

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigation of the effect of Samen-ista emulsion on the treatment of upper gastrointestinal non-bleeding visible vessel in comparison with the effect of adrenaline injection with Argon plasma coagulation or clips

#### Protocol summary

##### Study aim

Investigation of the effect of Samen-ista emulsion on the treatment of upper gastrointestinal non-bleeding visible vessel

##### Design

This clinical trial is carried out on 90 patients in 3 groups of 30 people including 2 control groups. Single-blinding is done and simple randomization is performed.

##### Settings and conduct

Patients with gastrointestinal bleeding who refer to the emergency wards of Imam Reza and Ghaem Hospitals in Mashhad are enrolled in the study. Prior to endoscopy, all patients fill out informed written consent forms and then undergo one of the following treatments: a) adrenaline injection and Argon plasma coagulation or b) adrenaline injection and clips or c) treatment with Samen-ista powder. Randomization is done through a randomization table. In order to conceal the randomized allocation of groups, sealed and numbered envelopes will be used. When a patient refers, envelopes are opened in turn and the treatment method will be determined.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with upper gastrointestinal bleeding who refer to the emergency wards of Ghaem and Imam Reza hospitals with non-bleeding visible vessel during initial endoscopy. Exclusion criteria: all types of bleeding except bleedings caused by a non-bleeding visible vessel, pregnancy, hemodynamic instability during endoscopy, peptic ulcers that have undergone endoscopic treatment within the last 7 days, Thrombocytopenia, kidney failure

##### Intervention groups

Patients with a non-bleeding visible vessel in the endoscopy, receive ulcer treatment in Intervention group: through lavage with Samen-ista emulsion, in control group1: through adrenaline injection and Argon plasma coagulation, in control group2: through

adrenaline injection and clips

##### Main outcome variables

Investigation of rate of complications (rebleeding) after Using Samen-ista powder on non-bleeding visible vessel in endoscopy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140824018915N6**

Registration date: **2018-04-27, 1397/02/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-27, 1397/02/07**

Update count: **0**

##### Registration date

2018-04-27, 1397/02/07

##### 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

2018-01-05, 1396/10/15

##### Expected recruitment end date

2018-07-06, 1397/04/15  
**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 the treatment of upper gastrointestinal non-bleeding visible vessel in comparison with the effect of adrenaline injection with Argon plasma coagulation or clips

**Public title**  
Investigation of the effect of Samen-ista emulsion on the treatment of upper gastrointestinal non-bleeding visible vessel

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with upper gastrointestinal bleeding who refer to the emergency wards of Ghaem and Imam Reza hospitals with non-bleeding visible vessel during initial endoscopy

**Exclusion criteria:**

All types of bleeding except bleedings caused by a non-bleeding visible vessel Pregnancy Hemodynamic instability during endoscopy Uncorrected coagulation disorders Peptic ulcers that have undergone endoscopic treatment within the last 7 days Thrombocytopenia less than 100,000 Kidney Failure (Creatinine > 1.5)

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done through a randomization table provided by a computer. In order to conceal the randomized allocation of groups, sealed and numbered envelopes will be used. When a patient refers, envelopes are opened in turn and the treatment methods will be determined.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This is a single-blinded study in which participants are not aware of their treatment method. Based on the sealed envelopes, type of treatment is determined in the time endoscopy.

**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**

345 - 91357

**Approval date**

2018-01-03, 1396/10/13

**Ethics committee reference number**

IR.MUMS.fm.REC.1396.652

**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**

Rate of complications (rebleeding)

**Timepoint**

In the first 24 hours, patient will be placed under precise monitoring (checking vital signs investigation of rebleeding) every 4 hours and then, for investigation of ulcer, another endoscopy is performed. follow ups will be done after 72 hours in the hospital and through phone calls after a month.

**Method of measurement**

Endoscopy

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: If there is a non-bleeding visible vessel in endoscopy, lavage with Samen-ista emulsion (a combination of minerals and herbals made by Simorgh Attar company) is done in the ulcer location once.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: If there is a non-bleeding visible vessel in endoscopy, ulcer treatment will be done through adrenaline injection and Argon plasma coagulation

#### Category

Treatment - Drugs

### 3

#### Description

Control group: If there is a non-bleeding visible vessel in endoscopy, ulcer treatment will be done through adrenaline injection and clips

#### 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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9176699199

##### Phone

##### Email

hoseinimr@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

##### Street address

Central Building of Mashhad University of Medical

Sciences (Ghorshi), Daneshgah 16, Daneshgah street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

345 - 91357

##### Phone

+98 51 3841 2081

##### Email

ramresearch@mums.ac.ir

#### Grant name

#### Grant code / Reference number

#### 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

Amir Abbas Hasanzadeh

##### Position

student of sub specialist

##### Latest degree

Specialist

##### Other areas of specialty/work

Internal Medicine

##### Street address

Emam Reza Sq, Ebne-Sina Ave, Emam Reza hospital

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##### Province

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##### Postal code

9137913316

##### Phone

+98 51 3801 2769

##### Email

HasanzadehA951@mums.ac.ir

## Person responsible for scientific 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

**Street address**

Ahmad Abad Ave, Ghaem hospital

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**Email**

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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****Person responsible for updating data****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

**Street address**

Ahmad Abad Ave, Ghaem hospital

**City**

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