021-06-15, 1400/03/25**
Registration timing: **prospective**

Last update: **2021-06-15, 1400/03/25**
Update count: **0**

Registration date
2021-06-15, 1400/03/25

Registrant information

Name
Seyed Alireza Seyed Siamdoust

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8877 1749

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of using laryngeal mask (LMA) with and without muscle relaxant in anesthesia of children one to four years old undergoing upper extremity reconstructive surgery in Hazrat Fatemeh Hospital.

Public title

Comparison of the use of laryngeal mask with and without muscle relaxant in anesthesia of children one to four years old.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children one to four years old Anesthesia score ASA 1, 2 Upper limb injury

Exclusion criteria:

Children with the possibility of difficult intubation Children with upper airway infections Children with congenital diseases with unusual airway Children with a history of seizures and neurological diseases Children at high risk for pulmonary aspiration

Age

From **1 year** old to **4 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the person evaluating the goals are unaware of the type of intervention being assigned.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

8874113911

Approval date

2021-01-03, 1399/10/14

Ethics committee reference number

IR.IUMS.FMD.REC.1399.550

Health conditions studied

1

Description of health condition studied

Children's diseases

ICD-10 code

Y81

ICD-10 code description

General- and plastic-surgery devices associated with adverse incidents

Primary outcomes

1

Description

Laryngeal mask placement

Timepoint

During anesthesia

Method of measurement

Using a three-point rating table

2

Description

Movement during laryngeal mask surgery

Timepoint

During anesthesia

Method of measurement

View by the anesthesiologist and the opinion of the anesthesia assistant

Secondary outcomes

1

Description
Laryngeal mask pressure
Timepoint
During anesthesia
Method of measurement
By barometer

2

Description
Complications of laryngeal mask
Timepoint
By barometer
Method of measurement
By observation and recording by the researcher

Intervention groups

1

Description
Intervention group: In one group of patients, the neuromuscular relaxant drug Atracurium made by Caspian Pharmaceutical Company at a dose of 0.5 mg / kg is used as an intervention during induction of anesthesia. The drug is drawn in a 5 cc syringe and labeled A.
Category
Treatment - Drugs

2

Description
Control group: In the other group, instead of using a neuromuscular relaxant, normal saline is used. The drug is drawn in a 5 cc syringe and labeled B.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat fatemeh hospital
Full name of responsible person
Seyed alireza seyed siamdoust
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21th Str. Asadabadi Ave. Hazrate Fatemeh Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Seyed alireza seyed siamdoust
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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

Undecided - It is not yet known if there will be 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