Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 erythropoeitin groups take 100 IU/kg erythropoeitin 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 ctiteria
Participants/Inclusion and exclusion criteria
inclusion patient over 18 years old who candidate for CABG if hemoglobin concentration less than 12 g/dl inwomen and less than 13 g/dl in men according to WorldHealth Organization criteria and have Iron deficiency anemia with this definition1-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 erythropoeitin use
Intervention groups
we have 2 groups with 77 patient in each group Patients in the IV Iron and erythropoeitin group received 100 IU/kg erythropoeitin 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)
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+98 21 6608 6109
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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 erythropoeitin 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 randomely 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
labaratory data in mg/dl

Intervention groups

1

Description
Intervention group: 77 patients with iron deficiency anemia give 100unit/kg erythropoeitin IV bolus with 200 mg iron sucrose in 200 ml normal salin 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

mohammad ali sahraeian

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

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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

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Position
professor

Latest degree
Specialist

Other areas of specialty/work
Cardiology

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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