

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

An investigation of the effect of prescribing erythropoietin on the rate of acute kidney injury following coronary artery bypass graft surgery by on pump method

Protocol summary

Summary

Title: Investigation of the effect of prescribing erythropoietin (EPO) on the rate of acute kidney injury (AKI) following coronary artery bypass graft surgery (CABG) by on-pump method. objectives; Introduction of EPO as a prophylaxis factor to reduce AKI following CABG surgery with on-pump. Design; Randomized, triple blind, placebo controlled. Setting and conduct; The project nurse will acquire a written informed consent from all patients of the study, then a code is going to be specified to each patient. In the next step, Another nurse will collect the samples from the patients and at the time of the induction of anesthesia, the anesthesia technician randomly (evenly or oddly) will intravenously inject either EPO (200 units per Kilogram) or saline. (EPO and saline will be prepared beforehand and will be handed to the anesthesia technician in syringes, so he or she will not be aware of the contents of the syringes) then the data shall be entered into the questionnaires by the student, and at the end, the information on both control and intervention groups will be categorized and utilized for statistical analysis. Major inclusion criteria; Patients among the candidates who have an elective CABG surgery by on pump method. Major exclusion criteria; AKI prior to the surgery .Intervention; Intravenously inject either EPO or saline, main outcome measures: the blood samples will be collected in order to determine serum creatinine (one sample prior to the surgery as a base, and three samples in 24 ,48 ,and 72 hours after the surgery to investigate the changes).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031617419N2**

Registration date: **2015-09-02, 1394/06/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-02, 1394/06/11

Registrant information

Name

Mahmood Hosseinzadeh Maleki

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-09-06, 1394/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An investigation of the effect of prescribing

erythropoietin on the rate of acute kidney injury following coronary artery bypass graft surgery by on pump method

Public title

Effect of prescribing erythropoietin on the rate of acute renal failure following open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria; Patients among the candidates who had an elective coronary artery bypass graft surgery by on pump method. Exclusion criteria; Acute kidney injury prior to the surgery; having erythropoietin prior to coronary artery bypass graft surgery before; uncontrolled blood pressure; erythropoietin allergy; using nephrotoxic drugs before surgery is 3 days.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences .Ghaffari Street. Birjand

City

Birjand

Postal code

0098

Approval date

2015-02-21, 1393/12/02

Ethics committee reference number

1393-12-02

Health conditions studied

1

Description of health condition studied

Acute kidney injury

ICD-10 code

n17

ICD-10 code description

Acute renal failure

Primary outcomes

1

Description

Creatinin

Timepoint

Before Surgery and 24hr,48hr,72hr after surgery

Method of measurement

Serum creatinin was measured using a Prestige 24i (Tokyo Boeki) device and then was measured by Pars Azmoun kits, the scale was mg/dl

Secondary outcomes

1

Description

duration of pump

Timepoint

Intraoperative

Method of measurement

hour

2

Description

the amount of transfused

Timepoint

Intraoperative

Method of measurement

unit

3

Description

Blood pressure

Timepoint

Intraoperative

Method of measurement

mmHg

4

Description

urinary output

Timepoint

Intraoperative

Method of measurement

Catheter and cc

Intervention groups

1

Description

Intervention group: Erythropoietin (PDpoetin10000IU.rh Erythropoietin Alpha)200 units per Kilogram was intravenously injected at the time of the induction of anesthesia

Category

Prevention

2

Description

control group: Saline was intravenously injected at the time of the induction of anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valie-Asr hospital,Birjand

Full name of responsible person

Mahmood Hosseinzadeh maleki.Assistant Professor

Street address

Department of Cardiovascular Surgery,Vali Asr Hospital, Ghafari Street

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Birjand University of Medical Sciences

Full name of responsible person

Mohammad hasan namaee

Street address

Birjand University of Medical Sciences,Ghafari St.

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Mahmood Hosseinzadeh maleki

Position

Cardiovascular Surgeon

Other areas of specialty/work

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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