Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, Ferrtin 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 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 bofore sugery.

Exclusion criteria:
Elimination of patients with liver disorders Elimination of patients with inherited and well-known coagulation disorders Elimination Emergency sugeries 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 randomizatio 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 pezeshki 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 l 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 Ferricarboxymaltose 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 Transfuion 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
Street address
No 2,Emam Hosine Ave,Ashrafi Esfahani Blvd.
City
Tehran
Province
Tehran
Postal code
1473179637
Phone
+98 21 4442 4414
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
No 2,Ayris building,Emam Hosyne Ave,Ashrafi Esfahani Blvd
City
Tehran
Province
Tehran
Postal code
147317937
Phone
+98 21 4442 4414
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