

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the Effectiveness of Ferric carboxymaltose versus Iron sucrose in Anemia correction /impact on Transfusion Requirements in patients undergoing cardiac surgery

#### Protocol summary

##### Study aim

Comparison the amount of changes Ferritin ,Hemoglobin, and Transfusion in Iron sucrose and Ferric-Carboxy Maltose groups

##### Design

Clinical trial, with parallel groups, randomized

##### Settings and conduct

The target population in this study is anemic patients over the age of 18 who have been nominated for heart surgery. Patients are selected from cathlab and the surgical office. Fe, TIBC, Ferritin tests are requested by cardiologist to diagnose iron deficiency anemia in patients. Patients will be included in the study if they meet the criteria for entering the study. Then, the consent form will be given to the patient. If satisfied, the patients will be based on the Randomization form and sealed envelope provided by the statistician. Allocating the iron to the two groups is carried out 3-5 weeks before the surgery. The relevant tests will be done again for the patient on the day before surgery and 3 days after surgery, and the number of transfused blood units will be recorded. Statistical analysis is performed after collecting all the data. Location of the project: Rajaei Hospital

##### Participants/Inclusion and exclusion criteria

The target population in this study is patients over the age of 18 who have been nominated for heart surgery and who have iron deficiency anemia according to WHO. Patients undergoing surgery or emergency surgery will not be included in the study.

##### Intervention groups

Iron Sucrose Group: Patients in this group receive Iron Sucrose (Venofer) at a dose of 1000 mg. Ferric-Carboxy Maltose Group: Patients in this group receive Ferric-carboxy Maltose (Frinject) at a dose of 1000 mg.

##### Main outcome variables

- 1) Increased ferritin levels in the two groups studied
- 2) Increased of Hb levels in the two groups studied

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170705034908N3**

Registration date: **2019-03-17, 1397/12/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-17, 1397/12/26**

Update count: **0**

##### Registration date

2019-03-17, 1397/12/26

##### Registrant information

##### Name

Elham Khalaf Adeli

##### Name of organization / entity

High Institute for Education and Research in Transfusion Medicine,

##### Country

Iran (Islamic Republic of)

##### Phone

+98 88601582

##### Email address

adeli.elham@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2020-02-20, 1398/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effectiveness of Ferric carboxymaltose versus Iron sucrose in Anemia correction /impact on Transfusion Requirements in patients undergoing cardiac surgery

**Public title**

Comparison of the Effectiveness of iron injectable drugs in anemia correction and blood transfusion rate

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

People over the age of 18 who are undergoing cardiac surgery for the first time. Men with Hb<13 and women with Hb<12 and (ferritin 100-299 ng / ml and transferransfine saturation < 20%) People who have discontinued the Warfarin at least 72 hours before surgery. People who have discontinued the anti-platelet at least drugs 3-5 days before surgery.

**Exclusion criteria:**

Elimination of patients with liver disorders Elimination of patients with inherited and well-known coagulation disorders Elimination Emergency surgeries Elimination pregnant women Redo surgery

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The permuted balanced block randomization method is used with four blocks. This is done by study colleagues who are not present in the therapeutic field. Random sequences are presented in envelopes depending on the original researcher of the study.

**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**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Golgasht Ave, Azadi Blvd, Oloom pezeshti Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

1157-14665

**Approval date**

2018-06-26, 1397/04/05

**Ethics committee reference number**

IR.TBZMED.VCR.REC.1397.118

**Health conditions studied****1****Description of health condition studied**

iron deficiency anaemia In patients undergoing cardiac surgery

**ICD-10 code**

D50.9

**ICD-10 code description**

Iron deficiency anaemia, unspecified

**Primary outcomes****1****Description**

1) Amount of ferritin changes in 2 groups studied

**Timepoint**

Before surgery and 3 days after surgery

**Method of measurement**

Ferritin Test

**2****Description**

2) Amount of Hb changes in 2 groups studied

**Timepoint**

Before surgery and 3 days after surgery

**Method of measurement**

CBC Test

**Secondary outcomes****1****Description**

1) frequency of patients who transfused

**Timepoint**

7 days after surgery

**Method of measurement**

Check patient records for the number of blood units consumed

## 2

### Description

2) Average number of blood units consumed

### Timepoint

7 days after surgery

### Method of measurement

Check patient records for the number of blood units consumed

## Intervention groups

### 1

#### Description

Iron sucrose group: Patients in this group receive 1000 mg of an Iron sucrose drug by injection and within 3 weeks of surgery.

#### Category

Treatment - Drugs

### 2

#### Description

Ferric carboxymaltose group: Patients in this group receive 1000 mg of Ferric carboxymaltose by injection and within 3 weeks of surgery.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rajaei hospital

##### Full name of responsible person

Fatemeh Ramezani

##### Street address

No 2, Ayris building, Emam hosyne Ave, Ashrafi Esfahani Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1473179637

##### Phone

+98 21 4442 4414

##### Email

forooghramzani@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Doctor Karim SHams

#### Street address

Blood Transfusion Center

#### City

Tehran

#### Province

Tehran

#### Postal code

11111111

#### Phone

+98 41 3335 5921

#### Fax

+98 41 3335 9680

#### Email

TBZMED@ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tabriz University of Medical Sciences

#### Proportion provided by this source

50

#### 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

### 2

#### Sponsor

##### Name of organization / entity

Blood Transfusion Center

##### Full name of responsible person

Doctor Elham KHalaf Adeli

##### Street address

Blood Transfusion Center, Hemat Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1111111111

##### Phone

+98 21 8885 5675

##### Email

ibto@email.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Blood Transfusion Center

#### Proportion provided by this source

50

#### 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**

Blood Transfusion Center

**Full name of responsible person**

Elham KHalaf Adeli

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Hematology

**Street address**

Blood Transfusion Center, Hemmat Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

11111111111111

**Phone**

+98 21 82050

**Email**

elhamadeli@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fatemeh Ramezani

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Hematology

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**Province**

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**Email**

forooghramzani@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fatemeh Ramezani

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Hematology

**Street address**

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**Province**

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**Postal code**

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**Phone**

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**Email**

forooghramzani@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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