Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Efficacy of Pantoprazole and Vonoprazan for Stress Ulcer Prophylaxis in Critically Patients Admitted to the ICU, a RCT study

Protocol summary

Study aim

Compare pantoprazole vs vonoprazan for stress bleeding prophylaxis in ICU.

Design

Parallel two-arm RCT, blocks 4&6, 1:1 allocation, opaque numbered envelopes. Double-blinded (patients, staff, analyst blinded). Drugs identically packaged by pharmacy.

Settings and conduct

The intensive care unit of Imam Reza Hospital in Kermanshah. Patients are screened daily; after obtaining informed consent, randomization and drug administration by the nurse are performed. Daily monitoring for bleeding, hemodynamic changes, transfusion needs, and other outcomes is recorded by a trained researcher on pre-designed checklists.

Participants/Inclusion and exclusion criteria

Age above 18 years; admission to the intensive care unit with anticipated stay beyond 48 hours; need for stress ulcer prophylaxis according to the American Society of Health-System Pharmacists or the Society of Critical Care Medicine guidelines, defined as having at least one major risk factor including mechanical ventilation beyond 48 hours, or coagulopathy with an international normalized ratio above 1.5 or platelet count below fifty thousand per mm^3, or having at least two minor risk factors including sepsis, shock, acute renal failure, liver failure, severe burns, trauma or severe central nervous system injury, or high-dose corticosteroid use equivalent to more than 250 milligrams of hydrocortisone daily.

Intervention groups

Pantoprazole: 40mg IV daily until discharge, full feeding, bleeding or 14d. Vonoprazan: 20mg oral via NG tube same duration.

Main outcome variables

Occurrence of clinically important gastrointestinal bleeding during intensive care unit stay; Occurrence of overt gastrointestinal bleeding without hemodynamic compromise; ventilator-associated pneumonia; Clostridioides difficile infection; length of intensive care unit stay; 28-day mortality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260908070967N1**
Registration date: **2026-09-25, 1405/07/03**
Registration timing: **prospective**

Last update: **2026-09-25, 1405/07/03**
Update count: **0**

Registration date

2026-09-25, 1405/07/03

Registrant information

Name

Mohammadjavad Alibakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6323

Email address

mjavad.alibakhshi@kums.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-21, 1405/08/30

Expected recruitment end date

2027-06-20, 1406/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the Efficacy of Pantoprazole and Vonoprazan for Stress Ulcer Prophylaxis in Critically Patients Admitted to the ICU, a RCT study

Public title
Comparison of the efficacy of vonoprazan and pantoprazole in the prevention of stress ulcers

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Admission to the ICU
Exclusion criteria:
Active gastrointestinal bleeding at admission History of gastric or duodenal surgery altering acid absorption or secretion Use of a proton pump inhibitor, histamine 2 receptor antagonist, or vonoprazan within the past 7 days Known hypersensitivity to any of the study drugs Pregnancy or breastfeeding Severe hepatic failure Impossibility of administering the study drug or withdrawal of the patient or legal guardian

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Method: Block randomization with variable block sizes (4 and 6). Unit of Randomization: Individual (each patient is allocated separately). The random sequence is generated by R software. Allocation is performed using sequentially numbered, opaque, sealed envelopes. The envelope for each patient is opened only after confirming eligibility and obtaining consent.

Blinding (investigator's opinion)
Double blinded

Blinding description
Eligible patients will be allocated in a 1:1 ratio to either the vonoprazan or pantoprazole group after obtaining informed consent. The randomization sequence will be generated using R software with block randomization, employing variable block sizes of 4 and 6, by a biostatistician who will have no involvement in the study execution. Patient allocation will be performed using sequentially numbered, opaque, sealed envelopes (SNOSE). After verification of eligibility criteria and obtaining consent, the corresponding envelope will be opened by the responsible individual, and the patient will be assigned to one of the two groups. Outcome assessors and the statistical analyst will remain blinded to the intervention type until the completion of the study. Drug type, demographic and clinical data (e.g., APACHE II score at admission), and daily outcomes will be collected solely by a trained researcher/nurse who has no role in the treatment process. Data will be recorded daily at the patient's bedside in the ICU using paper case report forms.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Kermanshah University of Medical Sciences, Bagh Abrisham ave.
City
Kermanshah
Province
Kermanshah
Postal code
6714869914

Approval date
2026-08-09, 1405/05/18

Ethics committee reference number
IR.KUMS.MED.REC.1405.143

Health conditions studied

1

Description of health condition studied
Gastric ulcer

ICD-10 code
K25

ICD-10 code description
Gastric ulcer

Primary outcomes

1

Description
Clinically important gastrointestinal bleeding (hematemesis, melena, hematochezia or frank blood in

gastric tube with hemodynamic instability or transfusion need)

Timepoint

The primary outcome is measured daily from intensive care unit admission until discharge, initiation of full oral feeding, occurrence of bleeding, or a maximum of 14 days.

Method of measurement

The primary outcome is measured through daily clinical monitoring and assessment of blood in the gastric tube, hematemesis, melena, or hematochezia, along with recording vital signs, hemoglobin testing, and transfusion need, using a pre-designed checklist.

Secondary outcomes

1

Description

Overt Gastrointestinal Bleeding without Hemodynamic Instability: Presence of visible evidence of gastrointestinal bleeding including hematemesis, melena, hematochezia, or blood observed in gastric suction or nasogastric tube, without hemodynamic instability.

Timepoint

Daily during Intensive Care Unit stay

Method of measurement

Clinical observation of nasogastric tube or gastric suction contents and patient record review by a trained researcher

2

Description

Ventilator-Associated Pneumonia: Occurrence of pneumonia in a mechanically ventilated patient that develops more than 48 hours after initiation of ventilation

Timepoint

Daily from initiation of mechanical ventilation

Method of measurement

Based on clinical and paraclinical criteria including fever, pulmonary secretions, chest radiography findings, and respiratory culture, recorded by the attending physician

3

Description

Clostridioides Difficile Infection: Occurrence of Clostridioides difficile-associated diarrhea

Timepoint

Daily during Intensive Care Unit stay

Method of measurement

Patient record review, clinical examination, and laboratory results (toxin test or stool culture)

Intervention groups

1

Description

Pantoprazole group: patients receive 40 milligrams of pantoprazole intravenously daily. Administration starts upon intensive care unit admission or initiation of enteral feeding and continues until discharge, initiation of full oral feeding, occurrence of gastrointestinal bleeding, or a maximum of 14 days.

Category

Prevention

2

Description

Vonoprazan group: patients receive 20 milligrams of vonoprazan orally via a nasogastric tube daily. Administration starts upon intensive care unit admission or initiation of enteral feeding and continues until discharge, initiation of full oral feeding, occurrence of gastrointestinal bleeding, or a maximum of 14 days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza hospital

Full name of responsible person
Mohammadjavad Alibakhshi

Street address
Imam Reza hospital, Baghabrisham Ave.

City
Kermanshah

Province
Kermanshah

Postal code
6742775333

Phone
+98 83 3427 6323

Email
irhk@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Zohreh Rahimi

Street address
Vice Chancellery for Research and Technology, Medical Sciences Building Number 2, Shahid Beheshti Blv

City
Kermanshah

Province
Kermanshah

Postal code
6714673159

Phone
+98 83 3838 6835
Email
research_it@kums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Mohammadjavad Alibakhshi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Reza hospital, Baghabrisham Ave.
City
Kermanshah
Province
Kermanshah
Postal code
6742775333
Phone
+98 83 3427 6323
Fax
Email
mjavad.alibakhshi@kums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mohammadjavad Alibakhshi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Reza hospital, Baghabrisham Ave.
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Province
Kermanshah
Postal code
6742775333
Phone
+98 83 3427 6323
Fax
Email
mjavad.alibakhshi@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mohammadjavad Alibakhshi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Reza hospital, Baghabrisham Ave.
City
Kermanshah
Province
Kermanshah
Postal code
6742775333
Phone
+98 83 3427 6323
Fax
Email
mjavad.alibakhshi@kums.ac.ir

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
Participant data file: individual participant data after removal of identifiers, including demographics,

intervention group, primary and secondary outcomes, and confounders, shareable upon request by qualified researchers. Study protocol: full version including objectives, methods, inclusion and exclusion criteria, and randomization method. Statistical analysis plan: description of statistical methods, tests, and models used. Informed consent form: the text of the consent form provided to participants and signed by them, without including participants' identifying information. Clinical study report: final report of the study results. Analysis codes: R software codes used for data analysis. Data dictionary: complete definition of all variables and their coding.

When the data will become available and for how long

Access to the data and documents begins 6 months after publication of the study results.

To whom data/document is available

Available only to researchers affiliated with academic institutions.

Under which criteria data/document could be used

The data and documents may be used only for research and academic purposes, including secondary analyses, reproduction of results, and meta-analysis. Commercial use, transfer of data to third parties, and any attempt to identify participants are prohibited. Applicants must submit a written request including the study title, objectives, analysis methods, and list of researchers. The request is accepted after review and approval by the scientific and ethics committee of the study, and upon signing a confidentiality and data use agreement. Results must be reported to the study team after publication.

From where data/document is obtainable

Applicants can submit their request via email to mjavad.alibakhshi@kums.ac.ir. If needed, correspondence is also possible through the postal address of the Vice Chancellery for Research and Technology, Medical Sciences Building Number 2, Shahid Beheshti Boulevard, Kermanshah, Iran. Responses are provided by the study principal investigator. The first priority for contact is email, followed by postal correspondence.

What processes are involved for a request to access data/document

The applicant first submits a written request including the study title, objectives, analysis methods, and list of researchers. The request is reviewed within 7 working days and referred to the scientific and ethics committee of the study for approval. This stage takes about 14 to 21 working days. After approval, a confidentiality and data use agreement is sent to the applicant, and upon signing and returning it, the data or documents are delivered within 7 working days. Overall, the process takes about 4 to 6 weeks.

Comments