

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 pump 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

Name

Noorodin Jamshyadian

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 33 1223 3920

Email address

jamshyadian.n@ajums.ac.ir

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 pump 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 Jamshyidian
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
Noorodin Jamshyidian
Position
Internal Medicine Resident
Other areas of specialty/work
Street address
Department of Internal Medicine, Imam Khomeini Hospital, Azadegan Street, Shohada Square
City
Ahvaz
Postal code
Phone
+98 33 1223 3920
Fax
Email
jamshyidian.n@ajums.ac.ir , noorejam1@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Abdollah Masjedizadeh
Position
Associate Professor
Other areas of specialty/work
Street address
Department of Internal Medicine, Imam Khomeini Hospital, Azadegan Street, Shohada Square
City
Ahvaz
Postal code
61936-73166
Phone
+98 61 1222 2114
Fax
Email
rmasjedi@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Noorodin Jamshyadian

Position

Internal Medicine Resident

Other areas of specialty/work**Street address**

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

City

Ahvaz

Postal code

61936-73166

Phone

+98 61 1222 2114

Fax

+98 61 1222 5763

Email

jamshyadian.n @ajums.ac.ir

Web page address

noorejam1@yahoo.com

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