

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\geq 16$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1337 6922

##### Email address

rmasjedi@ajums.ac.ir

##### 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  $\geq$  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

**City**

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**

Abdolrahim Masjedizadeh

**Position**

Association Professor

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

Azadgan Street-Imam hospital-Gastroentrology Ward

**City**

Ahvaz

**Postal code**

6193673166

**Phone**

+98 61 1222 2922

**Fax**

+98 61 1222 5763

**Email**

rmasjedi@hotmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Imam Hospital

**Full name of responsible person**

Eskandar Hajiani

**Position**

Association Professor

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

Azadgan Street, Imam hospital, Gasterology ward

**City**

Ahvaz

**Postal code**

6193673166

**Phone**

+98 61 1222 2922

**Fax****Email**

ehajiani@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Imam Hospital

**Full name of responsible person**

ABDOLRAHIM MASJEDIZADEH

**Position**

Association Professor

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

Azadgan street-Imam Hospital-GI Ward

**City**

Ahvaz

**Postal code**

6193673166

**Phone**

+98 61 1222 2922

**Fax**

+98 61 1222 5762

**Email**

rmasjedi@hotmail.com

**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*