Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of the Active And Passive Humidifiers On The Parameters Of Pulmonary And Ventilator Associated Pneumonia In Patients Admitted To Intensive Care Units.

Protocol summary

Study aim

The effect of the Active And Passive Humidifiers On The Parameters Of Pulmonary And Ventilator Associated Pneumonia In Patients Admitted To Intensive Care Units.

Design

In this study, 80 patients are selected under mechanical ventilation and are eligible to enter the study. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

Patients admitted to the ICU in the Ayatollah Mousavi Hospital affiliated to Zanjan University of Medical Sciences who have artificial airway were selected by convenience sampling metho .Initial sampling was done in random sampling by pilot method. Because of the sampling method and all the intervention methods in pilot sampling, as in the main samples, pilot samples were also considered as the main samples. After initial analysis of the results and using the formula, the final number of samples in both experimental and control groups was estimated to be approximately 80 patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing mechanical ventilation following 12 hours of intubation and mechanical ventilation and undergo mechanical ventilation during the study; Having vital signs in the normal range, not using dopamine, double-breasted or nitroglycerin, and hypotensive drugs؛ Patients should not have artificial teeth; Patients aged 18-60 years old; Modem of the ventilator is SIMV and the size of the tracheal tube is 7 to 8; patients have history of pneumonia, aspiration, chemotherapy, pulmonary injury in the lower airways, exacerbated myasthenia grave and recent MI; A pregnant woman is not pregnant or burn7; Exclusion criteria: Patients who take pentoprazole instead of ranitidine; Age over 60 years; Chronic pulmonary disease; Having a chest tube and a pulmonary canine; Patients diagnosed with burns

Intervention groups

After receiving the letter of the Ethics Committee from the University of Medical Sciences and introducing the letter to the hospital authorities, the study began on February 20, 2017 in ICU department of Ayatollah Mousavi Hospital. Inhibitory interventions using the HME for the first group and the active Humidity type (HHS) were used for the second group. This intervention begins on the first day of admission to the intensive care unit for patients undergoing mechanical ventilation and is monitored for up to seven days, and daily pulmonary parameters and pneumonia rates are measured and recorded in both groups. In this study, the pulmonary parameters are included in the volume of air flow and airway resistance, the volume of emergency storm and exhalation, small airways, airway pressure and lung compilation, which is measured by ventilation device. For pneumonia caused by a ventilator, CPIS is calculated through variables such as the number of white blood cells, the amount of blood oxygenation saturated (calculated based on PaO2 divided into respiration oxygen) and chest radiography. In this study, premature VAP (less than 96 hours) and late VAP (greater than 96 hours) were studied. The samples were followed up to seven days, and in the first, third, and seventh day at night shift, pneumonia was evaluated using the CPIS scale. The scores were accumulated in each day; if a score of six or more was obtained, the diagnosis of pneumonia was definite. In order to determine the VAP, the temperature of the pedicle was calculated and, for determining the central temperature, the value was calculated to be 0.6 to the temperature To measure the temperature, the average of the same day's temperature was used for diagnosis. Diagnosis of all CPIS cases except the pulmonary infiltrates by itself. The jaws were performed and the graphic interpretation of the lungs was handled by an ICU practitioner (ICU specialist).

Main outcome variables

Respiratory rate, airway resistance increased in inactive Humidifier group. There was no significant difference in the level of pneumonia between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171202037703N1**
Registration date: **2017-12-28, 1396/10/07**
Registration timing: **retrospective**

Last update: **2017-12-28, 1396/10/07**
Update count: **0**

Registration date

2017-12-28, 1396/10/07

Registrant information

Name

Mostafa Abin

Name of organization / entity

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Iran (Islamic Republic of)

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+98 24 3353 0867

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-16, 1396/05/25

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

2017-08-16, 1396/05/25

Actual recruitment end date

2017-12-02, 1396/09/11

Trial completion date

empty

Scientific title

The effect of the Active And Passive Humidifiers On The Parameters Of Pulmonary And Ventilator Associated Pneumonia In Patients Admitted To Intensive Care Units.

Public title

Comparison of two types of airway humidifier in ventilated patients on pulmonary parameters and infection rates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing mechanical ventilation following 12 hours of intubation and mechanical ventilation and undergo mechanical ventilation during the study; Having vital signs in the normal range, not using dopamine, double-breasted or nitroglycerin, and hypotensive drugs; Patients should not have artificial teeth; Patients aged 18-60 years old; Modem of the ventilator is SIMV and the size of the tracheal tube is 7 to 8; patients have history of pneumonia, aspiration, chemotherapy, pulmonary injury in the lower airways, exacerbated myasthenia grave and recent MI; A pregnant woman is not pregnant or burn7

Exclusion criteria:

Patients who take pentoprazole instead of ranitidine; Age over 60 years; Chronic pulmonary disease; Having a chest tube and a pulmonary canine; Patients diagnosed with burns;

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**
Actual sample size reached: **80**
More than 1 sample in each individual
Actual sample size in each individual: **40**
The research community includes all items that have common features and characteristics of research units or have a common trait

Randomization (investigator's opinion)

Randomized

Randomization description

Initial sampling was done in random sampling by pilot method. Because sampling method and all intervention methods were similar to pilot samples in pilot sampling, pilot samples were also considered as the main samples. In order to control the interventional variables and the equivalence of the samples in the two groups, after the selection of each sample, the sample is randomly selected and used by the blocking method in the test or control group to obtain the appropriate sample size. In the blocking technique, blocks with a pair size (usually four or six) are created, in which, randomly, half of the individuals in each block are placed in one group and the other in the other group; then, as much The block is selected to reach the required sample size. For example, if we want to put 80 people in two groups of 40 in A and B, then we first consider all four modes in which half of the individuals assigned to group A and the other half to group B. We will determine.

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 zanjan university of medical sciences

Street address
Azadi Square. Zanjan University of Medical Sciences

City
zanjan

Province
Zanjan

Postal code
4519936937

Approval date
2017-08-08, 1396/05/17

Ethics committee reference number
ZUMS.REC.1396.104

Health conditions studied

1

Description of health condition studied
Moisturizers act in a ventilator like an artificial nose. Oxygen, along with the volume produced, which is a dry gas, is heated and humidified by Humidifier, and is passed to the patient's lungs. Without proper moisturizing, it can damage the lungs and increase lung parameters and even infection (Ventilator Associated Pneumonia) causing Prolonging the process of separating patients from the device.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pneumonia is caused by a ventilator. Clinical pulmonary infection score (CPIS) was used to diagnose pneumonia. In this scale, body temperature, infiltration rate in the lung graph, fever, discharge volume and Pao2 to Fio2 ratio were evaluated. This tool is a standard method for diagnosis of pneumonia.

Timepoint
Within seven days

Method of measurement
Clinical pulmonary infection score (CPIS) was used to diagnose pneumonia. In this scale, body temperature, infiltration rate in the lung graph, fever, discharge volume and Pao2 to Fio2 ratio were evaluated. This tool is a standard method for diagnosis of pneumonia.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, in the intervention group, active Hymo modifiers are used and in the control group, the inactive mediums are used. In the intervention group (active method), Rafail brand ventilator devices that are made in Switzerland are used. The humidity system (active method) consists of a Humidifier and Chambre. This system is designed to give the patient the best amount of moisture to create a minimum of condensation. The cold and dry medical air (at a temperature of 37 ° C and humidity of 0.5 mg / l) outlet from the ventilator, pass through the Humidifier and pass through the chambers, warm and humid. Inactive Humidifier Control (HME) is used, which does not require external water, and is located between the Y (ventilator tube path) and the tracheal tube, which acts on the basis of the heat and moisture of the exhaled air and returns it to the lungs. Slowly

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital Ayatollah Mousavi Zanjan

Full name of responsible person
Parvin Shiri Gheydari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

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
Zanjan 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
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Position
Instructor, faculty of the university
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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
Yes - There is 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

Respiratory rate, airway resistance increased in inactive Humidifier group. There was no significant difference in the level of pneumonia between the two groups.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

All documents are encoded with dedicated numbers and are available to the statistics and referee.

Under which criteria data/document could be used

As an example work and do non parametric tests

From where data/document is obtainable

Parvin shiri

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

Respiratory rate, airway resistance increased in inactive Humidifier group. There was no significant difference in the level of pneumonia between the two groups.

Comments

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