

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of Samen eaista emulsion in the management of hemorrhage in ERCP due to sphinctrotomy in comparison with Argon plasma coagulation method

#### Protocol summary

##### Study aim

Determining the application and effect of static samen solution in controlling bleeding caused by sphincterotomy in comparison with argon plasma coagulation method

##### Design

Clinical trial with control group and parallel groups, phase 3 on 25 patients, simple randomization method using closed door envelope

##### Settings and conduct

Patients with gastrointestinal bleeding due to sphincterotomy referred to the emergency department of Ghaem Hospital in Mashhad, are included in the study and then the patient will undergo one of the injections and coagulation with argon gas or treatment with static samen solution. Randomization is based on a table of random numbers and in order to hide the random allocation of groups, the method of sealed envelopes will be used. With each patient's visit, the envelopes are opened in order and the method of treatment is determined. The study is double-blind and the researcher and analyst are not aware of patient grouping.

##### Participants/Inclusion and exclusion criteria

Patients with gastrointestinal bleeding due to sphincterotomy referred to Ghaem Hospital emergency department

##### Intervention groups

In this study, patients with gastrointestinal bleeding due to sphincterotomy are examined. First, patients who meet the inclusion criteria are selected and after obtaining the patient's consent, treatment with static samen substance prepared in powder form is used. Before use, the powder is dissolved with distilled water (static samen solution) and poured on the bleeding site from a distance of 1-2 mm through a catheter that enters the endoscope. During endoscopy, the effect of the solution to stop the bleeding is examined. In the control

group, the usual emergency treatment is performed by injection and coagulation with argon plasma.

##### Main outcome variables

The main variable is to stop bleeding due to sphincterotomy after using static samen solution up to 24 hours later.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140824018915N8**

Registration date: **2021-05-31, 1400/03/10**

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

Last update: **2021-05-31, 1400/03/10**

Update count: **0**

##### Registration date

2021-05-31, 1400/03/10

##### 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

2021-05-31, 1400/03/10

**Expected recruitment end date**

2021-07-01, 1400/04/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of Samen eaista emulsion in the management of hemorrhage in ERCP due to sphinctrotomy in comparison with Argon plasma coagulation method

**Public title**

Efficacy of Samen eaista emulsion in the management of hemorrhage due to sphinctrotomy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patients with upper gastrointestinal bleeding due to sphinctrotomy 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

**Age**

From **15 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**

Target sample size: **25**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups

**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**

2017-07-05, 1396/04/14

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1398.293

**Health conditions studied****1****Description of health condition studied**

Upper gastrointestinal bleeding

**ICD-10 code**

K25.0

**ICD-10 code description**

Acute gastric ulcer with hemorrhage

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

Stop bleeding from wounds caused by sphincterotomy

**Timepoint**

After using static samen solution and 24 hours after intervention.

**Method of measurement**

Endoscopy

**Secondary outcomes****1****Description**

Need for re-endoscopy due to bleeding

**Timepoint**

Up to 4 weeks after the intervention

**Method of measurement**

questionnaire

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, static samens substance prepared in powder form is used for treatment. Before use, the powder is dissolved with distilled water (static samens solution) and poured on the bleeding site from a distance of 1-2 mm through a catheter that enters the endoscope. Within a few seconds and during the same endoscopy, the effect of the solution to stop the bleeding is examined

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In the control group, conventional emergency treatment is performed by injection and coagulation with plasma argon

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital Emergency

##### Full name of responsible person

Dr Mousalreza Hoseini

##### Street address

Ahmad Abad Ave, Ghaem hospital

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9176699199

##### Phone

+98 51 3840 0000

##### 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

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##### 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

Mousalreza Hoseini

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Internal Medicine

##### Street address

Ahmad Abad Ave, Ghaem hospital

##### City

Mashhad

##### Province

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##### Postal code

9176699199

##### Phone

+98 51 3801 2742

##### Email

hoseinimr@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

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Specialist

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available