# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 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 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)
**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 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

**City**

tehran

**Province**

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**Postal code**

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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**

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**Phone**

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**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**

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**Postal code**

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## Person responsible for scientific inquiries

**Contact**

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Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

resident of clinical pharmacy

**Latest degree**

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**Other areas of specialty/work**

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## 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

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Heart center Hospital

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**Postal code**
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**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**