Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Assessment Effect of retrograde autologous priming on clinical outcome of heart lung bypassing on patients undergoing coronary artery bypass grafting

Protocol summary

Summary

This study is a randomized clinical trial in which the effect of autologous priming technique in patient that undergoing coronary artery bypass grafting by cardiopulmonary bypass machine will be examined. Patient who entered the study are the first and non emergency coronary surgery and age between 18 to 70 years old; hemoglobin between 8.5 to 14; weight between 45 to 100 kilogram and ejection fraction greater than 25 percent. If they have emergency surgery; have liver dysfunction; dialysis be; being connected to mechanical ventilation; have clotting problem, hemofilter and cell saver are used are excluded from study. Patient who have inclusion criteria randomly divided into two groups, intervention(40 person) and control (40 person). In people who are enrolled before and after cardiopulmonary bypass venous and arterial cannulation 300-600 ml of crystalloid fluid that is used to prime the bypass circuits of the arterial and venous out of orbit and is replaced with the patient's own blood. The result of this work on blood gas and hemoglobin and hematocrit in the operating room and the ward and its impact on the need for blood transfusions and blood products and ejection fraction of heart and the duration of mechanical ventilation connection in the intensive care unit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016073029123N1**
Registration date: **2016-10-11, 1395/07/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-11, 1395/07/20

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Iran University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment Effect of retrograde autologous priming on clinical outcome of heart lung bypassing on patients undergoing coronary artery bypass grafting

Public title

Assessment effect of replacement liquid (crystalloid and colloid) used for deairing circuits of cardiopulmonary bypass by patient own blood in patient undergoing

coronary artery bypass grafting on clinical outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: adult patients undergoing coronary artery bypass surgery using cardiopulmonary bypass; no history of past heart surgery; age older than 18 and less than 70 years old; hemoglobin level greater than 8.5 and less than 14; body weight more than 45 kg and less than 100 kg; left ventricular ejection fraction greater than 25%. Exclusion criteria: history of cardiac surgery; the patient or the patient's family withdraw from the study during the intervention period; emergency surgery; severe infection; clotting problems before surgery (INR> 1.2, aPTT> 40 s and blood platelet count less than 100 thousand per cubic meter); danapyroid and Lepyrudyn and dabigatran drug in the month before the operation; use Hemofilter and Cell Saver; the use of preoperative mechanical ventilation; dialysis before surgery; the existence of liver failure as (AST> 40 unit / L) and ((ALT> 40 unit / L before surgery.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Besides Milad Tower, Tehran, Hemmat Highway

City

Tehran

Postal code

1449614535

Approval date

2016-06-29, 1395/04/09

Ethics committee reference number

IR.IUMS.REC.1395.9311584002

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I20-I25

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

Changes in arterial blood gases

Timepoint

Before anesthesia, intraoperative and postoperative

Method of measurement

content of each gas in arterial blood Under the pressure of eac gas

2

Description

The need for blood and blood products transfusions during surgery

Timepoint

During Surgery

Method of measurement

The number of bags of blood and blood products in terms of unit

3

Description

The amount of postoperative blood and blood product transfusion

Timepoint

After surgery and during the hospitalization

Method of measurement

The number of bags of blood and blood products

4

Description

Duration of mechanical ventilation connection

Timepoint

During the intensive care unit

Method of measurement

Duration of mechanical ventilation connection based on hours

5

Description

Ejection fraction

Timepoint

After surgery in ward

Method of measurement

Ratio between strok volume to end diastolic volume according to percent

Secondary outcomes

1

Description

Hemoglobin - Hematocrit

Timepoint

During the operation, 12,24 and 48 hours after surgery

Method of measurement

The amount of hemoglobin according to milligrams per deciliter and hematocrit according percent

Intervention groups

1

Description

In the intervention group before the start of cardiopulmonary bypass and After the arterial cannulation by the surgeon we allow the patient blood reversely enter in arterial line by aorta pressure And at the same time we opened The bags Direction that had been placed on one of the output circuti and allowed equal the blood that inter from arterial line into circuit Priming fluid out.After leaving the arterial fluid circuit we have closed the arterial line and Action to spin pumps are connected to the oxygenator with slow motion And because the only output in the circuit is the collecting bags that connected to the circuit, liquid in the reservoir as much as possible inter in the collecting bag.In the final stage, when the patient's venous blood opens to the reservoir of the cardiopulmonary bypass, we attempt to extract this liquid from reservoir.Through the method that said in the intervention group In coordination with the Department of Anesthesiology to prevent hypotension,we extract 300-600 Milliliters of liquid prime and replace it with the patient's blood.

Category

Treatment - Other

2

Description

In the control group cardiopulmonary bypass circuits primed with conventional method (approximately1500 ml of crystalloid and colloid).And this fluid volume remains in the cardiopulmonary bypass circuit and inter to the patient body with the starting of the bypass.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heart Hospital Shahid Rajaei

Full name of responsible person

Doctor Mohammad Zia Totonchy Ghorbany

Street address

Heart Hospital Shahid Rajaei, ValiAsr and Niayesh highway intersection

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Technology and Research Deputy of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Musa Rafiee Vardanjany

Position

Graduate student of blood circulation technology

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