Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of clinical results and level of interleukin 6 using 20% albumin in comparison with prime valve colloid sample in Coronary artery bypass graft surgery

Protocol summary

Study aim
Clinical Outcomes and Inflammatory Response Using Interleukin 6 Levels after Cardiopulmonary Bypass Using 20% Albumin Compared with Voluven as Primary Colloid Fluid in Coronary Heart Transplant Surgery

Design
A clinical trial with two intervention groups, with parallel groups, non blind, randomized, phase two, was performed on forty patients. A simple method with coin tossing is used for randomization.

Settings and conduct
The study was performed non_blind The study site was in the operating room of Isfahan Chamran Hospital, using blood sampling and reviewing the patient's clinical results after surgery in the ICU, and finally comparing the results obtained using the two types of primers.

Participants/Inclusion and exclusion criteria
Admission requirements: Patient age between 40 _75 Ejection fraction> 35% Non-emergency surgery Discontinue aspirin and Plavix 48 hours before surgery Conditions for not entering the study: Children Candidates for open heart surgery without using a heart pump device Patients in the last stage of life Patients with liver failure Patients with renal failure Patients with preoperative infections such as infectious endocarditis Patients with recent inflammation Patients with recent myocardial infarction

Intervention groups
The study consists of two intervention groups: the first group of twenty patients who undergo coronary artery bypass graft surgery use 20% albumin as a prime solution during surgery and the second group of twenty patients who undergo coronary artery bypass graft surgery as a prime solution during surgery. We use voluven

Main outcome variables
Interleukin 6 Drainage rate after surgery The amount of blood product received after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220410054470N1**
Registration date: **2022-05-02, 1401/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-02, 1401/02/12**
Update count: **0**

Registration date
2022-05-02, 1401/02/12

Registrant information

Name
atefeh hashemabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3601 0583

Email address
ati.hashemabadi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-12, 1401/01/23

Expected recruitment end date
2023-01-13, 1401/10/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of clinical results and level of interleukin 6 using 20% albumin in comparison with prime valve colloid sample in Coronary artery bypass graft surgery

Public title
Evaluation of clinical results and level of interleukin 6 using 20% albumin in comparison with prime voluven colloid sample in CABG surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patient age between 40 to 75 Ejection fraction>35٪ Non-emergency surgery Discontinue aspirin and Plavix 48 hours before surgery

Exclusion criteria:
Children Candidate patients for cardiac surgery without using cardiopulmonary bypass device End Stage patients patients with liver failure patients with kidney failure Patients with preoperative infections such as infectious endocarditis Patients with recent inflammation Patients with recent MI

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was performed in a simple method, the randomization unit was individual, the envelope randomization tool was sealed, the random sequence was constructed by coin tossing method. The random allocation concealment was done at the beginning of the study. Lady Atefeh Hashemabadi created a random sequence with the mentioned method and examined the patients in terms of inclusion and exclusion criteria.

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 Isfahan University of Medical Sciences

Street address
Unit 223 , Narges Block 19,Shams Al-Shams Complex, Sepah Square, Tehran

City
Esfahan

Province
Isfehan

Postal code
8166173414

Approval date
2022-04-11, 1401/01/22

Ethics committee reference number
IR.MUI.MED.REC.1401.010

Health conditions studied

1

Description of health condition studied
Coronary artery heart disease

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Interleukin6

Timepoint
Measurement of interleukin 6 twelve hours after coronary heart surgery

Method of measurement
test

Secondary outcomes

1

Description
Postoperative drainage rate of coronary artery bypass graft surgery

Timepoint
48 hours after coronary aetery bypass graft surgery

Method of measurement
Chest bottle

2

Description
Rate of blood products received after coronary artery

bypass graft surgery

Timepoint

48 hours after coronary artery bypass graft surgery

Method of measurement

Check the blood sheet in the patient's file

Intervention groups

1

Description

First intervention: 20 patients receiving 50 cc of 20% albumin once in each intervention at the beginning of preparation of the pump device as a prime solution in the heart pump device for priming the oxygenator tank and the path of the tubes with a blood set as The injection is inserted into the oxygenator tank, used in coronary artery bypass graft surgery. The surgery is performed by coronary artery bypass graft using a saphenous vein; This number of interventions is done within 10 months.

Category

Rehabilitation

2

Description

Second intervention: 20 patients receiving 500 cc of Voluven serum once in each intervention at the beginning of preparation of the pump device as a prime solution in the heart pump device for priming the oxygenator tank and the path of the tubes that are injected with blood. It enters the oxygenator tank, is used in coronary artery bypass graft surgery. The surgery is performed as a coronary artery bypass graft using a saphenous vein; This number of interventions is done within 10 months.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital, Isfahan

Full name of responsible person

Atefeh Hashemabadi

Street address

Salman Farsi St. Shahid Chamran Hospital

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8166173414

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+98 31 3260 0961

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ati.hashemabadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Hosseini

Street address

Shahid Chamran Hospital, Isfahan

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Esfahan

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ati.hashemabadi@gmail.com

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

Full name of responsible person

Atefe Hashemabadi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Shahid Chamran Hospital, Isfahan

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Email

hosseiny@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Atefeh Hashemabadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Student

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only part of the participants' personal data such as information about the main outcome (changes in the interleukin test) and other consequences such as the amount of drainage and the amount of blood products received after coronary artery bypass graft surgery can be shared.

When the data will become available and for how long

Three months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For further studies in this field and other fields and for progress in the field of science and research, the use of study data can be used for researchers and students and university professors

From where data/document is obtainable

Atefeh Hashemabadi Master student of circulatory technology Via: Phone:09104532576 Email:ati.hashemabadi@gmail.com Correspondence mailing address: Isfahan, Salman Farsi Street, Chamran Heart Hospital

What processes are involved for a request to access data/document

The applicant first requests the use of documents and data by calling the respondent (Atefeh Hashemabadi), then by sending her or his e-mail to the respondent, the data will be sent to the applicant within 48 to 72 hours.

Comments