Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Comparision of two methods according to clinical judgment and protocol in extubation on mechanical ventilation duration and extubation failure in children

Protocol summary

Study aim
Comparison of two extubation methods on mechanical ventilation duration and extubation failure on children admitting in PICU

Design
Randomized clinical trial with parallel control group

Settings and conduct
This study is conducted in Isfahan Imam Hossein Children's Hospital,PICU. After determining the inclusion and exclusion criteria, patients are divided into two groups. In the intervention group, protocol is performed, and the tracheal tube is removed if it is successful. Extubation is performed in the control group based on the physician's clinical decision. The patients undergo non-invasive mechanical ventilation or reintubation if the failure criteria being met within two days of extubation.

Participants/Inclusion and exclusion criteria
All infants and children admitted and intubated in PICU and who have been receiving MV for >12 hrs,are included. The exclusion criteria are as follows: intubation due to upper airway obstruction, chronic MV use, cyanotic congenital heart disease, primary pulmonary hypertension,neuromuscular disease and tracheostomy.

Intervention groups
In study group, patients have to meet the readiness criteria undergo to spontaneous breathing test. Ventilator setting in 0.5 hour SBT is Spont/PSV. If there are stable vital signs,not hypoventilation and unconsciousness; and acceptable ABG during the test, patients are extubated and get 100% oxygen. Extubation is done in control group according to physician clinical judgment.

Main outcome variables
1- extubation failure 2- mechanical ventilation duration in successful extubation 3- length of PICU stay 4- length of hospital stay 5- mortality in PICU 6- reintubation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190219042766N1**
Registration date: **2019-09-28, 1398/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**
Update count: **0**

Registration date
2019-09-28, 1398/07/06

Registrant information

Name
Atefeh Sadeghizadeh

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3630 8104

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-27, 1398/04/06

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision of two methods according to clinical judgment and protocol in extubation on mechanical ventilation duration and extubation failure in children

Public title
Extubation method on extubation failure and mechanical ventilation duration

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All infants and children ،aged between 1 month to 14 years، admitted in PICU Patients have been receiving MV above 12 hours
Exclusion criteria:
Intubation due to upper airway obstruction (UAO) neuromuscular disease tracheostomy chronic MV use cyanotic congenital heart disease primary pulmonary hypertension.

Age
From **1 month** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization with two numbers in each block

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 Isfahan university of medical sciences
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Hezarjerib Avenue
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Approval date
2019-02-03, 1397/11/14
Ethics committee reference number
IR.MUI.MED.REC.1398.072

Health conditions studied

1

Description of health condition studied
Extubation method
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mechanical ventilation duration
Timepoint
9 months
Method of measurement
Hospital admission file

2

Description
extubation failure
Timepoint
9 months
Method of measurement
Hospital admission file

Secondary outcomes

1

Description
Length of hospital stay
Timepoint
9 months
Method of measurement
Hospital admission file

2

Description
Length of PICU stay
Timepoint
9 months
Method of measurement
Hospital admission file

3

Description
Mortality in PICU
Timepoint
9 months
Method of measurement

Hospital admission file

Intervention groups

1

Description

In intervention group,the readiness criteria included the following are evaluated: recovery or eliminating of their underlying causes for respiratory failure and intubation, T<38.5 ºC, HB> 8, ability to swallow secretions, having gag or cough reflexes during suctioning the secretions, having an acceptable level of consciousness, i.e. GCS score≥8 after discontinuing sedations and analgesics, correction of electrolytes, absence of new findings in the chest X-ray, no needs for increasing the settings of the ventilator over the previous 24 hours, the total discontinuation of sedations and analgesics in at least the previous six hours, no needs for vasoactive agents, an acceptable arterial-blood gas and air exchange with StO2>94% despite FiO2<40, PIP<20 and PEEP<5.If they meet all criteria, the ventilator settings are set as follows: Mode: Spont/PSV, PEEP≤5, FiO2≤40, PS according to ET size (3-3.5:10, 4-4.5:8, ≥5:6). The SBT failure is confirmed in case at least two of the following conditions are observed during the intervention: respiratory rate being outside the normal range by age, i.e. tachypnea or bradypnea, respiratory distress, VTe<5 ml/kg, SatO2<90%, hypotension based on PALS guidelines or an over 20% increase in blood pressure, impaired consciousness associated with hypoventilation, heart rate outside the normal range by age, i.e. tachycardia and bradycardia, Pco2>55 mmHg or an increase in Pco2 by at least 10mmHg in patients with chronic pulmonary disease in the final arterial-blood gas test. If the test failed, the parameters and mode of the ventilator are set as before the test, and if the clinical criteria are met as described, the test is repeated 24 hours later.Endotracheal tube is immediately extracted if the test is successful, and the patient is provided with a non-rebreathing face mask with a 10-15 l/min flow, and undergo100% oxygen therapy. Arterial-blood gas test is performed two hours after extubation. Extubation failure is confirmed in case at least two of the following symptoms emerged within two days of extubation: respiratory distress, hypoxia with SatO2<90%, respiratory rate outside the normal range by age, i.e. tachypnea or bradypnea , apnea>20 seconds, hypotension based on PALS guidelines or an over 20% increase in blood pressure, impaired consciousness associated with hypoventilation, heart rate outside the normal range by age, i.e. tachycardia and bradycardia, Pco2>55 mmHg or an increase in Pco2 by at least 10mmHg in patients with chronic pulmonary disease accompanied by PH<7.3 and symptoms of upper airway obstruction. In case of the absence of contraindications for NIMV, Bi-level positive airway pressure (BiPAP) is applied with minimum settings as EPAP:5 and IPAP:8-10, and tittered up to EPAP:8-10 and IPAP:5-22 and until clinical and laboratory symptoms of respiratory failure disappear. The patient is reintubated if respiratory failure symptoms persist after two hours of monitoring

Category

Treatment - Other

2

Description

In control group ,The attendant of pediatric or anesthesiology by ICU fellowship decides on ventilator settings and respiratory support reduction and extubation according to the results of arterial-blood gas tests performed at least once a day and based on the patient's clinical conditions, including eliminating the causes of intubation, appropriate ventilation and oxygenation and stable vital signs.The post-extubation oxygen supply method, the criteria of extubation failure and NIMV and reintubation protocols are as same as the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Imam Hussein Hospital

Full name of responsible person
Dr. Atefeh Sadeghizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr Atefeh Sadeghizadeh

Position

PICU fellowship

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

Specialist

Other areas of specialty/work

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Making decision after doing this study.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable