Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Metoclopramide and Erythromycin on Gastric Residual Volume in Critically Ill Patients Receiving Enteral Nutrition in the Intensive Care Unit

Protocol summary

Study aim

Comparison of the effect of metoclopramide versus erythromycin on gastric residual volume in critically ill patients under enteral nutrition admitted to the intensive care unit

Design

A prospective clinical trial conducted on two parallel groups of 30 patients each (total 60 patients) with equal allocation ratio. Randomization was performed to assign patients to each intervention group.

Settings and conduct

The study was conducted in the ICU of Payambar Azam Educational, Medical and Research Center, Bandar Abbas, in 2016–2017. Gastric residual volume was measured every 6 hours over three days. Blood sodium, potassium, and glucose were assessed at baseline and at 24, 48, and 72 hours after enteral nutrition initiation.

Participants/Inclusion and exclusion criteria

Critically ill patients admitted to the ICU of Payambar Azam Educational, Medical and Research Center under enteral nutrition via nasogastric tube and connected to mechanical ventilator were enrolled. Exclusion criteria included allergy to either drug, active gastrointestinal bleeding, recent abdominal surgery, or death within the first 24 hours.

Intervention groups

The first group received metoclopramide and the second received erythromycin as prokinetic agents. Both drugs were administered enterally. All patients received standard ICU care including hemodynamic monitoring, mechanical ventilation, and routine nasogastric enteral nutrition every three hours.

Main outcome variables

Primary outcome: gastric residual volume and number of patients with gastric reflux over 72 hours. Secondary outcomes: changes in blood sodium, potassium, and glucose levels over 72 hours and comparison between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240929063203N8**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**

Registration date

2026-06-20, 1405/03/30

Registrant information

Name
Milad Mohammadi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-20, 1405/03/30

Expected recruitment end date

2027-08-21, 1406/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Effects of Metoclopramide and Erythromycin on Gastric Residual Volume in Critically Ill Patients Receiving Enteral Nutrition in the Intensive Care Unit

Public title
Comparison of the Effects of Metoclopramide and Erythromycin on Gastric Residual Volume in Critically Ill Patients Receiving Enteral Nutrition in the Intensive Care Unit

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Individuals aged 18–70 years admitted to the intensive care unit Use of vasopressors Presence of a central venous catheter Receipt of platelet transfusion History of venous thromboembolism
Exclusion criteria:
Development of heparin-induced thrombocytopenia after treatment initiation Occurrence of surgical-site bleeding or intracranial hemorrhage (including epidural hematoma, subdural hematoma, intracerebral hemorrhage, or hemorrhagic stroke) Requirement for surgery during the study period; in such cases, heparin will be discontinued 6 hours before surgery and the patient will be withdrawn from the study

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
This clinical trial will employ simple randomization with individual participants as the unit of randomization. Eligible patients admitted to the Intensive Care Unit of Shahid Mohammadi Hospital, Bandar Abbas, who meet the inclusion criteria and provide informed consent, will be randomly assigned in a 1:1 ratio to either the subcutaneous heparin group or the intravenous heparin group. The randomization sequence will be generated using Random Allocation Software. Allocation concealment will be maintained through restricted access to the randomization list, separation of research responsibilities, and the use of sealed sequentially numbered envelopes to minimize the risk of selection bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is designed as a double-blind clinical trial. Patients, treating physicians, ward nurses (except the nurse responsible for drug preparation and administration), and outcome assessors will remain unaware of the intervention type and treatment allocation. Heparin preparation and administration will be performed by a designated nurse who is not involved in data collection or outcome assessment. Study medications will be labeled using coded identifiers, and allocation information will be stored in sealed envelopes. Allocation codes will only be disclosed in emergency situations or after completion of the study and final data analysis. This approach is intended to minimize both performance bias and detection bias.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Hormozgan University of Medical Sciences

Street address
Shahid Chamran Boulevard, University of Medical Sciences and Health Services, Bandar Abbas.

City
Bandar Abbas

Province
Hormozgan

Postal code
7916613885

Approval date
2019-01-06, 1397/10/16

Ethics committee reference number
IR.HUMS.REC.1397.259

Health conditions studied

1

Description of health condition studied
Delayed gastric emptying and gastric residual volume in critically ill patients under enteral nutrition

ICD-10 code
K31.8

ICD-10 code description
Other specified diseases of stomach and duodenum

Primary outcomes

1

Description
Gastric residual volume and occurrence of gastric content reflux in critically ill patients under enteral nutrition.
Timepoint
Every 6 hours over three consecutive days (at hours 6, 12, 18, and 24 of days 1, 2, and 3) after initiation of enteral nutrition.
Method of measurement
Aspiration of gastric contents via nasogastric tube before each feeding session; volume measured in milliliters. Reflux was defined as gastric residual volume exceeding the defined threshold.

2

Description
Changes in blood sodium level during 72 hours after enteral nutrition initiation.
Timepoint
Baseline (before enteral nutrition), and at 24, 48, and 72 hours after initiation.
Method of measurement
Laboratory measurement of serum sodium from a venous blood sample; unit: mEq/L.

3

Description
Changes in blood potassium level during 72 hours after enteral nutrition initiation.
Timepoint
Baseline (before enteral nutrition), and at 24, 48, and 72 hours after initiation.
Method of measurement
Laboratory measurement of serum potassium from a venous blood sample; unit: mEq/L.

4

Description
Changes in blood glucose level during 72 hours after enteral nutrition initiation.
Timepoint
Baseline (before enteral nutrition), and at 24, 48, and 72 hours after initiation.
Method of measurement
Laboratory measurement of blood glucose from a venous blood sample; unit: mg/dL.

Secondary outcomes

1

Description
Occurrence of aspiration pneumonia during intensive care unit hospitalization.
Timepoint
From admission to discharge from the intensive care unit.
Method of measurement
Clinical evaluation by the attending physician and review of medical records based on standard diagnostic criteria for aspiration pneumonia.

2

Description
Mortality during intensive care unit hospitalization.
Timepoint
From admission to discharge from the intensive care unit.
Method of measurement
Assessment of survival status through medical records during intensive care unit hospitalization.

3

Description
Length of intensive care unit stay.
Timepoint
At discharge from the intensive care unit.
Method of measurement
Calculation of the duration of intensive care unit hospitalization based on medical records; unit: days.

Intervention groups

1

Description
Intervention group: Critically ill patients admitted to the ICU received metoclopramide enterally via nasogastric tube as a prokinetic agent to reduce gastric residual volume; administration began on the day of enteral nutrition initiation and continued for three consecutive days.
Category
Treatment - Drugs

2

Description
Intervention group: Critically ill patients admitted to the ICU received erythromycin enterally via nasogastric tube as a prokinetic agent to reduce gastric residual volume; administration began on the day of enteral nutrition initiation and continued for three consecutive days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
The Great Prophet's (PBUH) educational, therapeutic and research center
Full name of responsible person

Pejman Shahrokhi

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The Great Prophet's (PBUH) educational, therapeutic and research center, Islamic Republic Blvd., Bandar Abbas

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Shahram Zare

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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Mehrdad Malekshoar

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Still undecided - no release schedule yet.

Study Protocol
No - There is not a plan to make this available

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

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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