Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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 Squre
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 an 4 weeks after intervention
Method of measurement
Endoscopy before intervention, check of blood pressureand 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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Person responsible for updating data

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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