

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of metoclopramide and erythromycin on aspiration pneumonia in intubated patients under mechanical ventilation

Protocol summary

Study aim

To compare the effect of metoclopramide and erythromycin on the occurrence aspiration pneumonia in mechanically ventilated patients

Design

Phase III assessor-blind randomized trial with parallel groups on 150 patients, block randomization with a block size of 4 based on the randomization table generated by the Randomization Main software.

Settings and conduct

This study will be performed on 150 intubated patients under mechanical ventilation admitted to the trauma and internal ICUs of Bandar Abbas Shahid Mohammadi Hospital. The patients will be randomized into two groups by block randomization. Intervention group 1 will receive metoclopramide 10 mg every 8 hours and the intervention group 2 erythromycin 50 mg every 6 hours. The occurrence of aspiration pneumonia will be assessed within 72 hours by assessors blinded to patient grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 17-70 years, intubated patients under mechanical ventilation, admission to ICU Exclusion criteria: underlying pulmonary disease, pulmonary contusion, pulmonary emboli, pneumonia on admission, corticosteroid use, cardiopulmonary arrest, acute respiratory distress syndrome due to extrapulmonary causes, end-stage renal disease

Intervention groups

Intervention group 1: Metoclopramide 10 mg every 8 hours Intervention group 2: Erythromycin 50 mg every 6 hours

Main outcome variables

Aspiration pneumonia rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230618058512N1**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Mohsen Sarafikhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 5009

Email address

dr.sarafikhah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of metoclopramide and erythromycin on aspiration pneumonia in intubated patients under mechanical ventilation

Public title

Metoclopramide versus erythromycin for the reduction of aspiration pneumonia in mechanically ventilated patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 17-70 years Intubated patients under mechanical ventilation Admitted to the ICU

Exclusion criteria:

Underlying pulmonary disease Pulmonary contusion
Pulmonary emboli Pneumonia on admission
Corticosteroid use Cardiopulmonary arrest Acute respiratory distress syndrome due to extrapulmonary causes end-stage renal disease

Age

From **17 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with a block size of 4 based on the randomization table generated by the Randomization Main software, without allocation concealment, so that 150 patients will be divided into 36 blocks of 4 and 2 blocks of 3, and each block of 4 and then 2 blocks of 3 will be randomly assigned to one of the groups according to the table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Aspiration pneumonia will be diagnosed based on clinical and imaging findings by ICU subspecialists and a pulmonologist who will be blinded to patient grouping; therefore, this will be an assessor-blind trial.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Faculty of Medicine, Across from Kargaran Sports Complex, Imam Hossein Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2023-06-13, 1402/03/23

Ethics committee reference number

IR.HUMS.REC.1402.100

Health conditions studied

1

Description of health condition studied

Aspiration pneumonia

ICD-10 code

J69.0

ICD-10 code description

Pneumonitis due to inhalation of food and vomit

Primary outcomes

1

Description

Aspiration pneumonia rate

Timepoint

Up to 72 hours after initiation of treatment

Method of measurement

Clinical Pulmonary Infection Score (CPIS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Metoclopramide (Darou Pakhsh Co., Iran) 10 mg every 8 hours

Category

Prevention

2

Description

Intervention group: Erythromycin (Darou Pakhsh Co., Iran) 50 mg every 6 hours

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان شهید محمدی

Full name of responsible person

Mohsen Sarafikhah

Street address

Shahid Mohammadi Hospital, Jomhuri Eslami Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research Hormozgan University
of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

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Faculty of Medicine, Across from Kargaran Sports
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<https://resv.hums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-Chancellery for Research Hormozgan 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

Mohsen Sarafikhah

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

There is no further information.

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