

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of fibrinogen injection on bleeding after Coronary Artery Bypass Graft bleeding

Protocol summary

Study aim

Determine the effect of fibrinogen Injection on the post coronary artery bypass Graft bleeding

Design

36 patients candidated for open heart surgery (50-70 years old), double blind randomized clinical trial, fibrinogen and control group, quadruple random permutations

Settings and conduct

36 patients with age range 50-70 years, who were candidates for open heart surgery at Ahvaz Imam Khomeini Hospital, were randomly divided by quadruple random permutations method into intervention (intravenous infusion of 1 gr of fibrinogen dissolved powder in 100 ml normal saline) and placebo (intravenous infusion of 100 ml normal saline) group. Patient, surgeon and researcher do not have any information on how to place people in groups. Post-operative bleeding, Hemoglobin, Prothrombin time are measured in 0, 3, 6, 12 and 24 hours after surgery in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: elective surgery, age 50-70 years with anesthesia risk 3 Exclusion criteria: Hematologic diseases, Liver problems, Insulin dependent diabetes, Creatinine above 130 micro mol/L, Ejection fraction less than 35%, Fibrinogen level greater than 3.5 g/l

Intervention groups

The intervention group: Intravenous infusion of one gram of fibrinogen dissolved powder manufactured by CSL Behring Company in 100 ml of normal saline after discontinuation of cardio pulmonary bypass pump
Control group: Intravenous infusion of 100 ml normal saline after discontinuation of cardio pulmonary bypass

Main outcome variables

Bleeding after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040979N1**

Registration date: **2019-01-23, 1397/11/03**

Registration timing: **retrospective**

Last update: **2019-01-23, 1397/11/03**

Update count: **0**

Registration date

2019-01-23, 1397/11/03

Registrant information

Name

MARYAM ZAMANKHANI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 4760

Email address

zamankhani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fibrinogen injection on bleeding after Coronary Artery Bypass Graft bleeding

Public title
The effect of fibrinogen injection on post CABG bleeding

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Elective surgery Coronary artery bypass graft American Society of Anesthesiologist 2-3
Exclusion criteria:
 Hematologic disorder Liver disease Diabetes (IDDM)
 Cratinine>130μmol/li Ejection Fraction<%35
 Fibrinogen>3.5gr/l

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: Individuals are randomly divided into two groups based on randomized block randomization method. Randomized blocks are used for this purpose. A random sample based on this method from Sealedenvelope.com has been extracted.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blindness: Patient, surgeon and researcher do not have any information on how to place people in groups. How to Blind: Considering that after dissolving fibrinogen in normal saline, no difference in color compared with normal saline solution, it can be said that the patient, surgeon and researcher do not have any information on how to place them in groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences., Research Deputy., Blvd. Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Approval date

2018-07-23, 1397/05/01

Ethics committee reference number

IR.AJUMS.REC.1397.291

Health conditions studied

1

Description of health condition studied

Presence of aortocoronary bypass graft

ICD-10 code

Z95.1

ICD-10 code description

Presence of aortocoronary bypass graft

Primary outcomes

1

Description

post operative bleeding

Timepoint

0, 3, 6, 9, 12 and 24 hours after surgery

Method of measurement

blood volume in chest bottels

Secondary outcomes

1

Description

hemoglobin

Timepoint

0, 3, 6, 9, 12 and 24 hours after surgery

Method of measurement

Blood test

2

Description

Prothrombin time

Timepoint

0, 6, 12 and 24 hours after surgery

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: intravenous administration of one gram of fibrinogen dissolved powder manufactured by CSL Behring USA in 100 ml of normal saline after weaning off cardio pulmonary bypass pump

Category

Treatment - Drugs

2

Description

Control group: intravenous administration of 100 ml of normal saline after weaning off cardio pulmonary bypass pump

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomini Hospital

Full name of responsible person

Fatemeh Javaherforoosh zadeh

Street address

Imam Khomeini Hospital, Azadegan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi, PhD

Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

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Grant name

PAIN-9704

Grant code / Reference number

330093743

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Javaherforoosh zadeh

Position

Anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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

Undecided - It is not yet known if there will be 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

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Javaherforoosh zadeh

Position

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