Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of using high-flow nasal cannula after early extubation On respiratory parameters and pulmonary complications after children's heart surgery

Protocol summary

Study aim
Effect of high flow nasal cannula after early extubation on respiratory parameters and pulmonary complications after pediatric heart surgery

Design
A randomized controlled clinical trial with parallel groups Accidental

Settings and conduct
The research is carried out in the pediatric intensive care unit of Imam Reza Research Center of Mashhad. Which has 10 beds and immediately after children and infants Corrective heart surgery is admitted here.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Children older than one month and less than two years old; Children with congenital heart problems based on Risk adjustment for congenital heart surgery (RACHS) score of 2 or 3; Complete vigilance Exclusion criteria: History of Kidney Disease; Pulmonary; Cerebral; Endocrine and preoperative infection; Preoperative mechanical ventilation; Malnutrition; Moderate to severe anemia And severe electrolyte and acid-base disturbances

Intervention groups
Intervention group: Respiratory support with high flow nasal cannula Control group: Respiratory support conventional oxygen therapy (simple nasal cannula)

Main outcome variables
Atelectasis; Pleural effusion; Respiratory failure; Simple pneumothorax; Need for re-intubation; Arterial oxygen pressure; Arterial carbon dioxide pressure; pao2 / Fio2 ratio

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190917044792N1**
Registration date: **2019-11-15, 1398/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-15, 1398/08/24**
Update count: **0**

Registration date
2019-11-15, 1398/08/24

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-23, 1398/08/01
Expected recruitment end date
2020-03-20, 1399/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of using high-flow nasal cannula after early extubation On respiratory parameters and pulmonary complications after children's heart surgery

Public title
The effect of using high-flow nasal cannula after early extubation respiratory after children's heart surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children older than one month and less than two years old Children with congenital heart problems based on RACHS 2 or 3 criteria Full conscious
Exclusion criteria:
History of renal Disease History of pulmonary disease History of brain disease History of Endocrine Disease Preoperative infection history Pre-operative mechanical ventilation Moderate to severe anemia (hemoglobin less than 10 mg / dL) Severe electrolyte and acid-base disturbances (pH lower than 7.30 and greater than 7.50) Malnutrition
Age
From **1 month** old to **24 months** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random method using statistical software
Blinding (investigator's opinion)
Not 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 Sabzevar University of Medical Sciences Research
Street address
No. 3 ،Elahieh32 ،Elahieh Blv، Misaq highway،Mashhad
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Province
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Postal code
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Approval date
2019-10-06, 1398/07/14
Ethics committee reference number
IR.MEDSAB.REC.1398.049

Health conditions studied

1

Description of health condition studied
Postoperative pulmonary complications
ICD-10 code
T81.9
ICD-10 code description
Unspecified complication of procedure

Primary outcomes

1

Description
Atelectasis is the sleeping or closing of the alveoli.
Timepoint
Evaluation of atelectasis is monitored and recorded daily using plain chest x-ray on arrival at the ICU as well as by ultrasound.
Method of measurement
Used for the evaluation of pulmonary complications, including atelectasis, a portable SonoSite EDGE ultrasound system with a pediatric size probe

2

Description
Arterial Oxygen Pressure: Oxygen pressure (Po2) is an indirect measure of arterial blood oxygen content and its normal range is between 80-100 mmHg.
Timepoint
On admission to the ICU and after 6 hours in the ICU during mechanical ventilation and before extubation and immediately after extubation and at 1, 2, 6, 12, 24 and 36 hours after HFNC or conventional oxygen therapy, respectively.will be measured.
Method of measurement
Arterial blood pressure was measured using an arterial blood sample and a GEM3000 blood gas analyzer.

3

Description
Arterial carbon dioxide pressure: The relative pressure of CO2 in arterial blood is called Pco2, which is a sign of ventilation. Normal body Pco2 ranges from 35 to 45 mm Hg in adults and 41 to 26 mm Hg in children younger than 2 years.
Timepoint
On admission to the ICU and after 6 hours in the ICU during mechanical ventilation and before extubation and immediately after extubation and at 1, 2, 6, 12, 24 and 36 hours after HFNC or conventional oxygen therapy, respectively.will be measured.
Method of measurement

Arterial blood pressure was measured using an arterial blood sample and a GEM3000 blood gas analyzer.

4

Description

PAO2 / FIO2 Ratio: The ratio of arterial oxygen pressure and tail oxygen content, a comparison between the level of oxygen in the blood and the oxygen concentration that breathes. Normal PaO2 content: FiO2 = 100 mmHg / 500 0.2 0.21

Timepoint

On admission to the ICU and after 6 hours in the ICU during mechanical ventilation and before extubation and immediately after extubation and at 1, 2, 6, 12, 24 and 36 hours after HFNC or conventional oxygen therapy, respectively.will be measured.

Method of measurement

Arterial blood samples and GEM3000 blood gas analyzer are used.

5

Description

Re-intubation: Inability to spontaneously breathe after removal of the artificial airway, leading to the need for endotracheal intubation over a specified period of time: either within 24-72 hours or up to 7 days after the first extubation.

Timepoint

In this study, 24 to 72 hours after the first extubation is considered to assess the need for re-intubation.

Method of measurement

According to the information recorded in the patient's file

6

Description

Respiratory insufficiency: A sudden and dangerous impairment of gas exchange by the lungs, with the lungs failing to balance oxygen and carbon dioxide, with arterial oxygen pressure less than 50 mm Hg and arterial carbon dioxide pressure greater than 50 mm Hg and arterial pH are less than 7.35

Timepoint

Case studiesSigns and symptoms are constantly monitored for respiratory failure during the study.

Method of measurement

According to respiratory parameters and arterial blood sample and analyzed with GEM3000 blood gas device.

7

Description

Pleural effusion: The fluid accumulates more than 15 cc in the lateral cavity.

Timepoint

Evaluation of pleural effusion is monitored and recorded daily using plain chest x-ray and ultrasound.

Method of measurement

To evaluate pulmonary complications such as pleural effusionA Portable SonoSite EDGE portable ultrasound system with a baby size probe is used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: From the Fisher & Paykel MR850 Series we select two types of nasal cannula based on baby weight and body mass index: nasal cannula that offers maximal flow rate of 8 l / min for infants less than 4 kg and nasal cannula That delivers a maximum flow of 20 l / min for children> 4 kg.And so when applied to an HFNC device, the gas mixture is set at 2 liters / kg for the first ten kilos and half liters / kg thereafter at 40% fiO2.

Category

Other

2

Description

Control group: Routinely receive normal nasal cannula section with Lit / min6 flow which produces 40% fio2

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Cardiac Surgery Intensive Care Unit Imam Reza Research Center of Mashhad

Full name of responsible person

Farzaneh Enayati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Fereshteh Ghorat

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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
Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
Farzaneh Enayati

Position
Graduate student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers and students will be available at academic and scientific institutions

Under which criteria data/document could be used

Nursing care for children undergoing heart surgery

From where data/document is obtainable

Farzaneh Enayati Email address: enayatifarzaneh26@gmail.com

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

Almost 1 month after sending the request

Comments