Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 gruop),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/پ/د

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 houres 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