Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the therapeutic effects of high-dose and low-dose pantoprazole after endoscopy in patients with peptic ulcer bleeding

Protocol summary

Summary

Upper gastrointestinal bleeding is one of the common complications in patients who admit in hospital. The therapeutic cost effects are high due to drugs and procedures that use for patients. Proton pomp inhibitor such as pantoprazole is cardinal drug that prescribed for these patients. The aim was to compare the clinical effectiveness of two doses of infusional pantoprazole in peptic ulcer bleeding. By reduction the total dose of pantoprazole drug side effects and the therapeutic cost effects decrease. This study is a double blind clinical trial that enrolled patients with upper gastro intestinal bleeding. Patients are randomized in two groups 1) Patients who receive 80 mg pantoprazole as bolus dose and 8 mg per hour as maintenance dose for 72 hours; 2) Patients in this group receive 40 mg pantoprazole as bolus dose and 4 mg per hour as maintenance dose for 72 hours. Then patients follow up for one month. Any groups consist of 83 patients who participate in this study from 21-3-2011 to 21-9-2011. Exclusion criteria are consumption of NSAID, Corticosteroid and PPI in last week, multiple ulcers, malignant ulcer, cirrhotic patients with coagulopathy disorders. Primary outcomes are need for surgery, re-bleeding, drop of HB (hemoglobin)>2 units, duration of admission more than 5 days and mean units of blood transfused. Secondary outcomes are mortality rate and readmission with upper gastrointestinal bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202289160N1**
Registration date: **2012-04-15, 1391/01/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-15, 1391/01/27

Registrant information

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutic effects of high-dose and low-dose pantoprazole after endoscopy in patients with peptic ulcer bleeding

Public title

Assessment the therapeutic effect of pantoprazole in patients with gastrointestinal bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients who admit and present signs and symptoms of upper gastrointestinal bleeding such as: 1-Vomits of blood or black material (Hematemesis), 2-Black and tarry stool (Melena), 3-The passage of bright red or blood from the rectum (Hematochesia), 4-Vertigo; light headness and hypotension. Exclusion criteria are: 1-Malignant ulcer; 2-Multiple ulcers; 3-Cirrhotic patient with coagulopathy or hemorrhagic varices; 4-Chronic Renal Failure (CRF); 5-Patients who admitted with gastrointestinal bleeding in last month; 6-Patients receive NSAID and Corticosteroid for underlying disease; 7-Patients under 16 years or upper 70 years;8-Patients who are treated with PPI (proton pomp inhibitor) in last week.

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **166**

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

Ahvaz Jundishapur University of Medical Sciences

Street address

University City

City

Ahvaz

Postal code

Approval date

2011-12-24, 1390/10/03

Ethics committee reference number

Eth-52

Health conditions studied

1

Description of health condition studied

Upper gastro intestinal bleeding

ICD-10 code

k20-k31

ICD-10 code description

Diseases of oesophagus, stomach and duodenum

Primary outcomes

1

Description

Mean units of blood transfusde

Timepoint

In period of admission

Method of measurement

Mean units of blood transfusde in period of admission

2

Description

Duration of admission more than 5 days

Timepoint

In period of admission

Method of measurement

This time evaluate from admission to discharge

3

Description

Need for surgery

Timepoint

In period of admission

Method of measurement

According to vital signs and hemodinamicaly status

4

Description

Rebleeding

Timepoint

In period of admission

Method of measurement

According to vital signs and hemodinamicaly status

Secondary outcomes

1

Description

Readmission due to upper gastrointestinal bleeding

Timepoint

First month after admission

Method of measurement

With take of history and hemodinamicaly status

2

Description

The mortality rate

Timepoint

First month of admission

Method of measurement

With take of history and hemodinamicaly status

Intervention groups

1

Description

Pantoprazole 80 mg bolus infusion followed by 8 mg/h intravenously as maintenance dose for 72 h after endoscopic treatment

Category

Treatment - Drugs

2

Description

Pantoprazole 80 mg bolus infusion followed by 4 mg/h intravenously as maintenance dose for 72 h after endoscopic treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Internal Medicine, Imam Khomeini Hospital

Full name of responsible person

Noorodin Jamshydian

Street address

Department of Internal Medicine, Imam Khomeini Hospital, Azadegan Street, Shohada Square

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Ahvaz University of Medical Sciences

Full name of responsible person

Mostafa Feghi

Street address

University City,Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Ahvaz University of Medical Sciences

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

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

Internal Medicine Resident

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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