

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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, andTransfusion 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: Rajaee 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 Ferriccarboxy 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 transferrin saturation < 20%) People who have discontinued the Warfarin at least 72 hours before surgery. People who have discontinued the anti-platelet at least 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 hosyane Ave, Ashrafi Esfahani Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Doctor Karim SHams

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Blood Transfuion Center

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Fax

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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

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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

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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

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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**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

Street address

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Province

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