Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Randomized control trial on effect of octereotide in control of nonvariceal upper gastrointestinal bleeding

Protocol summary

Summary

The study aims to determine the effect of octereotide in control of upper gastrointestinal bleeding in a randomized clinical trial. Human samples studied, patients with acute upper gastrointestinal bleeding admitted to the emergency room of shiraz nemazi hospital and faghihi hospital in 1394. All alert patients from 18 to 80 Y/O complained of melena or hematemesis or tarry stools, eligible for inclusion enter to study.Main exclusion criteria are: severe congestive heart failure,hemodialysis, pregnancy,lactation and child B, C cirrhosis .Each group consisted of 52 people, considering the possibility of optional leaving or any other reason for leaving of study,the number of patients were considered 70 in each groups(totally 140) After hemodynamic stability, pantoprazole 40 mg intravenously with either Octreotide or Placebo drug(100 mcg subcutaneously) will randomly prescribed to patients and in terms of the patients emergency conditions and bleeding severity,endoscopy will be done within 12 hours.Patients will be divided into two groups in a randomized, double-blind method.One group treated with pantoprazole 40 mg IV every 12 hours along with Octreotide 100 micrograms subcutaneously every 8 hours.Another group treated with the same dose of pantoprazole along with placebo and treatment will continue to72 hours or discharging time.patients with Clean base ulcers will be discharged after endoscopy.Patients received endoscopic hemostatic treatment will be discharged after 72 hours and other patients after 24 hours if no bleeding.They will be assessed weekly by phone for readmission and mortality till 30 days.Aims of study are evaluation of rebleeding and 30 days mortality, needs to blood products transfusion and surgery in hospital course,length of hospital stay and readmission rate within 30 days

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050322066N1**
Registration date: **2015-11-20, 1394/08/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-11-20, 1394/08/29

Registrant information

Name
Masoud Abrishami
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Randomized control trial on effect of octereotide in control of nonvariceal upper gastrointestinal bleeding

Public title
Effect of octereotide in nonvariceal upper gastrointestinal bleeding

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: Conscious patients; age between 18 to 80 years; with complaint of melena or hematemesis or tarry stools in rectal examination Exclusion criteria: patients with congestive heart failure class 4; ESRD patients on hemodialysis; pregnant patients; Patients with acute coronary events; nursing patients; cirrhotic Patients with child score B or C; make any complications of treatment with Octreotide at any time during the study; the patient's willingness to withdraw from the study at any time during the study; taking any anticoagulant; patients suffering from coagulation diseases

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Across Palestine Street, Zand Street

City
shiraz

Postal code
7134814336

Approval date
2015-11-01, 1394/08/10

Ethics committee reference number
IR.SUMS.REC.1394.130

Health conditions studied

1

Description of health condition studied
Upper GI bleeding

ICD-10 code
K25

ICD-10 code description
Gastric ulcer

2

Description of health condition studied
Upper GI bleeding

ICD-10 code
K26

ICD-10 code description
Duodenal ulcer

3

Description of health condition studied
Upper GI bleeding

ICD-10 code
K27

ICD-10 code description
Peptic ulcer, site unspecified

Primary outcomes

1

Description
Readmission in one month after bleeding

Timepoint
one month

Method of measurement
phone calling

2

Description
Mortality in one month after bleeding

Timepoint
one month

Method of measurement
phone calling

Secondary outcomes

1

Description
length of hospital admission

Timepoint
daily

Method of measurement

daily visit

2

Description
rate of blood products transfusion
Timepoint
daily
Method of measurement
visit and evaluation amounts of blood products use

3

Description
need for surgery due to bleeding
Timepoint
hospital stay time
Method of measurement
daily visit

4

Description
hospital readmission rate within 30 days after bleeding
Timepoint
weekly for one month
Method of measurement
weekly phone call

Intervention groups

1

Description
Intravenous pantoprazole 40 mg with 100 microg subcutaneous octereotide before endoscopy and pantoprazole 40 mg intravenously every 12 hours with Octreotide 100 micrograms subcutaneously every 8 hours after endoscopy that treatment will continue till 72 hrs or discharge time
Category
Treatment - Drugs

2

Description
Pantoprazole 40 mg intravenously with placebo in the same form and similar and consistent with Octreotide before endoscopy and pantoprazole 40 mg intravenously every 12 hours with subcutaneous placebo every 8 hours after the endoscopy for 72 hours or until discharge time
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Namazi Hospital
Full name of responsible person
Masoud Abrishami
Street address
Namazi Square, Zand Street
City
Shiraz

2

Recruitment center
Name of recruitment center
Shiraz Shahid Faghihi Hospital
Full name of responsible person
Masoud Abrishami
Street address
adjacent to Medical school, Zand Street
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, Shiraz University of Medical Sciences
Full name of responsible person
Seyed Basir Hashemi
Street address
Headquarters of Shiraz University of Medical Sciences, Across Palestine Street, Zand Street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, 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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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