

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the effect of Samen-ista emulsion on controlling gastric bleeding through gastric lavage with NG tube in emergency wards.

Protocol summary

Study aim

Investigation of the effect of Samen-ista emulsion on controlling gastric bleeding through gastric lavage with NG tube in emergency wards

Design

In this study 60 patients with upper gastrointestinal bleeding with normal INR and without platelet disorders who refer to emergency wards will be first hemodynamically investigated and if needed, receive initial resuscitation measures to be stabilized. Then through NG tube, gastric lavage will be done with either normal saline or Samen-ista. Patients are randomly divided to two groups of intervention and control each with 30 people. The grouping is done with Random Block Design.

Settings and conduct

Double blinding is done in a way that only intern and resident of that day in emergency wards of Ghaem Hospitals are aware of which person belongs to which group and the researcher and analyzer are not aware of the grouping.

Participants/Inclusion and exclusion criteria

Patients with upper gastrointestinal bleeding referring to emergency wards of Ghaem Hospital will be included in the study. These patients should not have platelet malfunctioning or Thrombocytopenia or coagulation disorders and should not use Warfarin and Clopidogrel.

Intervention groups

In both groups necessary measures for treating UGIB are taken in emergency wards. But the intervention group, in addition to those measures, will have gastric lavage through NG tube with Samen-ista and then the on-call gastroenterology fellow will be notified to perform endoscopy. During endoscopy, status of bleeding and ulcer will be carefully recorded and the need for endoscopic treatment will be investigated.

Main outcome variables

Increase of speed in stopping bleeding from ulcer in gastric lavage with Samen-ista and reduction of the need

for treatment with endoscopy and reduction of hospitalization time and also reduction of bleeding time numbers during hospitalization.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140824018915N5**

Registration date: **2018-01-15, 1396/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-15, 1396/10/25**

Update count: **0**

Registration date

2018-01-15, 1396/10/25

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

Expected recruitment start date

2017-06-21, 1396/03/31

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of Samen-ista emulsion on controlling gastric bleeding through gastric lavage with NG tube in emergency wards.

Public title

Investigation of the effect of Samen-ista emulsion on controlling gastric bleeding through gastric lavage with NG tube.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients with upper gastrointestinal bleeding who will be admitted in emergency wards of Ghaem Hospital

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

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Grouping is done with Random Block Design.

Blinding (investigator's opinion)

Double blinded

Blinding description

The intern and resident of the day are only aware of which person belongs to which group and the researcher and analyzer are not aware of the grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9117699199

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

IR.MUMS.REC.1395.553

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 hemorrhage

Primary outcomes**1****Description**

stopping bleeding from ulcer in gastric lavage

Timepoint

During endoscopy

Method of measurement

Through carefully recording bleeding status during endoscopy

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: gastric lavage with Samen-ista emulsion is done through NG tube and then endoscopy is carried out.

Category

Treatment - Drugs

2**Description**

Control group: gastric lavage with normal saline is done

through NG tube and then endoscopy is carried out.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Dr Mousalreza Hoseini

Street address

Ahmad Abad Ave, Ghaem hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Mohsen Tafaghodi

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Grant name

Grant code / Reference number

941742

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mousalreza Hoseini

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In case organizations ask for the data of participants, the data will become accessible for them.

When the data will become available and for how long

The data can be accessible for specific organization request 6 month after the article is published.

To whom data/document is available

All academic institutes and non-academic industrial institutes which are related to our studies will have access to our data after going through legal procedures.

Under which criteria data/document could be used

In case those people asking for data have the intention of optimizing the study an data and producing more results, access to data is allowed.

From where data/document is obtainable

Through sending an email to the corresponding author, data will be obtainable.

What processes are involved for a request to access data/document

In case someone asks for data, he must first get in contact with the corresponding author for his identity to be fully verified. Then if university allows propagation of data, it will be accessible in 3 months.

Comments