

# 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 to 72 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 3236

##### Email address

mabrishamim@sums.ac.ir

##### 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 octreotide in control of nonvariceal upper gastrointestinal bleeding

**Public title**

Effect of octreotide 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 octreotide 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

##### **Full name of responsible person**

Masoud Abrishami

##### **Position**

Adult GI fellow

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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*