Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 coagulopathyHematologic 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 samen substance prepared in powder form is used for treatment. 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.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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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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
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Person responsible for updating data

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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