

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of Continuous positive airway pressure ventilator with T-Piece and humidifier on outcome of weaning of children admitted to intensive care unit ward

Protocol summary

Summary

(1) Objectives: Our aim in this study is to compare effect of Continuous positive airway pressure ventilator and T-piece and humidifier in the outcome of weaning patients from mechanical ventilation. (2) Design: Fifty patients from both genders admitted for any reason to pediatric intensive care unit ward, Tabriz children Hospital, Tabriz will be included in the study. In a double blinded study patients will be randomized into two groups of Continuous positive airway pressure ventilator and T-piece and humidifier and will be included in the clinical trial after qualifying the inclusion and exclusion criteria and obtaining the informed consent. (3) Setting and conduct: Fifty patients from both genders admitted for any reason to pediatric intensive care unit ward, Tabriz children Hospital, Tabriz will be included in the study and will be divided into two groups of 25. Inclusion criteria are age between 1 month and 14 years old; admission to pediatric intensive care unit ward; being intubated. Exclusion criteria are patient intolerance in Continuous positive airway pressure stage; having difficulty to wean the patient as the result of neurological or muscular lesion. (4) Intervention: Fifty patients will be divided into two groups of Continuous positive airway pressure ventilator and T-piece and humidifier. If there is a spontaneous breathing with receiving a FiO₂ lower than 40 percent and PaO₂ is higher than 60, patient will be candidate for weaning. (5) Main outcome measures: Days of mechanical ventilation, need to reintubate the patient, days of hospital admission, days of intensive care unit ward admission and in-hospital mortality which will be evaluated daily for both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013043013189N1**

Registration date: **2013-06-20, 1392/03/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-20, 1392/03/30

Registrant information

Name

Shalaleh Ganji

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Continuous positive airway pressure

ventilator with T-Piece and humidifier on outcome of weaning of children admitted to intensive care unit ward

Public title

Comparison of using two kinds of devices in respiration of hospitalized children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 1 month and 14 years old; admission to pediatric intensive care unit ward; being intubated. Exclusion criteria: patient's intolerance in Continuous positive airway pressure ventilator stage; having difficulty to wean the patient as the result of neurological or muscular lesion.

Age

To **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

For randomizing patients into two groups we used pocket method. We used a double blinded study to prevent research outcomes from being influenced by the placebo effect or observer bias.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

Tabriz

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

91169

Health conditions studied

1

Description of health condition studied

Acute respiratory failure

ICD-10 code

J96.0

ICD-10 code description

Acute respiratory failure

2

Description of health condition studied

Chronic respiratory failure

ICD-10 code

J96.1

ICD-10 code description

Chronic respiratory failure

3

Description of health condition studied

Respiratory failure

ICD-10 code

J96.9

ICD-10 code description

Respiratory failure, unspecified

Primary outcomes

1

Description

Days of mechanical ventilation

Timepoint

After intubation will be counted daily

Method of measurement

Questionnaire

2

Description

Days of hospitalization

Timepoint

After admission will be counted daily

Method of measurement

Questionnaire

3

Description

Days of intensive care unit admission

Timepoint

After intubation will be counted daily

Method of measurement

Questionnaire

Secondary outcomes

1

Description

In-hospital mortality

Timepoint

At the end of admission period

Method of measurement

Questionnaire

Intervention groups

1

Description

In continuous positive airway pressure ventilator group, patients will be ventilated with continuous positive airway pressure ventilator

Category

Treatment - Devices

2

Description

In T-Piece and humidifier group, patients will be ventilated with T-Piece and humidifier

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Shalaleh Ganji

Street address

Tabriz Children Hospital, Sheshgelan Street,
Farmanfarmayan Street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of
Medical Sciences

Full name of responsible person

Dr. Seyyed Kazem Shakouri

Street address

Vice chancellor for research, Tabriz University of
Medical Sciences, Golgasht Street, Azadi Street,
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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

Vice chancellor for research, Tabriz University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz Children Hospital

Full name of responsible person

Dr. Shalaleh Ganji

Position

Pediatric diseases resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty