

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Erythropoietin effect on ischemic_reperfusion injury in coronary artery bypass graft surgery

Protocol summary

Summary

Coronary artery bypass graft surgery (CABG), an important treatment modality in ischemic patients, increases myocardial perfusion and ejection fraction (EF) in patients with coronary artery diseases. Although the rapid reperfusion by CABG significantly reduces mortality and morbidity, this reperfusion paradoxically may contribute to acute inflammatory reaction by ischemic-reperfusion injury and endotoxemia that lead to left ventricle remodeling, myocardial stunning injuries and/or death after CABG. Therefore, new treatment modalities should focus on decreasing inflammation and damage after reperfusion. In addition to the protective effect of EPO on myocardial ischemia, studies on animal models have shown that EPO can also reduce reperfusion tissue injuries. Studies on human models have, however, proved somewhat controversial and some of them support high dose EPO cardioprotective effect. In this randomized, double-blind, clinical trial, the study population is comprised of 90 patients that are referred to Shahid Modarres Hospital (Tehran, Iran) for elective CABG. Patients will randomly divide into three groups: the intervention group 1, receiving standard medication and CABG surgery plus EPO (20,000 IU), the intervention group 2, receiving standard medication and CABG surgery plus EPO (60,000 IU), and the control group, receiving standard medication and CABG surgery plus normal saline as placebo. To evaluate the effect of EPO infusion on reducing ischemia-reperfusion injuries and improvement of cardiac function we assess inflammatory markers (IL-6, YKL-40, TNF- α), BNP and ischemic markers (troponin and CK-MB).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011621087N1**

Registration date: **2016-01-16, 1394/10/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-16, 1394/10/26

Registrant information

Name

Zohre Mohammadi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

02188060860-02188046852

Email address

zohrem28@gmail.com

Recruitment status

Recruitment complete

Funding source

Pooyesh Darou company and Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Erythropoietin effect on ischemic_reperfusion injury in coronary artery bypass graft surgery

Public title

Erythropoietin effect on ischemic_reperfusion injury

Purpose
Treatment

Inclusion/Exclusion criteria
The inclusion criterion are revascularization requirement according to angiographic evidence, coronary artery bypass graft (CABG) surgery in elective situation, for the first time and with cardiopulmonary bypass (CPB). The exclusion criteria are comprised of history of myocardial infarction in the past 3 months, previous myocardial trauma or major surgery in the past 3 months, Cr > 2, receiving streptokinase or previous reperfusion treatments, EPO intake in the recent 6 months, known thrombo-embolic disorder, malignant disease, uncontrolled hypertension and polycythemia

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Shahid Beheshti university of medical science

Street address
Shahid Beheshti university of medical science

City
tehran

Postal code

Approval date
2015-10-18, 1394/07/26

Ethics committee reference number
IR.sbmum.rec.1394.292

Health conditions studied

1

Description of health condition studied
Ischemic reperfusion injury in chronic artery bypass graft surgery

ICD-10 code
I25.1, I25.

ICD-10 code description
Chronic ischaemic heart disease

Primary outcomes

1

Description
Interleukin 6

Timepoint
before operation (base), just after operation, 24 hours after operation, 48 hours after operation

Method of measurement
elisa

2

Description
YKL-40

Timepoint
before operation (base), just after operation, 24 hours after operation, 48 hours after operation

Method of measurement
elisa

3

Description
TNF-α

Timepoint
before operation (base), just after operation, 24 hours after operation, 48 hours after operation

Method of measurement
elisa

4

Description
Added at 2016-09-22: B type natriuretic peptide (BNP)

Timepoint
before operation (base), just after operation, 24 hours after operation, 48 hours after operation

Method of measurement
Added at 2016-09-22: ELISA

Secondary outcomes

1

Description
CPK-MB

Timepoint
before operation (base), 6 hour after operation, 12 hour after operation

Method of measurement
elisa

2

Description

bleeding

Timepoint

during operation,6 hour after operation,12 hour after operation,24 hour after operation

Method of measurement

volume of bleeding

3

Description

Troponin

Timepoint

befor operation(base),6 hour after operation,12 hour after operation

Method of measurement

elisa

Intervention groups

1

Description

Infusion of 50cc normal saline as placebo in control group, during aortic clamping(45-60 minutes)

Category

Treatment - Drugs

2

Description

Infusion of 60000 IU erythropoietin in intervention group,during aortic clamping (45-60 minutes)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Street address

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pooyesh Darou company and Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr foroughi

Street address

Shahid Modarres hospital

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pooyesh Darou company and Shahid Beheshti 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

heart surgery department of Shahid Modarres hospital

Full name of responsible person

dr foroughi

Position

cardiovascular surgeon/associate professor

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

heart surgery department of Shahid Modarres hospital

Full name of responsible person

dr foroughi

Position

cardiovascular surgeon/associate professor

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

zohre mohammadi

Position

Medical science student/intern

Other areas of specialty/work

Street address

Shahid Beheshti University of Medical Science

City

tehran

Postal code

Phone

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