Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Assessment of response to treatment in anemia (iron deficiency) after CABG in adults

Protocol summary

Study aim
Assessment of response to treatment in anemia (iron deficiency) after CABG in Adults

Design
This study is a before and after, non-Randomized, single blind clinical trial. After obtaining patient consent and the approval of the ethics committee and the selection based on the inclusion and exclusion criteria, patients enter the study.Each patient in this study is also in the control and intervention group. The number of study samples is 142 patients and the sample size is collected using available samples.

Settings and conduct
In this study, patients are first tested for ferritin, TIBC and reticulocytes. Oral therapy (ferrous sulfate) is started based on the results of experiments to treat iron deficiency anemia. The above tests are repeated one week later to evaluate the treatment. If the response to treatment is appropriate, the patient will be monitored once and up to three times a month for CBC, TIBC, ferritin, and reticulocytes. Injectable iron is used if the tests are not appropriate one week after the start of oral iron, and the same follow-up is performed quarterly.This study is being performed at Shahid Rajaei Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients are candidates for CABG for the first time Age between 18 until 72 years Exclusion criteria:Kidney disorders, Autoimmune diseases

Intervention groups
In this study, adult patients who have low hemoglobin after an CABG on the last day of their stay at the ICU are included in the study. First, the desired tests are taken from the patients and the patients enter the before phase of the intervention, and in the next step, after giving the pill or ferrosulfate ampoule according to the specified protocol, the next tests are taken and the patients enter the after phase of the intervention and the result is recorded.

Main outcome variables
Hemoglobin level, ferritin level, reticulocyte count

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170912036157N2**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-19, 1399/02/30**
Update count: **0**

Registration date
2020-05-19, 1399/02/30

Registrant information

Name
Ziae Totonchi

Name of organization / entity
IUMS

Country
Iran (Islamic Republic of)

Phone
+98 21 2392 2153

Email address
totonchi@rhc.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-19, 1399/01/31

Expected recruitment end date
2020-10-20, 1399/07/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of response to treatment in anemia (iron deficiency) after CABG in adults

Public title

Assessment of response to treatment in anemia (iron deficiency) after CABG in adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 until 72 years Patients are candidates for CABG for the first time Hemoglobin is less than 10 in women and less than 11 in men

Exclusion criteria:

History of previous surgery Kidney disorders Autoimmune diseases Bleeding disorders, Thalassemia

Age

From **18 years** old to **72 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **142**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, a person who is responsible for analyzing statistical data is not aware of the treatment process and study groups and the information is provided to that person in groups A and B. This helps the person's personal opinion not to affect the results.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City

Tehran

Province

Tehran

Postal code

1433933111

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.IUMS.FMD.REC.1399.078

Health conditions studied

1

Description of health condition studied

Chronic ischemic heart disease

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

Hemoglobin level

Timepoint

Before and after treatment

Method of measurement

Blood test

Secondary outcomes

1

Description

ferritin level

Timepoint

Before and after treatment

Method of measurement

blood test

Intervention groups

1

Description

Intervention group: In this study, each patient is placed in the control group first and enters the intervention group after the intervention.First, patients are tested for ferritin, TIBC, and reticulocytes. Oral therapy (ferrous sulfate) 60 mg three times a day is started based on the results of experiments to treat iron deficiency anemia. The above tests are repeated one week later to evaluate the treatment. If the response to treatment is appropriate, the patient will be monitored once and up to three times a month for CBC, TIBC, ferritin, and

reticulocytes. Injectable iron is used at a dose of 200 mg intravenously slowly over 2,5 minutes and five times at intervals of 14 days if the tests are not appropriate one week after the start of oral iron, and the same follow-up is performed quarterly.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaei Hospital

Full name of responsible person
Zia Totonchi

Street address
Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 2392 2153

Email
ziya189@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyed Abbas Motavalian

Street address
Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 2392 2153

Email
ziya189@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Zia Totonchi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 2392 2153

Email
ziya189@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Zia Totonchi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 2392 2153

Email
ziya189@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Minou Jolousi

Position
Doctor

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 2392 2153

Email
ziya189@yahoo.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