Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the effectiveness of injectable pantoprazole, oral pantoprazole and injectable famotidine for stress ulcer prophylaxis in the intensive care unit.

Protocol summary

Study aim

Comparison of the effects of injectable famotidine - injectable pantoprazole - oral pantoprazole in the rate of gastric PH change in patients hospitalized in the intensive care unit, so that the drug regimen with the lowest cost is evaluated to achieve the desired effects.

Design

Phase II randomized clinical trial on 60 patients admitted to the intensive care unit. According to the simple random table, patients are placed in three parallel groups of injectable pantoprazole (20 patients), oral pantoprazole (20 patients) and injection famotidine (20 patients). On days 1, 3, 5, 7, the pH of the stomach of the patients is determined by laboratory digital pH meters and pH meter paper (Torrance paper has been approved by two people to prevent vision errors) 3 times on the said days. Also, CRP/Alb index is measured on day 0 and day 7.

Settings and conduct

The intensive care units of Sinai Hospital

Participants/Inclusion and exclusion criteria

Patients over 18 years of age admitted to the intensive care unit, who have a nasogastric tube and are indicated for the prevention of gastric ulcer, will be included in the study on the condition of signing an informed consent form. Patients with bariatric surgery, gastrectomy surgery, gastric ulcer or active bleeding of the gastrointestinal tract and gastric malignancy, and patients who have received PPI and H2 Blocker drugs in the last 5 days or whose gastric acid base is above 5, will be excluded from the study.

Intervention groups

Intravenous pantoprazole group 40 mg daily Oral pantoprazole group 40 mg daily Famotidine group 20 mg injection twice a day

Main outcome variables

Comparison of the effect of injectable famotidine - injectable pantoprazole - oral pantoprazole on the amount of gastric acidity change in patients admitted to the intensive care unit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200322046833N3**
Registration date: **2024-01-04, 1402/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-04, 1402/10/14**
Update count: **0**

Registration date

2024-01-04, 1402/10/14

Registrant information

Name

Farhad Najmeddin

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6695 4709

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of injectable pantoprazole, oral pantoprazole and injectable famotidine for stress ulcer prophylaxis in the intensive care unit.

Public title
Comparing the effectiveness of injectable pantoprazole, oral pantoprazole and injectable famotidine for stress ulcer prophylaxis in the intensive care unit.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years of age hospitalized in the intensive care unit who have a nasogastric tube and are indicated for the prevention of peptic ulcer. Sign the informed consent
Exclusion criteria:
Bariatric surgery Gastrectomy surgery Active gastrointestinal ulcer or gastrointestinal bleeding Stomach malignancy Patients who have received PPI and H2 Blocker drugs in the last 5 days Patients whose gastric acid base is above 5
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into three parallel groups by simple random number table
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 Sina Hospital - Tehran University of Medical Sciences
Street address
Sina Hospital, Imam Khomeini St, Hasanabad Square, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2023-08-05, 1402/05/14
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1402.061

Health conditions studied

1

Description of health condition studied
gastric stress ulcer prophylaxes
ICD-10 code
K27
ICD-10 code description
Peptic ulcer, site unspecified

Primary outcomes

1

Description
Frequency of occurrence of pH less than 5 during the study
Timepoint
On day 1,3,5 and 7 stomach pH of patients is determined by digital laboratory pH meter and paper pH meter (to avoid the optical error of litmus paper, it is confirmed by two people), 3 times a day.
Method of measurement
about 10 cc of stomach contents are aspirated one hour after gavage and measured with digital laboratory pH meter and paper pH meter (to avoid the optical error of litmus paper, it is confirmed by two people).

Secondary outcomes

1

Description
Average changes of CRP/Alb - lymphocyte to neutrophil ratio - platelet to lymphocyte ratio on the first day compared to the seventh day in the group of injectable famotidine and injectable pantoprazole and oral pantoprazole in patients admitted to the intensive care unit. The number of days hospitalized in the intensive care unit in the group of injectable famotidine and injectable pantoprazole and oral pantoprazole in patients hospitalized in intensive care units. Mortality in the group of injectable famotidine and parenteral pantoprazole and oral pantoprazole in patients admitted to the intensive

care unit.

Timepoint

The inflammatory index CRP/Alb is checked on day 0 and day 7. The time of discharge from the intensive care unit or the death of patients is recorded.

Method of measurement

The inflammatory index CRP/Alb is checked on day 0 and day 7. The time of discharge from the intensive care unit or the death of patients is recorded.

Intervention groups

1

Description

Intervention group: intravenous pantoprazole

Category

Prevention

2

Description

Intervention group: intravenous famotidine

Category

Prevention

3

Description

Intervention group: oral pantoprazole

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Farhad Najmeddin

Street address

Sina Hospital, Imam Khomeini St, Hasanabad Square, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Farhad Najmeddin

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Web page address

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Clinical results will be published through an original article and All other data will be available on request

When the data will become available and for how long
Up to 5 years after publishing the clinical results

To whom data/document is available
Researchers and ethics committee

Under which criteria data/document could be used
Ethical evaluation and review articles without financial conflicts of interest.

From where data/document is obtainable
Responsible Researcher Dr Farhad Najmeddin by the following email f-najmeddin@tums.ac.ir

What processes are involved for a request to access data/document
Data will be available within 2 weeks after the email check. The email should include the Conflict of interest disclosure

Comments