Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Acute Normovolomic 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)

Phone

+98 45 3371 0404

Email address

s.khajoo@arums.ac.ir

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

surgery in the first 48 hours postoperative

Public title
Acute Normovolomic 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 houres; 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
IR.ARUMS.REC.1395.47

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 , Ataee 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 dogahe

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

Street address

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Akbar Pirzadeh

Position

Associate Professor / ENT specialist

Other areas of specialty/work

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Web page address

Person responsible for updating data

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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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