Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The Evaluation Of Adding Erythropoietin In Cardioplegic Solution On The Time Required for Mechanical Ventilation and The Need for Inotrop In Pattions After CABG In Rasool-e-Akram Hospital In The First 6 Months of 1398

Protocol summary

Study aim
Effect of Erythropoietin Injection on Cardioplegia Solution on Mechanical Ventilation and Inotropic Need in Patients After Coronary Artery Surgery in Rasoul Akram Hospital

Design
Clinical trial with control group with parallel and randomized groups

Settings and conduct
In this study performed in Hazrat Rasoul Hospital in Tehran, patients referred for open heart surgery were divided into two groups randomly divided into two groups. The solution is monitored for length of stay in the ICU and other variables.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with ischemic coronary artery disease who are not eligible for angiographic treatment and who are candidates for surgery for coronary artery disease (CABG). Exclusion criteria: Patients undergoing cardiopulmonary bypass surgery for other reasons such as valve replacement or repair, anatomical heart disease or any other cause other than coronary artery disease are excluded. . Patients with coronary artery disease who have had cardiopulmonary arrest for any reason and who undergo cardiopulmonary bypass resuscitation are excluded.

Intervention groups
The intervention group receiving an erythropoietin vial of 4000 units is not added to the cardioplegia solution and in the control group.

Main outcome variables
Duration of ICU admission, total postoperative hospital stay, presence or absence of erythropoietin in cardioplegia solution, dose of inotropes required after surgery, type of inotropes required after surgery, number of inotropes required after surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191216045755N1**
Registration date: **2019-12-27, 1398/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-27, 1398/10/06**
Update count: **0**

Registration date
2019-12-27, 1398/10/06

Registrant information

Name
behdad maadani

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 2277 2861

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Evaluation Of Adding Erythropoietin In Cardioplegic Solution On The Time Required for Mechanical Ventilation and The Need for Inotrop In Pattions After CABG In Rasool-e-Akram Hospital In The First 6 Months of 1398

Public title
The Evaluation Of Adding Erythropoietin In Cardioplegic Solution On The Time Required for Mechanical Ventilation and The Need for Inotrop In Pattions After CABG In Rasool-e-Akram Hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with ischemic coronary artery disease who are not eligible for angiographic treatment and who are candidates for surgery for coronary artery disease (CABG) 2-Patients with ischemic coronary artery disease aged 40 to 80 years

Exclusion criteria:
1- Patients undergoing heart replacement surgery under open heart surgery 2- Anatomical heart disease undergoing open heart surgery 3- Patients with coronary artery disease who have cardiac-respiratory arrest under open heart surgery

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
According to inclusion and exclusion criteria, patients are admitted to the hospital within the specified interval. Then, patients are divided into two intervention and control groups using simple random method and random number table. Patients are identified and then each patient is assigned a code, and patients are selected by pointing the finger or the tip of the pen or closing their eyes according to the code, one of which is divided into the intervention and comparison groups.

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
Iran University of Medical Sciences

Street address
Mansoori Ave, Niayesh Ave ,Sattarkhan Town

City
Tehran

Province
Tehran

Postal code
8874113911

Approval date
2019-08-27, 1398/06/05

Ethics committee reference number
IR.IUMS.FMD.REC.1398.178

Health conditions studied

1

Description of health condition studied
Coronary ischemic patients

ICD-10 code
I25

ICD-10 code description
Chronic ischemic heart disease

Primary outcomes

1

Description
The presence or absence of erythropoietin in the cardioplegia solution

Timepoint
After surgery

Method of measurement
Researcher Information

Secondary outcomes

1

Description
Total postoperative hospital stay

Timepoint
After Surgery

Method of measurement
Based on the case

2

Description
Duration of ICU admission

Timepoint
Operation time until leaving ICU
Method of measurement
Based on the case

3

Description
The dose of inotropes required after surgery
Timepoint
After Surgery
Method of measurement
Based on the case

Intervention groups

1

Description
Intervention group:Erythropoietin is a precursor of erythrocytes (erythrocytes) which in the intravenous form has no side effects except mild nausea and hypertension and also has a protective effect against cardiac ischemia. Anesthesia (given as premedication midazolam .015mg / kg and Fentanyl 2_10macro / kg ketamin 50mg infusion and given as induction of neonatal 2_5mg / kg and pawlone 0.1mg / kg in patients with primary creatinine above 1.5 instead of Pavlovian Atracoril) Specific ionic and preservative concentrations and compounds in accordance with the national protocol of 15 cc per kg of bad weight It is injected over 3 minutes at 4 ° C with a pressure of 50-50 mm Hg through the aortic root to achieve complete cardiac arrest. In this group, a vial of erythropoietin manufactured by Synagen. 4,000 units are added intravenously to the cardioplegia solution, which is injected with the other compounds into the cardiovascular system.
Category
Treatment - Drugs

2

Description
Control group: No extra work
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool-e-Akram Hospital
Full name of responsible person
Behdad Maadani
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Mansoori Ave, Niayesh Ave ,Sattarkhan Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
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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
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
Iran University of Medical Sciences
Full name of responsible person
Behdad Maadani
Position
Doctor
Latest degree
Medical doctor
Other areas of specialty/work
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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