Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effects of 5% albumin and 6% hydroxyethyl starch 130/0.4 on glomerular filtration rate and serum creatinine when used as priming solutions for cardiopulmonary bypass pump.

Protocol summary

Summary

The aim of this study is Comparing the effects of 5% albumin and 6% hydroxyethyl starch 130/0.4 on glomerular filtration rate and serum creatinine when used as priming solutions for cardiopulmonary bypass pump. Sixty adult patients undergoing coronary bypass graft heart surgery were randomly assigned to either the human albumin orhydroxyethyl starch group. Inclusion criteria: patients undergoing elective coronary artery bypass grafting; age between 30 - 60 . Exclusion criteria: chronic renal failure; cardiopulmonary by pass pomp time over 2 hours; Patients were underwent an emergency operation; infective endocarditis; preoperative coagulation disorder; liver insufficiency; a left ventricular ejection fraction of less than 50%; previous cardiac surgery; a hemoglobin level of less than 10 milligram per deciliter before surgery. 500 milliliter of 5% human albumin (human albumin group), N:30 or orhydroxyethyl starch 130/0.4 (starch group), N:30 were added to the priming solution of the Cardiopulmonary bypass pump circuit for each group, respectively. renal function variables included serum creatinine and glomerular filtration rate were measured preoperative and postoperative at 24, 48 and 72 hour.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011620112N4**
Registration date: **2015-02-04, 1393/11/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-04, 1393/11/15

Registrant information

Name
Pooya Derakhshan

Name of organization / entity
Birjand Univesity of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Birjand University Of Medical Sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2014-09-01, 1393/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of 5% albumin and 6% hydroxyethyl starch 130/0.4 on glomerular filtration rate and serum creatinine when used as priming solutions for cardiopulmonary bypass pump.

Public title

Albumin Versus Hydroxyethyl Starch in Cardiopulmonary Bypass Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing elective coronary artery bypass grafting; age between 30 - 60 . Exclusion criteria: chronic renal failure; cardiopulmonary by pass pomp time over 2 hours; Patients were underwent an emergency operation; infective endocarditis; preoperative coagulation disorder; liver insufficiency; a left ventricular ejection fraction of less than 50%; previous cardiac surgery; a hemoglobin level of less than 10 milligram per deciliter before surgery.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Sciences

Street address
N:56, Ghafari Ave.

City
Birjand

Postal code
1973456783421589

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
1391-78-90

Health conditions studied

1

Description of health condition studied
Atherosclerotic heart disease

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
serum Creatinine

Timepoint
preoprative and every 24 houre to 72 hour postoperatively

Method of measurement
isotope dilution mass spectrometry

Secondary outcomes

1

Description
Glomerular filtration rate

Timepoint
preoperative and Every 24 hour to 72 hour postoperatively

Method of measurement
isotope dilution mass spectrometry

Intervention groups

1

Description
500 milliliter human albumin 5% as a priming solution of cardiopulmonary bypass pump.

Category
Treatment - Drugs

2

Description
500 milliliter 6% hydroxyethyl starch 130/0.4 as priming solution of cardiopulmonary bypass pump

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali Asr Hospital

Full name of responsible person
Pooya Derakhshan

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Imam Reza Hostipal, Taleghani St.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
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Mahmood Hosssein Zadeh Maleki
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Ghafari Ave.
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Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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

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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