Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Erythropoietin effect on ischemic_reperfusion injury in cronary 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 reduces 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 evaluation the effect of EPO infusion on reducing ischemia-reperfusion injuries and improvement of cardiac function we asses inflammatory markers(IL-6,YKL-40,TNNF-a), 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 cronary 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,cronary 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.sbmu.ram.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-a

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

befor 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 bleeeding

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 ofShahid 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
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Position
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Other areas of specialty/work
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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