

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The comparison of ranitidine and pantoprazole in prevention of stress ulcer in ICU

Protocol summary

Summary

Objective: The comparison of ranitidine and pantoprazole in prevention of stress ulcer in ICU. Design: Double blind clinical trial Population: 92 people from traumatic patients (multiple trauma and head trauma) who were admitted in ICU . Inclusion criteria: patients who required mechanical ventilation and were admitted to the ICU, aged more than 18 years old, with APACHE SCORE II less than 25. Exclusion criteria: history of GI bleeding, liver or kidney insufficiency. In control group,(ranitidine group),Amp ranitidine will prescribe 50mg twice daily; and in intervention group(pantoprazole);Amp pantoprazole will prescribe 40mg once daily. The efficacy of each drug was measured by the gastric secretion PH. Immediately after admission of the patient to the ICU, prophylaxis will begin and before using the first dosage of prophylactic drug, the gastric PH will measure 8 hours after using the first dosage of drug the PH will measure again and after that the gastric Ph will measure every 8 hours in two next days. Primary outcome is the level of gastric PH and the secondary one is GI bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104134578N2**

Registration date: **2011-05-08, 1390/02/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-08, 1390/02/18

Registrant information

Name

Farshid Rahimibashar

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 811264002151

Email address

f.rahimi@umsh.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2011-06-20, 1390/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of ranitidine and pantoprazole in prevention of stress ulcer in ICU

Public title

Ranitidine and pantoprazole in prevention of stress ulcer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients who required mechanical ventilation, Age more than 18 years old, Admission to the ICU, APACHE SCORE II less than 25, Admission at least 24 hour in ICU, Patients with suctionable secretion, No GI bleeding at the beginning of study Exclusion criteria: History of GI bleeding, liver or kidney insufficiency, History of corticosteroids or NSAIDs usage, Gastric PH more than 4 before beginning of prophylaxis

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University Of Medical Sciences

Street address

Mahdiye Street, Hamedan University Of Medical Sciences

City

Hamedan

Postal code

Approval date

2011-04-07, 1390/01/18

Ethics committee reference number

16/35/9/20/د/پ

Health conditions studied

1

Description of health condition studied

stress ulcer

ICD-10 code

K25

ICD-10 code description

Gastric ulcer

Primary outcomes

1

Description

Gastric PH

Timepoint

Before intervention, every 8 hours after intervention for two next days

Method of measurement

The level of gastric PH which is measured by AZ8685 PH metery instrument

Secondary outcomes

1

Description

GI bleeding

Timepoint

Daily

Method of measurement

Evaluating the secretion which lavaged from the patient NG tube to the end of admission in the ICU

Intervention groups

1

Description

In intervention group Pantoprazol 40 mg once a day will infuse till to end of patient admission.

Category

Prevention

2

Description

In control group Ranitidine 50 mg twice a day will infuse till to end of patient admission.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Farshid Rahimi Bashar

Street address

BESAT Hospital, General ICU, Motahhari Avenue_Resalat square

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences-vice chancellor for research

Full name of responsible person

Ali GHaleiha

Street address

Mahdiye Street, Hamedan University Of Medical Sciences

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences-vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Farshid Rahimi Bashar

Position

Assistant Professor/Intensive care fellowship

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty