

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Effect of intravenous 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 States 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

Name

Nader Tavakoli

Name of organization / entity

Iran University Of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 8891 5410

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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 intravenous fibrinogen versus placebo on blood transfusion requirements in patients with acute gastrointestinal bleeding

Public title

Effect of intravenous 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 used 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

Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Kazem Malekoti

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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

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

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Person responsible for updating data

Contact

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Iran University of Medical Sciences

Full name of responsible person

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Position

Resident of Emergency Medicine

Latest degree

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Other areas of specialty/work

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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

