Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Effect of intravenus fibrinogen versus placebo on blood transfusion requirements in patients with acute gastrointestinal bleeding

Protocol summary

Study aim

The aim of study was to evaluate the effect of fibrinogen administration in patients with acute gastrointestinal bleeding, which will examine the effect of fibrinogen on the rate of rebleeding, mortality and need for blood or its products among participants in the study.

Design

The design of the study is a parallel randomized control trials. Sample size is 60 patients which will be assigned to intervention and control groups using the blocked randomization method.

Settings and conduct

This study will be carried out at Rasoul Akram hospital that depending on Iran University of Medical Sciences to reduce blood transfusion and risk of rebleeding in patients with acute gastrointestinal bleeding that received fibrinogen. The effect of fibrinogen will be measured on the rate of rebleeding, mortality, and the need to transfer blood or any product at 24, 72 hours, and 28 days after the interventions. Participants in the study and physicians assessing the outcomes on the patients will be blinded the type of interventions that patients will be receive.

Participants/Inclusion and exclusion criteria

Having acute gastrointestinal bleeding and over 18 years of age are inclusion criteria for study. Exclusion criteria are congenital or acquired congenital anomalies; myocardial infarction two months ago; history of gastrointestinal bleeding and sensitivity to fibrinogen.

Intervention groups

The intervention group will be consisting of one gram of fibrinogen in 50 milliliters distilled water. Fibrinogen manufactured by CSL Behring pharmaceutical company in United Stated plus a standard pharmaceutical regimen. In the control group, 9% saline solution Samen Pharmaceutical company in Iran will be administered in 50 milliliters with a standard pharmaceutical regimen.

Main outcome variables

Rebleeding, the need for blood transfusion or its products

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140528017891N6**
Registration date: **2019-02-24, 1397/12/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-24, 1397/12/05**
Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-29, 1397/11/09

Expected recruitment end date

2019-06-15, 1398/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of intravenus fibrinogen versus placebo on blood transfusion requirements in patients with acute gastrointestinal bleeding

Public title
Effect of intravenus fibrinogen on blood transfusion in patients with acute gastrointestinal bleeding

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having acute gastrointestinal bleeding At least 18 years old

Exclusion criteria:
Congenital diseases or acquired coagulation disorder Myocardial infarction two months ago History of gastrointestinal bleeding History of heart disease Fibrinogen sensitivity Pregnancy Cirrhosis Vasculitis The presence of any type of cancer

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To prevent the occurrence of bias in selecting participants for study groups, we will use the randomization method until the researchers' opinion is reduced in selecting participants for the study groups. Participants after selecting to study with blocked randomization method (with random blocks) will be allocated to receive intervention and placebo. The Random Allocation Software will be use to a randomization process since this study consists of two groups, the output of the allocation of participants will be specified with the A and B until intervention to be blinded for the members of the research team. In the software, randomization type will be selected of block randomization, with random blocks. Software output of the allocation participants is not predictable on the basis of blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
We will inform the supervisor after selecting each patient for the study and they are based on the randomized output of the randomization software and its matching to the patient's number the intervention will be sent in a form that is not known to the patients, prescriptive, and evaluator of the outcomes. For this, the shape and color of the interventions will be the same. Blinding process in this study is double blinded. Participants in the study will be blinded of interventions also the physicians will be blinded of the type of interventions received by the participants when they evaluated the outcome.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2019-01-26, 1397/11/06

Ethics committee reference number
IR.IUMS.FMD.REC.1397.286

Health conditions studied

1

Description of health condition studied
Acute haemorrhagic gastritis

ICD-10 code
K29.01

ICD-10 code description
Acute gastritis with bleeding

Primary outcomes

1

Description
Rebleeding

Timepoint
24 and 72 hours and 28 days after intervention

Method of measurement
Hemoglobin test

2

Description

The need for blood transfusion or its products

Timepoint

24 and 72 hours and 28 days after intervention

Method of measurement

Hemoglobin test

Secondary outcomes

1

Description

Mortality

Timepoint

24 and 72 hours and 28 days after intervention

Method of measurement

Observation and clinical examinations of the patient

2

Description

Administration in intensive care unit

Timepoint

24 and 72 hours and 28 days after intervention

Method of measurement

Administrated patients in the intensive care unit

3

Description

Need for endoscopy

Timepoint

24 and 72 hours and 28 days after intervention

Method of measurement

Endoscopy performed in patients under study

Intervention groups

1

Description

Intervention group: Fibrinogen one gram diluted in 50 milliliters of distilled water. Fibrinogen manufactured by CSL Behring company in USA. In addition, the standard treatment of acute gastrointestinal bleeding of intravenous pantoprazole and hydration will be performed.

Category

Treatment - Drugs

2

Description

Control group: In this group, 50 milliliters of saline solution will be infused nine percent. Saline solution manufactured by Samen company in Iran. In addition, the standard treatment of acute gastrointestinal bleeding of intravenous pantoprazole and hydration will be performed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Nader Tavakoli

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Rasoul Akram hospital, Niyayesh St, Sattarkhan St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Nader Tavakoli
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Findings of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.
When the data will become available and for how long
Availability eight months after the end of study
To whom data/document is available
Emergency Medicine and Gastroenterologists specialists
Under which criteria data/document could be used
In the case of comparison with other similar trials or treatment
From where data/document is obtainable
Iran University of Medical Sciences
What processes are involved for a request to access data/document
By referring to the central library and clinical trial center in Iran University of Medical Sciences can access to the documents of participants, data and results.
Comments