

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of proton pump inhibitors, oral and injectable, in preventing rebleeding in patients with bleeding peptic ulcer after successful endoscopic therapy.

Protocol summary

Summary

In this randomized clinical trial, we compare the efficacy of proton pump inhibitors (oral or injectable forms) in patients with bleeding peptic ulcer after endoscopic treatment. Every person with upper gastrointestinal bleeding due to peptic ulcer (DU or GU), which have endoscopic evidence of active bleeding will be included and any person with bleeding from esophageal or gastric varices or cancer will be excluded. A total of 260 patients with upper gastrointestinal bleeding due to peptic ulcer refer to Sari Imam Khomeini Hospital will be enrolled. After endoscopic therapy of bleeding peptic ulcer by adrenaline injection and APC, the patients will be placed in two groups randomly. In the case group, we will give them oral pantoprazole 40 mg every 12 hours, and the control group, intravenous pantoprazole 80 mg stat dose, and 8 mg per hour for 72 hours. Then both groups will take oral pantoprazole 40 mg every 12 hours for 4 weeks. During the study period all patients will be evaluate for hemoglobin level, blood pressure in lying and standing stat, the need for blood transfusions, need for re-endoscopy and or surgical intervention due to re-bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082515510N2**
Registration date: **2014-10-04, 1393/07/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-04, 1393/07/12

Registrant information

Name

Seyed Mohammad Valizadeh Toosi

Name of organization / entity

Mazandaran University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3320 2242

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of proton pump inhibitors, oral and injectable, in preventing rebleeding in patients with bleeding peptic ulcer after successful endoscopic therapy.

Public title

Proton pump inhibitors, oral and injectable, in preventing peptic ulcer re-bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Every person with upper gastrointestinal bleeding due to peptic ulcer, which is the new log endoscopic bleeding (bleeding ulcer in the jet, the vessel featured in the wound bed, the wound with mild persistent bleeding, and ulcers with adherent clots in bed). Exclusion criteria: patients with upper GI bleeding with other causes, such as bleeding from esophageal or gastric varices or cancer and patients with clean base peptic ulcer without active bleeding.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **260**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

NO

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University Of
Medical sciences

Street address

Moallem Squire

City

Sari

Postal code

324776119

Approval date

2014-09-06, 1393/06/15

Ethics committee reference number

93-4-18

Health conditions studied

1

Description of health condition studied

gastroduodenal ulcer

ICD-10 code

k27

ICD-10 code description

Peptic ulcer, site unspecified

Primary outcomes

1

Description

Endoscopic evidence of bleeding from gastric or duodenal ulcer

Timepoint

Before intervention, 72 hours and 4 weeks after intervention

Method of measurement

Endoscopy before intervention, check of blood pressure and hemoglobin 72 hours and 4 weeks after intervention

Secondary outcomes

1

Description

The number of units of blood required

Timepoint

8 weeks after intervention

Method of measurement

Questionnaire

2

Description

Need for surgery

Timepoint

Upto 4 weeks after intervention

Method of measurement

Questionnaire

3

Description

Days of hospitalization

Timepoint

Upto 4 weeks after intervention

Method of measurement

Questionnaire

4

Description

The need for re-endoscopy because of bleeding

Timepoint

Upto 4 weeks after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

" intervention group: We will give pantoprazole tablet 40 mg every 12 hours for 72 hours and then will continue with same dose for 4 weeks

Category

Treatment - Drugs

2

Description

"Control group: We will give IV pantoprazole 40 mg as stat dose and then 8 mgr per hours for 72 hours .we will continue pantoprazole tablet 40 mgr twice daily for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari, Imam Khomeni Hospital, Endoscopic Ward

Full name of responsible person

Dr Seyed Mohammad Valizadeh Toosi

Street address

Imam Khomeni Hospital, Amir Mazandarani Street

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmad Ali Aenayati

Street address

Moallem Square

City

Sari

Grant name

Grant code / Reference number

849

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

Yes

Title of funding source

Vice Chancellor for research of Mazandaran 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

Inflammatory Diseases of Upper Gastrointestinal Tract Research Center

Full name of responsible person

Seyed Mohammad Valizadeh Toosi

Position

Asistant Professor Of GI Ward

Other areas of specialty/work

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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