Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Comparison of effect of Valuven versus ringer solution in cardiopulmonary bypass prime on the postoperative bleeding and renal function in coronary artery bypass graft surgery

Protocol summary

Summary

Objective: To compare the effects of Valuven versus ringer solution in cardiopulmonary bypass prime on the postoperative bleeding and renal function in coronary artery bypass graft surgery. Design: prospective, randomized Clinical trial. Inclusion criteria: patients undergoing coronary artery bypass graft (CABG) for the first time. Exclusion criteria: undergoing cardiac surgery for the second time; emergency coronary artery bypass; coagulation disorders prior to surgery; the preoperative clopidogrel (Plavix); congestive heart failure before surgery; renal failure before surgery (creatinine greater than (1 / 3) with a previous history of heart surgery; heart failure; coagulation disorders including abnormal PT and PTT, INR, PLAT; kidney disease included high chromium 1.3 and taking Plavix (clopidogrel). Methods: 60 patients were divided into two groups of 30. Patients in group A received 1500 cc Ringer as a prime solution during preparation of (CPB). Patients in group B received Valuven1500 ml, 130/04 (hydroxyethyl starch) during preparation of CPB. Monitoring of vital signs is recorded. After sternotomy and grafting, patient cannulation is performed by the surgeon and the CPB device is connected. Aorta is clamped and cold blood cardioplegia solution with antigrad method will be injected. Cardioplegia solution is cold blood type and same in all patients. Simultaneously patient is cooled to the 34 to 32 degrees. Distal graft anastomosis is performed at the time of arrest and warming the patients begins. Patient is wined from CPB patients based on standard protocols and the patient is transferred to the ICU. Finally, the post-operative drainage of blood discharge in the ICU within the first 24 hours and patient's kidney function and urine out will be checked. The amount of blood transfusion during and after surgery recorded and blood samples taking from both groups for the tests including CR - Na-K -HB- hematocrit- PT- PTT-INR before surgery and 24 hours after surgery in the ICU. Hemodynamic changes at the arrival to the ICU and 6 and 24 hours after surgery will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041519470N56**
Registration date: **2017-04-21, 1396/02/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-21, 1396/02/01

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-04-16, 1396/01/27

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of effect of Valuven versus ringer solution in cardiopulmonary bypass prime on the postoperative bleeding and renal function in coronary artery bypass graft surgery

Public title

The Comparison of effect of Valuven versus ringer solution in cardiopulmonary bypass prime on the postoperative bleeding and renal function in coronary artery bypass graft surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing coronary artery bypass graft (CABG) for the first time. Exclusion criteria: undergoing cardiac surgery for the second time; emergency coronary artery bypass; coagulation disorders prior to surgery; the preoperative clopidogrel (Plavix); congestive heart failure before surgery; renal failure before surgery (creatinine greater than (1 / 3) with a previous history of heart surgery; heart failure; coagulation disorders including abnormal PT and PTT, INR, PLAT; kidney disease included high chromium 1.3 and taking Plavix (clopidogrel).

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.SUMS.MED.REC.1394.31

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Surgery

ICD-10 code

125.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

bleeding

Timepoint

during and after surgery

Method of measurement

Observasion

Secondary outcomes

1

Description

lab data (CR - Na-K -HB- hematocrit- PT- PTT-INR)

Timepoint

before surgery and 24 hours after surgery in the ICU

Method of measurement

blood sample

Intervention groups

1

Description

Patients in group A received 1500 cc Ringer as a prime solution during preparation of (CPB).

Category

Treatment - Drugs

2

Description

Patients in group B received Valuven1500 ml, 130/04 (hydroxyethyl starch) during preparation of CPB. Monitoring of vital signs is recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahi Faghihi Hospital

Full name of responsible person

Alireza Sadeghi Gilavani

Street address

Shahid Faghihi Hospital, Zand Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

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Shiraz

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, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Elahe allahyari

Position

Fellow ship of cardoanesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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MS in english teaching ,BS in anesthesia/English Consultant

Other areas of specialty/work

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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