

# 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/mm<sup>3</sup> history of thromboembolism, seizure, malignant disease, liver dysfunction, confirmed renal impairment (serum creatinine[Cr]<sup>2</sup> 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/mm<sup>3</sup> 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  
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## 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  
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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

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**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**