Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Samen-ista emulsion on treatment of bleeding from benign ulcers of upper gastrointestinal tract in comparison with Argon plasma coagulation method.

Protocol summary

Summary

We will do our study on 40 conscious and stable patients whom will be admitted in Ghaem and Imamreza hospitals of Mashhad due to upper gastrointestinal bleeding from an ulcer with benign endoscopic view. After completing consent form and considering of exclusion criteria, they will be randomized according to the table of numbers into two groups. The first group will be treated with 20cc from 20% Samen-ista emulsion, which is a mineralo-herbal emulsion with anticoagulant property in animal models. This emulsion will be poured on the bleeding ulcer from 2mm distance, via an ERCP-catheter. The patient will be under observation for 5 minutes during the endoscopy to evaluate stop bleeding, if any bleeding was seen after 5 minutes, treatment with Argon plasma coagulation will be done. In the second group the gastrointestinal bleeding will be treated with Argon plasma coagulation method. The rate of success in bleeding control at 5min after treatment during first endoscopy and also in the second endoscopy which will be done 72 hours later will be compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016033118915N4**
Registration date: **2016-08-07, 1395/05/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-07, 1395/05/17

Registrant information

Name

Mousalreza Hosseini

Name of organization / entity

Mashhad University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 80 1274 2513

Email address

hoseinimr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashad University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

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

The effect of Samen-ista emulsion on treatment of bleeding from benign ulcers of upper gastrointestinal tract in comparison with Argon plasma coagulation method.

Public title

The effect of Samen-ista emulsion on treatment of bleeding from benign ulcers of upper gastrointestinal tract.

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: The patients with Upper gastrointestinal bleeding who will be admitted in emergency wards of Ghaem and Imam-reza Hospitals. Exclusion criteria: Bleeding from esophageal or gastric varices; Bleeding from esophageal or gastric malignancy; Bleeding in a patient with coagulopathy, hematologic malignancy or renal failure.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashad University Of Medical Sciences
Street address
Goreyshi Building, Doktora Square, Daneshgah Street, Mashhad
City
Mashhad
Postal code
Approval date
2015-11-11, 1394/08/20
Ethics committee reference number
IR.MUMS.REC.1394.564

Health conditions studied

1

Description of health condition studied
Diseases of esophagus, stomach and duodenum
ICD-10 code
K25.0
ICD-10 code description
acute gastric ulcer with hemorrhge

Primary outcomes

1

Description
Bleeding
Timepoint
5 min and third day after procedure
Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: The first group will be treated with 20cc from 20% samen-ista emulsion which will be poured on the bleeding ulcer from 2mm distance, via a ERCP-catheter
Category
Treatment - Drugs

2

Description
Control: The second group will be treated with argon plasma coagulation method.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem and Imam-reza Hospitals
Full name of responsible person
Mousalreza Hosseini
Street address
Internal Department, Ghaem Hospital, Shariati Square, Ahmadabad Street, Mashhad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashad University of Medical Sciences
Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Ghoreishi Building, Doktora Square, Danseshgah Street, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashad 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

Mashhad University Of Medical Sciences

Full name of responsible person

Mousalreza Hosseini

Position

Assistant Professor

Other areas of specialty/work

Street address

Internal Department, Ghaem Hospital, Shariati Square, Ahmadabad Street, Mashhad

City

Mashhad

Postal code

Phone

+98 51 3801 2742

Fax

Email

hoseinimr@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Mousalreza Hosseini

Position

Assistant Professor

Other areas of specialty/work

Street address

Internal Department, Ghaem Hospital, Shariati Square, Ahmadabad Street, Mashhad

City

Mashhad

Postal code

Phone

+98 51 3801 2742

Fax

Email

hoseinimr@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Masoumeh Salari

Position

Assistant professor

Other areas of specialty/work

Street address

Internal Department, Ghaem Hospital, Shariati Square, Ahmadabad Street, Mashhad

City

Mashhad

Postal code

Phone

+98 51 3801 2742

Fax

Email

salarim@mums.ac.ir

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