

# 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

###### Name

Farzaneh Enayati

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3501 6559

###### Email address

enayatif97@medsab.ac.ir

##### 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9189864398

**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**

PAO<sub>2</sub> / FIO<sub>2</sub> Ratio: The ratio of arterial oxygen pressure and arterial oxygen content, a comparison between the level of oxygen in the blood and the oxygen concentration that breathes. Normal PaO<sub>2</sub> content: FIO<sub>2</sub> = 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 studies Signs 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.

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##### **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 effusion A 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% fIO<sub>2</sub>.

#### **Category**

Other

### 2

#### **Description**

Control group: Routinely receive normal nasal cannula section with Lit / min 6 flow which produces 40% fIO<sub>2</sub>

#### **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

##### **Street address**

No. 3 ,Elahieh32 ,Elahieh Blv, Misaq highway, Mashhad

##### **City**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Sabzevar University of Medical Sciences

##### **Full name of responsible person**

Fereshteh Ghorat

##### **Street address**

Educational block,Campus of Sabzevar University of  
Medical Sciences,Tohidshahr,Sabzevar,

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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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**Person responsible for scientific  
inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mojgan Ansari

**Position**

Consultant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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Farzaneh Enayati

**Position**

Postgraduate student

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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**