

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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- $\alpha$ ), 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.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

before operation (base), 6 hours after operation, 12 hours 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**

Shahid Modarres hospital

##### **City**

tehran

##### **Postal code**

##### **Phone**

+98 917 161 3954

##### **Fax**

##### **Email**

mahnoosh.foroughi@gmail.com

##### **Web page address**

## **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**

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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*