

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effect of injective pantoprazole and oral Rabeprazol in patients with upper gastrointestinal bleeding

#### Protocol summary

##### Summary

Objectives: The effectiveness of treatment with injection of pantoprazole and the oral Rabeprazol in patients with upper gastrointestinal bleeding. Methods and materials: In this randomized clinical trial, The Patients were excluded from the study if they were pregnant, did not obtain initial haemostasis with endoscopic injection of epinephrine, did not give written informed consent, had bleeding tendency , had uraemia or bleeding gastric cancer. 114 patients were randomly divided into two groups of Pantoprazole 8 mg per hour and edible Rabeprazole 40 mg each 12 hours and the rate of rebleeding, mortality, blood transfusion volume, hospital stay, and need to urgent surgery were compared between two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013050713261N1**

Registration date: **2013-08-03, 1392/05/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-08-03, 1392/05/12

##### Registrant information

##### Name

Mohamad amir Sarabi

##### Name of organization / entity

Shahid sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1823 8605

##### Email address

masarabi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2011-04-03, 1390/01/14

##### Expected recruitment end date

2012-11-21, 1391/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of injective pantoprazole and oral Rabeprazol in patients with upper gastrointestinal bleeding

##### Public title

Gi bleeding treathment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

The patients with upper gastrointestinal bleeding and treated by epinephrine injection who wanted to participate in the study and do not had allergy to the Inclusion criteria: underwent urgent endoscopy within 24 h after presentation, had peptic ulcers in the distal oesophagus, stomach or duodenum, had high-risk stigmata including active bleeding , nonbleeding visible vessels , or adherent clots , and successful haemostasis was achieved with endoscopic injection of epinephrine. Written informed consent was obtained before enrolment. Exclusion criteria: pregnant; did not obtain initial haemostasis with endoscopic injection of epinephrine; did not give written informed consent; had

bleeding tendency (platelet count <50000 , PT > 3 s of normal, CT and BT prolong or were taking anticoagulants); had uraemia ; bleeding gastric cancer.

#### Age

From **19 years** old to **100 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **114**

#### 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

Shahid Sadoughi University of Medical Sciences

##### Street address

Ebne Sina ave. , , Atlasi sq. , Yazd, Iran

##### City

Yazd

##### Postal code

8916886938

#### Approval date

2013-03-06, 1391/12/16

#### Ethics committee reference number

17/1/180770/پ

## Health conditions studied

### 1

#### Description of health condition studied

Upper gibleeding

#### ICD-10 code

K92.2

#### ICD-10 code description

Gastrointestinal haemorrhage, unspecified

## Primary outcomes

### 1

#### Description

No rebleeding

#### Timepoint

72h

#### Method of measurement

patient Symptoms and endoscopy in second 24 h

## Secondary outcomes

### 1

#### Description

Hospital stay and mortality and blood transfusion

#### Timepoint

72h

#### Method of measurement

symptoms

## Intervention groups

### 1

#### Description

Initial treatment included water and electrolyte balancing and injection of Pantoprazole 80 mg and 8 mg per hour and in 24 hours endoscopy was performed on the patients and in patients who had active bleeding or their veins could be seen or had affixed clots based on Rockall, Forrest and Blatch Ford measures epinephrine was injected and if the bleeding was controlled another injection of Pantoprazole was performed in 6 hours and if the clinical signs were stable liquid was started and the patients were randomly (according to random number generator table) divided into two groups a group that continued injection of Pantoprazole 8 mg per hour . Also the drug side effects were determined in the patients.for all patient endoscopy done in 2 th days.

#### Category

Treatment - Drugs

### 2

#### Description

The second group that consumes edible Rabeprazole 40 mg each 12 hours. For all patient endoscopy done in 2 th days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadoughi Hospital

##### Full name of responsible person

Mohammad Amir Sarabi

##### Street address

Shahid Sadoughi Hospital, Ebne Sina ave. , Shahid

Ghandi Blvd. ,  
**City**  
Yazd

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Personal

**Full name of responsible person**

Mohammad Amir Sarabi

**Street address**

Shahid Sadoughi Hospital , Ebne Sina ave. , Shahid  
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**City**

Yazd

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Personal

**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**

personal

**Full name of responsible person**

Mohammad Amir Sarabi

**Position**

PHD

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

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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*