Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of direct laryngoscopy with video laryngoscopy in pediatric airways management for Congenital Heart surgery

Protocol summary

Study aim

Comparison of direct laryngoscopy with video laryngoscopy in pediatric airway management for Congenital Heart surgery

Design

This clinical trial will be performed on 60 children aged 1 to 5 years with anesthesia class1 to 3 who will be candidates for tracheal intubation for elective congenital cardiac surgery. After the necessary monitoring was performed, pulse oximetry, electrocardiography, non-invasive pressure and anesthesia were performed by an anesthetist by a constant method (including fentanyl 20 micrograms per kilogram and atracurium 5 / mg / kg) randomly In one group (direct laryngoscopy or laryngoscopy by video laryngoscopy). The The choice of patient for intubation by video laryngoscope or direct laryngoscope is one way. The input view and the intubation time will be recorded in each group.

Settings and conduct

This study will be done in the open heart surgery room of Golestan Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria:1- Children aged 1 to 5 years 2- Elective congenital cardiac surgery 3- Class anesthesia 1 to 3 Exclusion criteria:There are difficult airway 2. There are risk of pulmonary aspiration.

Intervention groups

In group 1 , tracheal intubation with direct layngoscopy will be done. In group 2, tracheal intubation with video layngoscopy will be done.

Main outcome variables

the primary outcome is:the number of success rate in the first attempt to intubation, and the secondary outcomes are: including the duration of successful intubation and the number of intubation failures in the first attempt

General information

Reason for update

This project was conducted as double-blind

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040979N2**
Registration date: **2019-03-18, 1397/12/27**
Registration timing: **prospective**

Last update: **2020-04-08, 1399/01/20**
Update count: **1**

Registration date

2019-03-18, 1397/12/27

Registrant information

Name

MARYAM ZAMANKHANI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 4760

Email address

zamankhani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of direct laryngoscopy with video laryngoscopy in pediatric airways management for

Congenital Heart surgery

Public title
Comparison of direct laryngoscopy with video laryngoscopy
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Anesthesia class 1-3 Candidate for tracheal intubation Candidate for elective congenital cardiac surgery
Exclusion criteria:
There are difficult airway There are at risk for pulmonary aspiration
Age
From **1 year** old to **5 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Principal investigator and the patient is not aware of the type of intervention
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences., Research Deputy.,Blvd. Golestan .Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2019-03-04, 1397/12/13
Ethics committee reference number
IR.AJUMS.REC.1397.907

Health conditions studied

1

Description of health condition studied
Intubation
ICD-10 code
T88.4
ICD-10 code description
Failed or difficult intubation

Primary outcomes

1

Description
The success rate for intubation in first attempt
Timepoint
After intubation
Method of measurement
Capnograph

Secondary outcomes

1

Description
Success intubation time
Timepoint
After intubation
Method of measurement
Cronometer

2

Description
Failed intubation
Timepoint
After intubation
Method of measurement
Capnograph

Intervention groups

1

Description
Control group: In control group intubations are done using direct laryngoscopy in which rigid laryngoscope is used to expose the laryngeal inlet under direct vision to facilitate intubation.
Category
Prevention

2

Description

Intervention group: in intervention group intubations are done using video laryngoscope. Video laryngoscope utilizes video camera technology to visualize airway structures and facilitate endotracheal intubation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Fatemeh Javaherforoosh zadeh

Street address

Golestan hospital.Blvd golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Phone

+98 61 3391 9315

Email

f_javaherforoosh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohamad Badavi

Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Phone

+98 61 3336 7550

Email

Badavi-m@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Javaherforoosh zadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

No.1,West Maroon,East13,Kianpars

City

Ahvaz

Province

Khouzestan

Postal code

6155979939

Phone

+98 61 3391 9315

Email

f_javaherforoosh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

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Person responsible for updating data

Contact

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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