

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 method. 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; Mode 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 gravis and recent MI; A pregnant woman is not pregnant or burn; Exclusion criteria: Patients who take pantoprazole 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  $\text{PaO}_2$  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

#### Country

Iran (Islamic Republic of)

#### Phone

+98 24 3353 0867

#### Email address

abin@zums.ac.ir

### 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 pantoprazole 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

##### Street address

Ayatollah Mousavi Hospital, Gavazang Road

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4519936938

##### Phone

+98 24 3347 1049

##### Email

shirig@zums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Parvin Shiri Gheydari

##### Street address

No. 5, Mosalla Ave, Païen koh, Zanjan

##### City

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##### Province

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**Postal code**  
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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**  
Zanjan University of Medical Sciences

**Full name of responsible person**  
Parvin Shiri Gheydari

**Position**  
Instructor, faculty of the university

**Latest degree**  
Master

**Other areas of specialty/work**  
Nursery

**Street address**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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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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