

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Efficacy of early *Helicobacter Pylori* eradication versus continuous pantoprazol infusion in prevention of rebleeding in peptic ulcer patients

Protocol summary

Summary

Aim: the efficacy of *Helicobacter Pylori* eradication in prevention of peptic ulcer recurrence have been verified in different investigations but it's efficacy in preventing of early re bleeding in comparison with PPI infusion has not been elucidated. The aim of this study is comparison of efficacy of these two therapeutic modalities in patients with peptic ulcer bleeding. Method: the bleeding peptic ulcer patients who have stigmata of recent bleeding like active spurting (Forrest IA), non bleeding visible vessel (Forrest IIA), oozing or adherent clot with visible vessel (Forrest IA, IB, IIA) were included in study. Design:after achieving endoscopic homeostasis with epinephrine injection (1:10000) plus APC or bipolar ECT, 2 samples from antrum and 2 from corpus will obtain by forceps biopsy. The samples will check for rapid urease test and all of the positive samples randomly, according to balance block render and with submitting confounding factors like age, sex and endoscopy results divided to 2 groups. Intervention: The group P treat with 80mg IV pantoprazol as bolus and then continuous IV infusion 8mg/h for 48h. The group H have receiv H. pylori eradication regimen including Omeprazole 20mg BID, tetracycline 1000mg BID, metronidazole 500mg BID and bismuth subcytrate 240mg BID for 14 days. Inclusion/exclusion criteria : The bleeding peptic ulcer patients with age ≥ 16 y old who had stigmata of recent bleeding .The exclusion criteria include esophageal varices, liver cirrhosis, malignancy, concomitant morbidity, cardiac pacemaker, NSAID consumption, current therapy with anti coagulant, antibiotic or PPI and multiple ulcers. Outcome:the primary and secondary outcomes define according to rate of re bleeding, need to surgery, number of transfusions and duration of hospitalization in the first week and first month.The patients risk score will determine according to Rockall score and re bleeding define as hematemesis, repeating melena, $>2\text{gr/dl}$ decrease in Hb level, pulse rate $> 90/\text{min}$ or sudden drop in blood pressure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108073836N2**

Registration date: **2011-08-23, 1390/06/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-08-23, 1390/06/01

Registrant information

Name

Abdolrahim Masjedi Zadeh

Name of organization / entity

Jundishapour Ahvaz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Jundishapour Ahvaz University of Medical Sciences

Expected recruitment start date

2011-12-14, 1390/09/23

Expected recruitment end date

2012-12-22, 1391/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of early Helicobacter Pylori eradication versus continuous pantoprazol infusion in prevention of rebleeding in peptic ulcer patients

Public title

Efficacy of early Helicobacter Pylori eradication versus continuous pantoprazol Infusion in prevention of rebleeding in peptic ulcer patients

Purpose

Prevention

Inclusion/Exclusion criteria

The bleeding peptic ulcer patients with age ≥ 16 y old who have stigmata of recent bleeding like active spurting (Forrest IA), non bleeding visible vessel (Forrest IIA), oozing or adherent clot with visible vessel (Forrest IA, IB, IIA) will be included in study. The exclusion criteria are: esophageal varicose, liver cirrhosis, malignancy, concomitant morbidity, cardiac pacemaker, NSAID consumption, current therapy with anti coagulant, antibiotic or PPI and multiple ulcers.

Age

From **16 years** old to **89 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **102**

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**

Jundishapour Ahvaz University of Medical Sciences

Street address

Golestan-University city-Ethnical and research committee of Jundishapour University of Medical Sciences

City

Ahvaz

Postal code

61357-15794

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

u-88016

Health conditions studied**1****Description of health condition studied**

Peptic ulcer-GI bleeding

ICD-10 code

k25-k26

ICD-10 code description

Gastric ulcer -Duodenal ulcer -Acute with haemorrhage

Primary outcomes**1****Description**

Rebleeding

Timepoint

One week

Method of measurement

Hematemesis, Repeating melena, >2gr/dl Decrease in Hb level, Pulse rate > 90/min or sudden drop in blood pressure

2**Description**

Surgery

Timepoint

One Week

Method of measurement

Number

3**Description**

Transfusion

Timepoint

One week

Method of measurement

Number

4**Description**

Mortality

Timepoint

One week

Method of measurement

Number

5**Description**

Duration of admission

Timepoint

One week

Method of measurement

Day

Secondary outcomes**1****Description**

Rebleeding

Timepoint

One month

Method of measurement

Hematemesis, Repeating melena, >2gr/dl Decrease in Hb level, Pulse rate > 90/min or sudden drop in blood pressure

2**Description**

Surgery

Timepoint

One month

Method of measurement

Number

3**Description**

Transfusion

Timepoint

One month

Method of measurement

Number

4**Description**

Mortality

Timepoint

One month

Method of measurement

Number

5**Description**

Duration Admission

Timepoint

One month

Method of measurement

Day

Intervention groups**1****Description**

Group H (control group) will be treated by Omeprazole 20mg two times a day(BID), subcytrate bismuth 240mg BID, metronidazole 500mg BID and tetracycline 1000mg BID for 14 days

Category

Treatment - Drugs

2**Description**

The group P (case) will receive pantoprazol 80 mg intravenously, stat and then 8mg/h infusion for 72 hours

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hospital

Full name of responsible person**Street address****City**

Ahvaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Jundishapour Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Fegghi

Street address

Golestan, University city, Vice chancellor for research, Jundishapour University of Medical Sciences

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Ahvaz

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

Yes

Title of funding source

Jundishapour 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**

Imam Hospital

Full name of responsible person

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Position

Association Professor

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Web page address**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