

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of clinical effects of adding Albumin and Hydroxy ethyl Starch to prime solution in adult patients undergoing heart valve surgery

Protocol summary

Study aim

Determine and compare the clinical effects of adding the Albumin and Starch to the prime solution in adult patients undergoing heart valve surgery

Design

Clinical trial, with control group, with parallel groups, blinded, randomized

Settings and conduct

This study was performed on patients undergoing heart valve surgery in Rajaie Heart Center. Patients were randomly assigned to case and control groups. In case group 50 cc albumin and in control group 500cc Hydroxyethyl Starch were added to the prime solution. Clinical outcomes were evaluated in both groups.

Participants/Inclusion and exclusion criteria

Adult patients undergoing heart valve surgery using by cardiopulmonary bypass entered the study; Withdrawal of the patient and the pump's extended time (more than 150 minutes) were excluded.

Intervention groups

In the intervention group, Albumin was used for the prime the oxygenator, in control group, Starch was used for the prime the oxygenator.

Main outcome variables

Determination and comparison of coagulation parameters in albumin and starch groups; amount of the used blood products; Length of stay in the intensive care unit; amount of Serum creatinine level.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190512043568N1**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Egbal Ahadmohebi

Name of organization / entity

Rajei heart center hospital

Country

Iran (Islamic Republic of)

Phone

+98 41 3230 0066

Email address

egbalmohebi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-31, 1397/06/09

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

2019-01-06, 1397/10/16

Actual recruitment end date

2019-04-11, 1398/01/22

Trial completion date

2019-04-16, 1398/01/27

Scientific title

Comparison of clinical effects of adding Albumin and Hydroxy ethyl Starch to prime solution in adult patients undergoing heart valve surgery

Public title

"Albumin in heart surgery": Effect of Starch in valve heart surgery "

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults undergo heart valve surgery by cardiopulmonary by pass

Exclusion criteria:

Cancer History of heart surgery Endocarditis Platelet under 100000 unit Emergence operation Hemoglobin under 10 Ejection fraction under 25% Aortic clamp time above 120 minutes and pump time above 150 minutes

Age

From **17 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization. 80 blocks include 40 patients in Albumin group and 40 patients in Starch group. Use sealed envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The prime solution was prepared by a technician and covered then poured to the oxygenator and the perfusionist did not aware the kind of prime solution.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran shahid Rajaei heart center

Street address

Valiasr Ave., shahid Rajaei heart center

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.RHC.REC.1397.072

Health conditions studied

1

Description of health condition studied

Assess the effect of Albumin and Starch on patients undergo heart valve surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Prothrombin time (Pt)

Timepoint

Pre operation , 24 and 48 hours post operation

Method of measurement

Laboratory tests

2

Description

Amount use of Red Blood cells

Timepoint

Before and after the operation daily

Method of measurement

Laboratory tests

3

Description

Amount of used platelets

Timepoint

Before and after the operation daily.

Method of measurement

Laboratory tests

4

Description

Creatinine

Timepoint

Pre operation, 24 and 48 hours post operation

Method of measurement

Laboratory tests

5

Description

Intensive care unit stay

Timepoint

Entrance time to intensive care unit until discharge intensive care unit

Method of measurement

Intensive care unit stay (day)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:in this group added 50 cc Albumin to Oxygenator prime solution .

Category

Treatment - Other

2

Description

Control group:in this group added 500 cc Starch to oxygenator prime solution .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei heart center

Full name of responsible person

Alireza Ghavidel

Street address

Valiasr Ave., Rajaei heart center

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 2204 2026

Fax

Email

Rajaei@domian.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ragaei heart center

Full name of responsible person

Maziyar Kholampour

Street address

Valiasr Ave., Rajaei heart center

City

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Postal code

1995614331

Phone

+98 21 2204 2026

Email

rajaei@domian.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ragaei heart center

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

Rajaei heart center

Full name of responsible person

Egbal Ahadmohebi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Valiasr Ave., Rajaei heart center

City

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Email

egbalmohebi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajaei heart center

Full name of responsible person

Egbal Ahadmohebi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery
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Person responsible for updating data

Contact

Name of organization / entity
Rajaei heart center
Full name of responsible person
Egbal Ahadmohebi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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