

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the efficacy of Erythropoietin and Intravenous Iron on transfusion requirements in patients undergoing cardiac surgery

Protocol summary

Study aim

comparisons transfusion requirement before surgery

Design

in this clinical trial patients that Have inclusion criteria divided into 2 groups with 77 patients patients in intravenous iron and erythropoietin groups take 100 IU/kg erythropoietin via IV bolus administration With 200 mg iron sucrose mixed with 100 ml normal saline iv for 1 h at 24 h before surgery In Control Group no intervention was done

Settings and conduct

patient who candidate for CABG in Tehran Heart Center Hospital if have inclusion criteria

Participants/Inclusion and exclusion criteria

inclusion patient over 18 years old who candidate for CABG if hemoglobin concentration less than 12 g/dl in women and less than 13 g/dl in men according to WorldHealth Organization criteria and have Iron deficiency anemia with this definition 1-ferritin < 30 mcg/l 2-ferritin 30-100 mcg /l or TSAT<20% OR CRP>5 mg/l Exclusion Patients with uncontrolled hypertension (BP>180/110)-platelet count more than 450,000/mm³ history of thromboembolism, seizure, malignant disease, liver dysfunction, confirmed renal impairment (serum creatinine[Cr]² mg/dl), aplastic or iron deficiency anemia and hypersensitivity to iron.history of erythropoietin use

Intervention groups

we have 2 groups with 77 patient in each group Patients in the IV Iron and erythropoietin group received 100 IU/kg erythropoietin via intravenous bolus administration at 24 h before surgery. At the same time, 200 mg iron sucrose supplement mixed with 200 ml normal saline was administered intravenously for 1 h. The patients in the control group received no Intervention

Main outcome variables

comparisons perioperative transfusion requirement and mean number of units of packed erythrocytes transfused per patient during the surgery and for 4 days after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190121042447N1**

Registration date: **2019-11-23, 1398/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-23, 1398/09/02**

Update count: **0**

Registration date

2019-11-23, 1398/09/02

Registrant information

Name

Shima Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6608 6109

Email address

shima.jafariy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-04, 1398/02/14

Expected recruitment end date

2020-01-04, 1398/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of Erythropoietin and Intravenous Iron on transfusion requirements in patients undergoing cardiac surgery

Public title

Evaluating the efficacy of Erythropoietin and Intravenous Iron on transfusion requirements in patients undergoing cardiac surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patient over 18 years old CABG candidate if hemoglobin concentration less than 12 g/dl in women and less than 13 g/dl in men 1-ferritin < 30 mcg/l 2-ferritin 30-100 mcg /l or TSAT<20% OR CRP>5 mg/l

Exclusion criteria:

Patients with uncontrolled hypertension (BP>180/110) - platelet count more than 450,000/mm³ history of thromboembolism, history of seizure, history of malignant disease liver dysfunction(transaminase>3ULN), confirmed renal impairment (serum creatinine[Cr]2 mg/dl), aplastic anemia hypersensitivity to iron history of erythropoietin use

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 154

Randomization (investigator's opinion)

Randomized

Randomization description

In this study,Permuted Block Randomization method was used individually.the randomized list of numbers 1 to 154 is randomly divided into two groups A or B,and the admitted patients are listed in group A or B,respectively.

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

Islamic Republic of Tehran University Of Medical

SCIENCE

Street address

North Kargar street- jalal street-Tehran Heart Center Hospital

City

TEHRAN

Province

Tehran

Postal code

1937836814

Approval date

2019-07-18, 1398/04/27

Ethics committee reference number

IR.TUMS.TIPS.REC.1398.027

Health conditions studied

1

Description of health condition studied

iron deficiency anemia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

transfusion requirement

Timepoint

before surgery until seven days after surgery

Method of measurement

transfused volume in mili litre

Secondary outcomes

1

Description

hemoglobin concentration changes

Timepoint

before surgery until seven days after surgery

Method of measurement

laboratory data in mg/dl

Intervention groups

1

Description

Intervention group: 77 patients with iron deficiency anemia give 100unit/kg erythropoietin IV bolus with 200 mg iron sucrose in 200 ml normal saline iv infusion in 1 hours

Category

Treatment - Drugs

2

Description

Control group: no intervention
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center Hospital

Full name of responsible person

Azita Haj Hossein Talasaz

Street address

north kargar street-jalal street-tehran heart center hospital

City

tehran

Province

Tehran

Postal code

1937836814

Phone

+98 21 2223 4214

Fax**Email**

shima.jafariy@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

mohammad ali sahraeian

Street address

Vice Chancellor for research,Tehran Univercity of medical sciences,Ghods Ave,Tehran Iran

City

tehran

Province

Tehran

Postal code

02166706141

Phone

+98 21 7381 8898

Email

msahrai@sina.tums.ac.ir

Grant name

Mohammad ali sahraian

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

shima jafari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

tehran heart center hospital

City

tehran

Province

Tehran

Postal code

1343966544

Phone

+98 21 8802 9600

Email

shima.jafariy@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

shima jafari

Position

resident of clinical pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

north kargar street-jalal street-tehran heart center hospital

City

tehran

Province

Tehran

Postal code

1937836814

Phone

+98 21 2223 4214

Email

shima.jafariy@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

azita haj hossein talasaz

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Heart center Hospital

City

Tehran

Province

Tehran

Postal code

1937836814

Phone

+98 21 6608 6109

Fax**Email**

shima.jafariy@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

the last result and analytical data

When the data will become available and for how long

at the end of the work

To whom data/document is available

all reasearchers

Under which criteria data/document could be used

no criteria

From where data/document is obtainable

from email

What processes are involved for a request to access data/document

they should send email then we share our data with them

Comments