Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation and comparison of bleeding and Activated Clotting Time (ACT) after coronary artery bypass grafting in protamine-heparin injection 1: 1 and protamine-heparin 0.5: 1

Protocol summary

Study aim
Evaluation and comparison of bleeding and Activated Clotting Time after coronary bypass grafting in protamine-heparin 1: 1 and 0.5: 1

Design
Clinical trial containing control double blind randomized group and parallel group phase 3 has been tried on 60 patients randomized by SPSS.

Settings and conduct
The study is conducted in Isfahan in Operation room department and Heart intensive care unit at Chamran and Milad Hospitals, according to entry and exit criteria on 60 person involve two 30-participant groups who were randomly grouped, the study is done. and the study is double blind and participants and Health care providers and Implication evaluators are unknowing from allocation participant to which group and all the interference procedures are utterly similar as regards the aspects of volume and color and appearance and time. After the end of Coronary By pass surgery in the intervention group, received Heparin is neutralized with a half routine dose of Protamine and in control group with complete dose of Protamine. Performance in each of two group is completely similar. Protamine it is infused in 100 milliliter of Normal saline serum during 15 minuets. 5 minuets after the end of infusion, Activated Clotting Time, evaluate with coagulometer device and bleeding level after surgery, 12 hours and 36 hours after surgery evaluate with drain and chest tubs box control.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Discontinue use anti-coagulation drugs for at least one week prior to surgery, absence of Hemostatic Disorders Exclusion criteria: Pregnancy, Emergency surgery

Intervention groups
Intervention group receives protamine in a ratio of 0.5 to 1 in proportion to heparin. Control group receives protamine in a ratio of 1 to 1 in proportion to heparin.

Main outcome variables
Activated Clotting Time, bleeding, re-exploration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220610055128N1**
Registration date: **2023-03-02, 1401/12/11**
Registration timing: **prospective**

Last update: **2023-03-02, 1401/12/11**
Update count: **0**

Registration date
2023-03-02, 1401/12/11

Registrant information

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Amir Mirmohammadsadeghi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-10, 1401/12/19

Expected recruitment end date
2023-09-10, 1402/06/19

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and comparison of bleeding and Activated Clotting Time (ACT) after coronary artery bypass grafting in protamine-heparin injection 1: 1 and protamine-heparin 0.5: 1

Public title
The Evaluation of the impact of reduction in the Protamine dose in comparison to its total dose after coronary artery bypass grafting
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Omitting anti-coagulation drugs at least one week prior to surgery Patient should be a candidate for coronary artery bypass grafting Informed consent to participate in the study CPB duration less than 100 minutes
Exclusion criteria:
Allergy and the risk of anaphylaxia shock Coagulation abnormality Bleeding and hemostasis dysfunctions due to non-medical causes Patients dependent on dialysis and patients suffering from blood dyscrasia and known platelet dysfunction Pregnancy Heparin re-administration Need for emergency surgery Patients with BMIs higher than 30 Under 28 degrees hypothermia Dissent to participate in the study
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling in two super specialist hospital Milad and Chamran in Isfahan is done. Patients portion from each one of this two hospitals determined with portion apportionment formula. For defined portion of each hospital to be assigned individuals for each hospital to A group and B group to be used the method double randomized blocks. In this way that with reference to the hospital reception by patients, respectively each two persons that have inclusion criteria, considered as one block and this blocking for each hospital continue until the enough blocks according to sample size. After formation each block, people of each block they are arranged according to the national code, this matter running in total blocks equally and by using random number table, if let the number 0 to 4 first person is allocated to A group and the second person is allocated to B group, if let the number 5 to 9 first person is allocated to B group and second person to A group. Eventually persons are allocated to A group or B group. Nomenclature is placed in envelope and is delivered to reception area in operating room. In operating room determine an evaluator that again specifies that which one to recieve routine treatment and which one recieve new treatment with random number table. If let the number 0 to 4 consider A group routine that is mean to give total dose Protamine Sulfate and if let the number 5 to 9 consider B group routine, and then give other group new treatment that is mean decrease Protamine Sulfate to half dose of routine dose. Without us knowing that which one has received patient routine treatment and which one new treatment. When we go to collect and analyze data this evaluator informs relationship individuals to A or B group and type of treatment.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants and caretakers including nurses and doctors and implication evaluators are totally unaware of the categorization of participants into which study groups and all the interference procedures are utterly similar as regards the aspects of appearance such as the volume and the color of the drug and the type and the volume of the serum used for infusion and also the time frame needed for the drug to be administered.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Chamran Hospital, Salman-E-Farsi Street
City
Isfahan
Province
Isfehan
Postal code
81583-88994
Approval date
2022-05-25, 1401/03/04
Ethics committee reference number
IR.MUI.MED.REC.1401.088

Health conditions studied

1

Description of health condition studied
Patients in need of coronary artery bypass grafting
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Percent of participants with number of Activated Clotting Time near normal domain (70-120) second
Timepoint
5 minutes after the end of protamine injection
Method of measurement
Activated Clotting Time assessment with Coagulometer device according to second

2

Description
Percent of abnormal bleeding
Timepoint
Drainage assessment of the drains and chest tubes 12 hours and 36 hours after the end of surgery
Method of measurement
Drainage assessment of the drains and chest tubes according to cubic centimeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group involve 30 person that intervention means reduction Protamine dose to the half the usual amount in they is done. In this group relative to the amount received Heparin, in the end of surgery, a half dose of Protamine receive in 15 minutes as infusion in 100 milliliter of Normal saline serum. 5 minuets after the end of Protamine receipt, evaluate Activated Clotting Time level with coagulometer device. Bleeding level control after 12 hours and 36 hours after surgery through evaluation blood drainage level inside of the chest tubes box. Heparin as Heparin Sodium, it is produced in SHAHID GHAZI PHARMACEUTICAL company as 5000 unit in milliliter in ampule and Protamine as Protamine Sulfate, it is produced in Ronak pharmaceutical company as 1000 unit in milliliter in 5 milliliter in vial.
Category
Treatment - Drugs

2

Description
Control group: This group involve 30 person that intervention means reduction Protamine dose in they it is not done . In this group relative to the amount received Heparin, in the end of surgery, a one dose of Protamine receive in 15 minutes as infusion in 100 milliliter of Normal saline serum. 5 minuets after the end of Protamine receipt, evaluate Activated Clotting Time level with coagulometer device. Bleeding level control after 12 hours and 36 hours after surgery through evaluation blood drainage level inside of the chest tubes box. Heparin as Heparin Sodium , it is produced in SHAHID GHAZI pharmaceutical company as 5000 unit in milliliter in ampule and Protamine as Protamine3Sulfate, it is produced in Ronak pharmaceutical company as 1000 unit in milliliter in 5 milliliter in vial.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital, Milad hospital
Full name of responsible person
Amir Mirmohammadsadeghi
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan 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
Esfahan University of Medical Sciences
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Assistant Professor
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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