

# 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

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Tehran

**Province**

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**Phone**

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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

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**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

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

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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

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Minou Jolousi

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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