

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of the heat and moisture exchanger (HME)Filter and heated Humidifier on respiratory mechanics and gas exchange in patients undergoing mechanical ventilation with CPAP mode in intensive care units .

Protocol summary

Respiratory dead space ventilation,Static compliance, Dynamic compliance,inspiratory Resistance

Study aim

Comparison the effect of HME filter and heated humidifiers on gas exchange and lung mechanical parameters in patients undergoing mechanical ventilation with CPAP mode.

Design

Cross-over clinical trial In two groups with sample size of 21 persons Samples were selected as available and randomly assigned to one of two groups.

Settings and conduct

Research Environment: Intensive care units, strokes and general strokes of Ghaem Hospital. In the first group, the HME filter is first connected to the ventilation path of the patients and the numerical values of gas exchange and lung mechanical parameters At fifteen and thirty and Sixty minutes, as shown by the ventilator monitor, are recorded on the chart and then subjected to humidification with respiratory air humidification.And after 30 minutes, numerical values of gas exchange and lung mechanical indexes are recorded on the chart in minutes, fifteen thirty and sixty, as shown by the ventilator monitor.In the second group, it is time to switch tools. .

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age 18 - 85 years 2. Patient with endotracheal tube and tracheostomy under CPAP 4- Patients with hemodynamic stability 5. RASS score between +1 and -4. Exclusion criteria: 1- Having active hemoptysis or tracheal fistula 2 - systolic blood pressure< 90 mm Hg

Intervention groups

In the intervention group and control group the effect of HME filter and heated humidifiers on gas exchange and Indicators of lung mechanics are reviewed.

Main outcome variables

Exhaust end carbon dioxide,Alveolar ventilation,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191112045414N1**

Registration date: **2020-01-19, 1398/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-19, 1398/10/29**

Update count: **0**

Registration date

2020-01-19, 1398/10/29

Registrant information

Name

Elyas Motamedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3851 4261

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

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
Effect of the heat and moisture exchanger (HME)Filter and heated Humidifier on respiratory mechanics and gas exchange in patients undergoing mechanical ventilation with CPAP mode in intensive care units .

Public title
Effect of the heat and moisture exchanger (HME)Filter and heated Humidifier on respiratory mechanics and gas exchange in patients undergoing mechanical ventilation with CPAP mode

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with tracheo tube or tracheostomy patients under mechanical ventilation patients with stable hemo dynamic status Richmond score within +1 and -4
Exclusion criteria:
patients under mechanical ventilation expect of CPAP mode Patients hospitalized due to hemoptesis blood pressure under 90 mmHg Patient with rib fracture or chest tube Patient under surgery

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are selected as available and then assigned to either the HME group or the heated humidifier based on Permuted Block Randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sabzevar University of Medical Sciences

Street address

University of Medical sciences .Shohada Hastee
Blv.Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Approval date

2019-11-01, 1398/08/10

Ethics committee reference number

IR.MEDSAB.REC.1398.058

Health conditions studied

1

Description of health condition studied

Patients under mechanical ventilation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

respiratory mechanic and gas exchange

Timepoint

Beginning of the research and minutes 15,30,60

Method of measurement

Capnograph

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:In the first group, the HME filter is first connected to the ventilation path of the patients and the numerical values of gas exchange and lung mechanical parameters At fifteen and thirty and Sixty minutes, as shown by the ventilator monitor, are recorded on the chart and then subjected to humidification with respiratory air humidification.And after 30 minutes, numerical values of gas exchange and lung mechanical indexes are recorded on the chart in minutes, fifteen thirty and sixty, as shown by the ventilator monitor.

Category

Treatment - Devices

2

Description

Control group: In the second group, the humidifier is first connected to the ventilation path of the patients and the numerical values of gas exchange and lung mechanical parameters At fifteen and thirty and Sixty minutes, as shown by the ventilator monitor, are recorded on the chart and then subjected to the HME filter .And after 30 minutes, numerical values of gas exchange and lung mechanical indexes are recorded on the chart in minutes, fifteen thirty and sixty, as shown by the ventilator monitor.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Gaeem hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

50

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

Elyas Motamedi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Subspecialist

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Latest degree

Bachelor

Other areas of specialty/work

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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