

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparing the effect of of ranitidine and pantoprazole on the occurrence of ventilated associated pneumonia

#### Protocol summary

##### Summary

According to this fact that hospitalized patients in Intensive Care Unit (ICU) are susceptible to stress ulcer, they are given Ranitidin or Pantoprazol routinely. These two drugs not only prevent stress ulcer but also have effect in preventing from Ventilator Associated Pneumonia (VAP). In this study we compare this effect of these two drugs. 180 intubated hospitalized patients in Imam Reza Emergency Department who are connected to mechanical ventilator and have no active lung disease are chosen. They will continue their treatment in ICU. They are divided into two groups: group A: 90 patients, group B: 90 patients. These two groups treatment with Ranitidin or Pantoprazol is started from the first day of hospitalization in ED and will continue until the end of hospitalization time in ICU. Routinely and weekly a CXR will be taken for showing new opacities until the releasing time. Diagnostic criteria for VAP are: new infiltration in CXR plus two criteria of these three criteria: 1. fever higher than 38.5, 2. leukocytes more than 100000, 3. pus in suctioning the tracheal tube secretion. The final diagnosis for VAP is based on the culture of the tracheal tube secretion. The existence of more than 100000 bacterial colony counts will be positive. The incidence of VAP in the specific period of time will be documented and the results will be given to the statistician specialist for analysis.

#### General information

##### Acronym

ventilator\_associated pneumonia

##### IRCT registration information

IRCT registration number: **IRCT2014112611956N3**

Registration date: **2015-03-16, 1393/12/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-03-16, 1393/12/25

##### Registrant information

###### Name

Morteza Talebi Doluee

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3852 5312

###### Email address

talebidm@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### Expected recruitment end date

2015-08-23, 1394/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of of ranitidine and pantoprazole on the occurrence of ventilated associated pneumonia

##### Public title

Comparing the effect of of ranitidine and pantoprazole on the occurrence of ventilated associated pneumonia

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: hospitalized intubated patients in

intensive care unit of Imam Reza hospital during the study. Exclusion criteria: patients showing allergic reactions to ranitidin and pantoprazol; patients with active lung disease before receiving these two drugs; patients with active gastrointestinal bleeding at the beginning of our study; immune compromised patients or the history of receiving antibiotics or any factor that changes the immune condition toward VAP.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **180**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences

**Street address**

Mashhad University of Medical Sciences, Daneshgah street

**City**

Mashhad

**Postal code**

913753316

**Approval date**

2014-11-01, 1393/08/10

**Ethics committee reference number**

930275

**Health conditions studied****1****Description of health condition studied**

pneumonia

**ICD-10 code**

J18.9

**ICD-10 code description**

Pneumonia, unspecified

**Primary outcomes****1****Description**

Decreased incidence of ventilator associated pneumonia in intubated patients under mechanical ventilation

**Timepoint**

End of stay in the ICU

**Method of measurement**

Diagnostic criteria for VAP are: new infiltration in CXR plus two criteria of these three criteria:1.fever higher than 38.5,2.leukocytes more than 100000,3.pus in suctioning the tracheal tube secretion.the final diagnosis for VAP is based on the culture of the tracheal tube secretion.the existence of more than 100000 bacterial colony count will be positive

**Secondary outcomes****1****Description**

Fever more than 38.5 degree

**Timepoint**

Every day

**Method of measurement**

Thermometer

**2****Description**

Lekusytosis more than 10000

**Timepoint**

Every day

**Method of measurement**

CBC

**3****Description**

Colony count more than 100000 in tracheal tube culture

**Timepoint**

Every day

**Method of measurement**

Tracheal tube specimen culture

**4****Description**

New infiltration in CXR

**Timepoint**

Every week

**Method of measurement**

Chest X Ray

**Intervention groups**

## 1

### Description

First group(intervention): 90 patients; from the beginning until the end of hospitalization intravenous Ranitidine 50 mg will be given three times a day and after tolerating oral nutrition will be continued 150 mg twice a day.

### Category

Treatment - Drugs

## 2

### Description

Second group (control):90 patients; starting treatment with intravenous pantoprazole 40Mg twice a day from the beginning of hospitalization and will be continued until the releasing time. After tolerating oral nutrition pantoprazole 40mg oral will be given to patients through nasogastric tube (intracapsular granules are extracted and washed with 20 cc water through nasogastric tube).

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

ICU, Imam Reza Hospital

#### Full name of responsible person

#### Street address

#### City

Mashhad

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr Mohsen Tafaghodi

#### Street address

Ghoreishi building, Mashhad University of Medical Sciences, Daneshgah street,

#### City

Mashhad

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr Sara Rozmina

#### Position

MD, Resident of emergency medicine

#### Other areas of specialty/work

#### Street address

Emergency Department Office, Imam Reza Hospital,Razi Street

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sararozmina@gmail.com

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

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Dr Morteza Talebi Deloie

#### Position

Emergency Medicine speacilist, Assistant professor

#### Other areas of specialty/work

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**Web page address****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*