Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing effect of oral omeprazole versus intravenous pantaprazole in peptic ulcer bleeding

Protocol summary

Summary

This study is aimed to compare clinical effectiveness of oral omeprazole and intravenous infusion of pantaprazole in prevention of peptic ulcers rebleeding. INCLUSION CRITERIA :Patients who refer to hospital due to hematemesis ,melena and hematochesia .EXCLUSION CRITERIA :patients who have history of liver cirrhosis, GI malignancy uremia or bleeding tendency .83 enrolled patients randomly allocate to receive either oral omeprazole (OMP group ,40 mg twice daily for 3 days) or i.v. pantaprazole (PAN group ,80 mg stat then 8mg each hour for 72 or 48 hour) .All patient evaluate endoscopically and endoscopic intervention would take if neccesary . Subsequently the enrolled patients will receive oral omeprazole 20 mg daily for 14 days .The primary end point is in hospital recurrent bleeding , surgery or mortality. m.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711191650N1**
Registration date: **2010-01-03, 1388/10/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-01-03, 1388/10/13

Registrant information

Name

Seyed Alireza Hashemi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research departement -Shiraz University of Medical Science

Expected recruitment start date

2008-11-20, 1387/08/30

Expected recruitment end date

2009-06-20, 1388/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of oral omeprazole versus intravenous pantaprazole in peptic ulcer bleeding

Public title

Comparing effect of oral omeprazole versus intravenous pantaprazole in peptic ulcer bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

INCLUSION CRITERIA ;All patient who admite in hospital due to GI bleeding and have high risk ulcer in endoscopic evaluation. EXCLUSION CRITERIA ;Any patient who find to have esophageal varices ,bleeding tendency ,GI cancer ,uremia or Mallory Weiss tear.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Departement -Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences -Zand avenue -Shiraz -Iran
City
Shiraz
Postal code
Approval date
empty
Ethics committee reference number
CT-87-4431

Health conditions studied

1

Description of health condition studied
Peptic ulcer, bleeding
ICD-10 code
K-27.0
ICD-10 code description
Peptic ulcer, site unspecified

Primary outcomes

1

Description
recurrent bleeding
Timepoint
daily up to discharge and after 14 days
Method of measurement
hypotension,tachucardia ,Hb drop ,hematemesis after stabilization and recurrence of melena after normal stool

2

Description
surgery
Timepoint
daily up to discharge and after 14 days
Method of measurement
daily up to discharge and phone call after 2 weeks

3

Description
mortality (All cause)
Timepoint
daily up to discharge
Method of measurement
daily up to discharge and phone call after 2 weeks

Secondary outcomes

1

Description
blood transfusion
Timepoint
during discharge
Method of measurement
number of transfused blood packed cells

2

Description
hospital stay
Timepoint
daily
Method of measurement
assess during discharge

Intervention groups

1

Description
All patients who admit in odd days will take oral omeprazole (40 mg po BID) and then 20 mg omeprazole daily up to 14 days.All patient will evaluate endoscopically and endoscopic intervention would be done if need.
Category
Treatment - Drugs

2

Description
patients who will admit in even days will recieve pantoprazole (8 mg / hour) for 72 or 48 hour and then take omeprazole 20 mg daily up to 14 days .
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Nemazi and shahid-faghihi hospitals
Full name of responsible person
Seyed Alireza Hashemi
Street address
koocheh 2 -Poostchi avenue-Shiraz -Iran
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mostaghni .Amir Ahmad
Street address
Internal Ward -Shiraz University of Medical Sciences
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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