Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating and comparing the severity and prevalence of ventilator-induced pneumonia in patients taking famotidine and pantoprazole in the intensive care unit

Protocol summary

Study aim

To determine the effects of famotidine and pantoprazole on the incidence of ventilator-induced pneumonia in the intensive care unit.

Design

This prospective experimental study will be conducted as a randomized clinical trial. The study population in this study will be patients hospitalized in the intensive care unit of Tehran Bou-Ali Hospital in 1403 who use mechanical ventilation.

Settings and conduct

Eligible patients will be assigned to two treatment groups by a random block method of four by the attending physician. One group will be treated with a stress ulcer prophylaxis regimen with intravenous pantoprazole 40 mg daily and the second group with a stress ulcer prophylaxis regimen with intravenous famotidine 20 mg twice a day. Pneumonia assessment will also be based on the criteria provided by the ATS/IDSA and CDC guidelines.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study include the use of patients aged 18 to 80 years in intensive care units who have mechanical ventilation for at least 48 hours. Patients with active pulmonary infection, patients with immunosuppression, patients with liver problems, renal (high creatinine levels), people with a history of sensitivity, and those with active gastrointestinal bleeding will not be included.

Intervention groups

One group will be treated with the stress ulcer prophylaxis regimen with intravenous pantoprazole 40 mg daily and the second group will be treated with the stress ulcer prophylaxis regimen with intravenous famotidine 20 mg twice daily.

Main outcome variables

Incidence of pneumonia, which is measured by the occurrence of infection and non-occurrence of pneumonia infection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231220060484N2**
Registration date: **2024-04-09, 1403/01/21**
Registration timing: **prospective**

Last update: **2024-04-09, 1403/01/21**
Update count: **0**

Registration date

2024-04-09, 1403/01/21

Registrant information

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Amirhossein Ghanbarzamani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-11, 1403/02/22

Expected recruitment end date

2024-11-18, 1403/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and comparing the severity and prevalence of ventilator-induced pneumonia in patients taking famotidine and pantoprazole in the intensive care unit

Public title

Investigating and comparing the severity and prevalence of ventilator-induced pneumonia in patients taking famotidine and pantoprazole in the intensive care unit

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

The inclusion criteria for the study of patients include the use of patients aged 18 to 80 years in intensive care units who have mechanical ventilation for at least 48 hours.

Exclusion criteria:

Patients with active pulmonary infection, patients with immunosuppression, patients with liver problems, renal problems (high creatinine levels), people with a history of sensitivity, and those with active gastrointestinal bleeding will not be included.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups receiving Pantoprazole (A) and Famotidine (B). The permutations of the block will thus be BBAA-BAAB-BABA-ABBA-ABBAAB. Each block will be numbered from one to six, then a random number will be selected from one to six. Corresponding the extracted number of the target block will be extracted and according to its permutations, patients will be assigned to two groups of treatment Pantoprazole (A) and Famotidine (B) treatment group. Selection of patients and allocating patients to study groups and drug interventions will be performed by the physician. Data extracted from each patient will be done by the researcher and based on the form.

Blinding (investigator's opinion)

Double blinded

Blinding description

The two study groups are placed according to the existing guidelines for stress ulcer prophylaxis. The patient will not know the type of prophylaxis regimen, and the researcher will not know the type of treatment received by the patients until the end of the sampling and decoding of the drugs. As a result, the study is done in a double-blind manner.

Placebo

Not used

Assignment

Parallel

Other design features

This experimental clinical trial study will be conducted on 124 patients (62 patients in each group) hospitalized in the special care department of BouAli Hospital in Tehran in 2024 who use mechanical ventilation. Considering the physical and physical conditions of the patients, the objectives of the study will be explained to the patient's companions or legal guardians and informed consent will be obtained from them. Patients eligible to enter the study will be selected as available and will be assigned to two treatment groups by a random block method of four. Patients will be assigned to two groups receiving pantoprazole (A) and famotidine (B) by random block method of four. The block permutations will thus be BBAA-BAAB-BABA-ABBA-ABAB-AABB. Each block will be numbered from 1 to 6, then a random number from 1 to 6 will be selected. One group will be treated with a stress ulcer prophylaxis regimen with intravenous pantoprazole 40 mg daily and the second group with a stress ulcer prophylaxis regimen with intravenous famotidine 20 mg twice a day. Corresponding to the extracted number of the desired block and according to its permutations, patients will be assigned to two treatment groups (A) pantoprazole drug and treatment group (B) famotidine drug. Selection of patients and allocation of patients to the studied groups and performed Medical interventions will be carried out by the attending physician. The data obtained from each patient will be extracted by the researcher based on the form. APACHE II score will be measured for the examined patients. Pneumonia diagnosis will also be based on the criteria provided by ATS/IDSA and CDC guidelines. The data will be entered into 27spss software and analyzed with descriptive statistics and independent t-tests, U-Man-Whitney, Chi-score, or Fisher's exact test at a significance level of 0.05.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Tehran medical sciences

Street address

No.99, Yakhchal street, Gholhak, Dr. Shariati

City

Tehran

Province

Tehran

Postal code
1941933111
Approval date
2024-03-10, 1402/12/20
Ethics committee reference number
IR.IAU.PS.REC.1402.655

Health conditions studied

1

Description of health condition studied
ventilator-induced pneumonia
ICD-10 code
J95.851
ICD-10 code description
ventilator-associated pneumonia

Primary outcomes

1

Description
Pneumonia incidence is measured by the occurrence of infection or its non-occurrence.
Timepoint
Investigating the occurrence of pneumonia after 48 hours of hospitalization
Method of measurement
Qualitative measurement with CT scan or Chest X-ray criteria / Quantitative measurement with CPIS criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One group will be treated with stress ulcer prophylaxis regimen with intravenous pantoprazole 40 mg daily and the second group will be treated with stress ulcer prophylaxis regimen with intravenous famotidine 20 mg twice a day. Pneumonia diagnosis will also be based on the criteria provided by ATS/IDSA and CDC guidelines.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Booali Hospital
Full name of responsible person
Sanaz Omidi
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Damavand street, Imam Hossein square, Tehran, Iran
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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?
No
Title of funding source
Islamic Azad University
Proportion provided by this source
1
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
Islamic Azad University
Full name of responsible person
Sanaz Omidi
Position

pharmacy student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The personal data of people is received and recorded confidentially and with their informed consent.

When the data will become available and for how long
Access is possible after the publication of the article.

To whom data/document is available
All researchers can access the data by searching the global databases after the publication of the article.

Under which criteria data/document could be used
No more information

From where data/document is obtainable
Applicants can refer to the Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran Medical Sciences, Islamic Azad University, Dr. Amirhossein Ghanbarzamani, or contact the researcher by sending an email to omidi.san@gmail.com

What processes are involved for a request to access data/document
Applicants can apply for research information by visiting the department or by contacting the e-mail address and telephone number as well as providing information on academic studies and the purpose of requesting the information. Applicants must commit themselves to mention the source. If the request is sent six months after the publication of the research information, there searcher will send the data to the requesting party by email within a week.

Comments