

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison Ventilator Associated Pneumonia in two groups of adult ICU patients under prophylactic treatment by intravenous Pantoprazole or intravenous Ranitidine

Protocol summary

Summary

Objectives: To investigate the incidence of ventilator associated pneumonia (VAP) in both groups of the study treated with prophylactic intravenous Pantoprazole and Ranitidine; Research Design: Conduction of a randomized, double-blind, clinical trial, method of randomization: simple randomization by computer; Major Inclusion Criteria: Patients aged 18 or over with no history of pneumonia within three months prior to or at the time of admission and no history of gastrointestinal bleeding, reflux, and immunodeficiency; Major Exclusion Criteria: Drug intervention, renal failure, and gastrointestinal bleeding; Sample Size: 166 patients found eligible based on the inclusion criteria; Interventions: Pantoprazole 40 mg will be used twice a day for the experimental group. While, Ranitidine 50 mg will be administered three times a day for the control group. Then, the patients will be evaluated in terms of ventilator associated pneumonia that will be diagnosed based on the clinical symptoms, pulmonary infection scoring system, and sputum culture; Time of the Intervention: Immediately after the admission of the qualified patients into the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072014079N1**
Registration date: **2013-12-28, 1392/10/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-28, 1392/10/07

Registrant information

Name

Hajar Faghihi

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Science

Expected recruitment start date

2013-06-17, 1392/03/27

Expected recruitment end date

2014-06-17, 1393/03/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Ventilator Associated Pneumonia in two groups of adult ICU patients under prophylactic treatment by intravenous Pantoprazole or intravenous Ranitidine

Public title

Comparison of Pantoprazole and Ranitidine for preventing pulmonary infection in ICU

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: 1. 18 Years of age and over 2. Intubation for more than 48 hours 3. No history of pneumonia within 3 months prior to or at the time of admission 4. No history of severe dysphagia 5. No history of deficiency in the immune system 6. No history of gastrointestinal bleeding 7. No history of gastrectomy, erosive gastritis, and reflux 8. No history of lung cancer 9. No transferring of patients from other ICUs. Exclusion Criteria: 1. Renal failure 2. Drug interference 3. Incidence of drug side effects 4. Gastrointestinal bleeding.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **166**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences- Zand Street- Shiraz- Fars- Iran

City

Shiraz

Postal code

Approval date

2013-06-16, 1392/03/26

Ethics committee reference number

CT-P-92-4227

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J15

ICD-10 code description

Bacterial pneumonia, not elsewhere classified

2

Description of health condition studied

GI bleeding

ICD-10 code

K92.2

ICD-10 code description

K92.2 is a billable ICD-10-CM code that can be used to specify a diagnosis.

Primary outcomes

1

Description

Ventilator Associated Pneumonia

Timepoint

Daily until the sputum is positively cultured or 48 hours after extubation

Method of measurement

Clinical Pulmonary Infection Score (CPIS)- Sputum Culture

Secondary outcomes

1

Description

GI bleeding

Timepoint

Daily until the patient remains hospitalized

Method of measurement

Observing the coffee grain contents in the naso- or oro-gastric tube and Melena; checking vital signs such as blood pressure and heart rate, and hemoglobin

2

Description

Length of stay in ICU

Timepoint

At the end

Method of measurement

Observation

3

Description

Mortality in ICU

Timepoint

At the end

Method of measurement

Observation

4

Description

Mortality in ward

Timepoint

At the end

Method of measurement

Observation

5

Description

Duration of Mechanical Ventilation

Timepoint

Since the start of mechanical ventilation until the patient is disconnected from the machine.

Method of measurement

Observation

Intervention groups

1

Description

In the Experimental Group: Pantoprazole 40 mg ampoule is administrated intravenously every 12 hours until the patient is infected with pneumonia; the procedure continues for up to 48 hours following extubation. Manufacturing Company: Nycomed, Germany; Brand name: Pantazol.

Category

Prevention

2

Description

In the Control Group: Ranitidine 50 mg is administrated intravenously every 8 hours until the patient is infected with pneumonia; the procedure continues for up to 48 hours following extubation. Manufacturing Company: Alborze darou.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency ICU- Nemazee Hospital

Full name of responsible person

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

General ICU- Nemazee Hospital

Full name of responsible person

Street address

City

Shiraz

3

Recruitment center

Name of recruitment center

Central ICU- Nemazee Hospital

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam

Street address

Vice chancellor for research, Shiraz University of Medical Sciences- 7th floor- Central Building of Shiraz University of Medical Sciences- Zand Street

City

Shiraz

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, Shiraz 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

Shiraz University Medical Sciences

Full name of responsible person

Hajar Faghihi

Position

Anesthesiology Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact
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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