

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Acute Normovolemic Hemodilution effect on the amount of bleeding after Coronary Artery Bypass Grafting surgery in the first 48 hours postoperative

Protocol summary

Summary

(1) Objectives: The main aim of this study is to consider acute normovolemic hemodilution effect on the amount of bleeding after coronary artery bypass grafting surgery in the first 48 hours after surgery. (2 and 3) Design, Setting and conduct: The study is a single-blind, single-centre, interventional clinical trial in which, 100 patients who are candidate for coronary artery bypass graft (CABG) surgery at Imam Khomeini hospital of Ardabil will be randomly allocated into two equal groups of intervention and control. (4) Participants including major eligibility criteria: no previous known history of coagulation disorders, and, no previous treatment with drugs used in coagulation disorders. The exclusion criteria are as follows: anemia (hemoglobin less than 11), massive transfusion (more than 1 blood volume or 20 packed cell), platelet transfusion, FFP transfusion, receiving medications such as Plavix and Transamine, connection to the CPB pump more than 3 hours, and platelet count less than 100 thousand. (5) Intervention: After induction of anesthesia in the operating room and before connecting the patient to the CPB pump, a blood unit is taken from patients in the intervention group. After completion of the surgical procedure and disconnecting of patients from the CPB pump and receiving protamine, the whole blood of patients in intervention group is retransfused. For patients in the control group, the surgery process will be performed without these measures. (6) main outcome measures (variables): Patients in the two groups will be compared in terms of bleeding within 48 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041933529N1**

Registration date: **2017-08-07, 1396/05/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-07, 1396/05/16

Registrant information

Name

Sahar Khakavi

Name of organization / entity

Ardabil University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 45 3371 0404

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Recruitment status

Recruitment complete

Funding source

Deputy of research, Ardabil medical university, Ardabil

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Acute Normovolemic Hemodilution effect on the amount of bleeding after Coronary Artery Bypass Grafting

surgery in the first 48 hours postoperative

IR.ARUMS.REC.1395.47

Public title

Acute Normovolemic Hemodilution effect on the amount of bleeding after Coronary Artery Bypass Grafting surgery in the first 48 hours postoperative

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: No previous known history of coagulation disorders; No previous treatment with drugs used in coagulation disorders. Exclusion criteria: Anemia (hemoglobin less than 11); Massive transfusion (more than 1 blood volume or 20 packed cell); Platelet transfusion; FFP transfusion; Receiving medications such as Plavix and Transamine; Connection to the CPB pump more than 3 hours; platelet count less than 100 thousand.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee Of Ardabil University Of Medical Sciences

Street address

Ardabil Complex Univesity, Daneshgah st., Ardabil, Ardabil Province.

City

Ardabil

Postal code

5615751147

Approval date

2016-06-27, 1395/04/07

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

coronary artery bypass graft

ICD-10 code

I25.70

ICD-10 code description

unspecified coronary artery bypass graft

Primary outcomes

1

Description

amount of bleeding

Timepoint

36 measurements in 2-hour intervals (12 times per day, in the first 3 days)

Method of measurement

by graduated drains (in terms of mL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After induction of anesthesia in the operating room and before connecting the patient to the CPB pump, a blood unit is taken from patients in the intervention group. After completion of the surgical procedure and disconnecting of patients from the CPB pump and receiving protamine, the whole blood of patients in intervention group is retransfused.

Category

Treatment - Other

2

Description

Control group: No intervention will be given in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital of Ardabil city

Full name of responsible person

Sahar Khajavi

Street address

Imam Khomeini hospital , Atae St, Ardabil
City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Dr Hadi Piri dogaha

Street address

Ardabil Complex Univesity, Daneshgah st., Ardabil, Ardabil Province.

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University Of Medical Sciences

Full name of responsible person

Sahar Khajavi

Position

medical student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr. Akbar Pirzadeh

Position

Associate Professor / ENT specialist

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty