Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Vonoprazan and Pantoprazole in Achieving Target Gastric pH for the Prevention of Stress Ulcers in the Intensive Care Unit: A Randomized Controlled Trial

Protocol summary

Study aim
To compare the efficacy and safety of Vonoprazan versus Pantoprazole in achieving target gastric pH for the prevention of stress ulcers in ICU patients.

Design
A randomized, single-blind, active-controlled, single-center, parallel-group, Phase 3 clinical trial with a sample size of 40 patients. Randomization will be performed using block randomization with a 1:1 ratio.

Settings and conduct
This study will be conducted in the ICU of Kosar Hospital in Semnan. Eligible patients are randomly assigned to one of the two treatment groups (vonoprazan or pantoprazole) after informed consent. Drug intervention will continue until discharge from the ICU.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult ICU patients requiring stress ulcer prophylaxis; Exclusion criteria: active GI bleeding, current PPI/H2RA use, contraindications, severe organ impairment, pregnancy/lactation, anticipated ICU stay < 72 hours.

Intervention groups
Intervention group: Vonoprazan 20 mg orally or via NGT every 24 hours. Control group: Pantoprazole 40 mg IV every 24 hours.

Main outcome variables
Mean gastric fluid pH in the first 72 hours of intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260226068954N1**
Registration date: **2026-03-25, 1405/01/05**
Registration timing: **prospective**
Last update: **2026-03-25, 1405/01/05**
Update count: **0**

Registration date
2026-03-25, 1405/01/05

Registrant information

Name
Paniz Bahoosh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3344 1022

Email address
paniz1re@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-05, 1405/02/15

Expected recruitment end date
2026-11-06, 1405/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Vonoprazan and Pantoprazole in Achieving Target Gastric pH for the Prevention of Stress Ulcers in the Intensive Care Unit: A Randomized Controlled Trial

Public title
Vonoprazan vs. Pantoprazole for Stress Ulcer Prophylaxis in ICU Patients

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age > 18 years Functional nasogastric tube (NGT) in place Patients requiring stress ulcer prophylaxis with at least one indication: mechanical ventilation > 48 hours, coagulopathy, shock, traumatic brain injury or spinal cord injury, severe burns > 30% body surface area, receiving > 250 mg hydrocortisone/week Informed consent obtained from patient or legally authorized representative
Exclusion criteria:
Absolute indications for PPI use including active bleeding, confirmed peptic ulcer, or recent GI bleed admission Ongoing PPI or H2RA treatment within 48 hours prior to enrollment Known contraindications to PPIs or Vonoprazan (allergy, HIV medication use, advanced liver failure) Concurrent use of strong CYP3A4 inducers or inhibitors Concurrent use of antacids or gastric pH altering medications Severe renal or hepatic impairment Pregnancy or lactation Anatomical abnormalities of the stomach Zollinger-Ellison syndrome or other hypersecretory conditions Predicted ICU stay < 72 hours Concurrent participation in another clinical trial
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly allocated to the intervention (Vonoprazan) and control (Pantoprazole) groups in a 1:1 ratio using block randomization. The operational steps are as follows: 1. Sequence Generation: An independent researcher, uninvolved in sampling, will generate the random allocation sequence using the Sealed Envelope website (www.sealedenvelope.com) with a block size of 4. 2. Allocation Concealment: The generated codes will be placed inside sequentially numbered, opaque, and sealed envelopes. 3. Implementation: Upon the admission of an eligible patient to the ICU, the researcher will open the envelope in sequential order to determine and assign the patient’s treatment group.
Blinding (investigator's opinion)
Single blinded
Blinding description
This is a single-blind study in which only the data analyst is blinded to the allocated interventions. To ensure the data analyst remains unaware of the treatment groups, the collected data will be coded by another researcher (uninvolved in data analysis) before being handed over. The column containing the actual drug names will be removed, and the groups will be renamed using anonymous codes, such as “Group A” and “Group B”. The data analyst will perform all statistical analyses on these coded groups and will remain completely blinded to which code represents Vonoprazan or Pantoprazole until the final analysis is completed and the results are extracted.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Semnan University Of Medical Sciences and Health Services
Street address
Staff of Semnan University of Medical Sciences and Health Services, Basij Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2026-02-16, 1404/11/27
Ethics committee reference number
IR.SEMUMS.REC.1404.315

Health conditions studied

1

Description of health condition studied
Stress ulcers in ICU patients
ICD-10 code
K25.4
ICD-10 code description
Chronic or unspecified gastric ulcer with hemorrhage

Primary outcomes

1

Description
Mean Gastric pH during the first 72 hours of intervention
Timepoint
Baseline, 3 hours, 5 hours, 24 hours, 48 hours, and 72 hours after the first dose
Method of measurement
Calibrated portable digital pH meter using gastric aspirates from nasogastric tube (NGT)

Secondary outcomes

1

Description
Mean pH at specific time points (baseline, 3h, 5h, and daily fasting)
Timepoint
Baseline, 3 hours, 5 hours, and daily fasting measurements within the first 72 hours
Method of measurement
Calibrated portable digital pH meter using gastric aspirates from nasogastric tube (NGT)

2

Description
Percentage of samples with pH ≥ 4 during the first 72 hours of intervention
Timepoint
All valid samples collected within the first 72 hours
Method of measurement
Calculated from pH meter readings.

3

Description
Time-to-first pH ≥ 4.
Timepoint
From the start of intervention until the first pH measurement ≥ 4 and sustained in subsequent measurements.
Method of measurement
Measured in hours from the start of intervention using gastric aspirates and a calibrated pH meter.

4

Description
Incidence of clinically significant gastrointestinal bleeding.
Timepoint
During the 72-hour intervention period.
Method of measurement
Defined as overt bleeding (hematemesis, melena, or NGT bleeding) with hemodynamic instability, need for blood transfusion (≥2 units in 24 hours), or hemoglobin drop ≥2 g/dL. Assessed through clinical observation, medical record review, and lab tests.

5

Description
Incidence of Ventilator-Associated Pneumonia (VAP).
Timepoint
During ICU stay.
Method of measurement
Based on standard clinical and radiographic criteria, confirmed by respiratory secretion cultures. Assessed through clinical observation, medical record review, and culture results.

6

Description
Incidence of Clostridioides difficile infection (CDI).
Timepoint
During ICU stay.
Method of measurement
Presence of ≥3 loose stools in 24 hours with a positive C. difficile toxin assay. Assessed through clinical observation, medical record review, and laboratory results.

7

Description
Length of stay in ICU and hospital.
Timepoint
From admission to ICU/hospital discharge.
Method of measurement
Number of full days spent from ICU/hospital admission to discharge. Recorded in medical records.

8

Description
28-day all-cause mortality.
Timepoint
Assessed on day 28 after randomization.
Method of measurement
Patient's survival status (alive or deceased). Assessed through medical records and follow-up contact.

9

Description
Incidence of Adverse Events (AEs) and Serious Adverse Events (SAEs): Any untoward medical occurrence, including serious events leading to death, hospitalization, disability, or congenital anomaly.
Timepoint
Throughout the study duration.
Method of measurement
Assessed through clinical observation and medical record review.

Intervention groups

1

Description
Intervention group: Vonoprazan 20 mg tablet, administered orally or via nasogastric tube (NGT), once every 24 hours. The drug administration will start upon study enrollment and continue until the last day of admission and discharge from the Intensive Care Unit (ICU).
Category
Treatment - Drugs

2

Description
Control group: Pantoprazole 40 mg vial, administered

intravenously (IV), once every 24 hours. The drug administration will start upon study enrollment and continue until the last day of admission and discharge from the Intensive Care Unit (ICU).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital

Full name of responsible person
Mohammad Memarian

Street address
Amin Boulevard, Golestan Town

City
Semnan

Province
Semnan

Postal code
3519899951

Phone
+98 23 3343 7821

Email
paniz1re@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Majid Eslami

Street address
Deputy of Research and Technology, Central Headquarters of Semnan University of Medical Sciences, Basij Blvd.

City
Semnan

Province
Semnan

Postal code
3514799442

Phone
+98 23 3345 1336

Email
sem.ums.res@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Mohammad Memarian

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Basij Boulevard

City
Semnan

Province
Semnan

Postal code
3519899951

Phone
+98 23 3343 7821

Fax
+98 23 3343 7838

Email
aria2018@gmail.com

Web page address
https://kosarhos.semums.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Hossein Karbalaei

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Medical Pharmacy

Street address
Semnan Department University of Medical Sciences, Basij Boulevard

City
Semnan

Province
Semnan

Postal code

3519899951

Phone

+98 23 3343 7838

Email

Karbalayihossein1363@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammad Memarian

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Basij Boulevard

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3343 7821

Fax

+98 23 3343 7838

Email

aria2018@gmail.com

Web page address

https://kosarhos.semums.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

No - There is not 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

Yes - There is a plan to make this available

Title and more details about the data/document

Anonymized Individual Participant Data (IPD): All collected participant data after removal of identifying information (e.g., name, national ID, exact date of birth, etc.), including demographic information, physiological parameters (e.g., gastric pH at various time points), clinical outcomes (e.g., GI bleeding, VAP, CDI, length of stay, mortality), and other variables recorded in the Case Report Form (CRF). Study Protocol: The complete version of the study protocol, including details of methodology, inclusion/exclusion criteria, intervention procedures, outcomes, and data analysis methods. Statistical Analysis Plan: A detailed plan of the statistical analyses intended for examining study outcomes and hypotheses. Clinical Study Report: A comprehensive report of the study findings after completion and data analysis. Data Dictionary: A file containing precise definitions of all collected variables, their units of measurement, and coding methods.

When the data will become available and for how long

Access Period Start: 6 months after the publication of the study results (journal article print). Access Duration: Data and documents will be available for 10 years from the start of the access period.

To whom data/document is available

Researchers affiliated with accredited academic and scientific institutions, clinicians, and healthcare professionals who present a relevant research proposal and require the data for non-commercial research purposes.

Under which criteria data/document could be used

Purpose: Analysis and examination of primary and secondary study outcomes. Conducting secondary and ancillary studies based on the available data. Validation of the current study's findings. Use in related research projects concerning stress ulcer prophylaxis and gastric acid management in ICU patients. Conditions: Submission of a written request detailing the research plan, objectives, methodology, and data analysis strategy. Completion of a Non-Disclosure Agreement (NDA) and Data Use Agreement. Approval of the research proposal by the Institutional Review Board (IRB) or Ethics Committee of the researcher's institution. Exclusive use for non-commercial research purposes; no redistribution of data to third parties without explicit permission. Proper citation of the original study in all reports and publications derived from this data.

From where data/document is obtainable

Interested applicants may contact the study's research coordinator via email: Contact Person: Dr. Mohammad Memarian Title: Supervisor, Research Officer Email: aria2018@gmail.com paniz1re@gmail.com Mailing address: Semnan, Golestan Town, Amin Boulevard, Kowsar Hospital Postal Code: 3519899951

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

1. Request Submission: The applicant submits a written request along with their research proposal and completed forms (NDA, Data Use Agreement) via email or mail. 2. Request Review: The request is reviewed by the research lead and relevant committee. Upon approval of the research proposal and adherence to the terms, further steps are initiated. (Estimated Review Time: 2-4 weeks) 3. Notification of Decision: The applicant is informed of the decision (approval or rejection). 4. Data/Document Delivery: Upon approval, the data and documents will be securely delivered to the applicant (e.g., via an encrypted download link or secure cloud storage). (Estimated Delivery Time: 1-2 weeks post-approval)

Comments

This study was conducted with the aim of advancing scientific knowledge and improving patient care in intensive care units. We are eager to collaborate with other interested researchers to leverage this data for the advancement of scientific research.