

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effectiveness of ferric carboxymaltose and oral iron in treatment of chronic iron deficiency anemia in colon cancer patients

Protocol summary

Summary

(1) Objectives: Comparing the effectiveness of a new form of intravenous iron (ferric carboxymaltose) with the oral form ferrous sulfate in Iran. (2) Design: Sixty colon cancer patients who admit in single clinical center will be randomly divided into two groups based on balanced block randomization method. (3) Setting and conduct: After dividing, patients in group I will be treated two months duration, but group II patients will receive one drug dose. Lab test will be repeated 8 weeks in both groups. (4) Participants including colon cancer patients with chronic iron deficiency anemia. (5) Intervention: Patients will be treated with oral iron tablets and intravenous iron injection in group I and II, respectively. (6) Primary outcome variables include hemoglobin and ferritin serum level changes in all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092111560N9**

Registration date: **2015-12-12, 1394/09/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name

Tayeb Ramim

Name of organization / entity

Sina Trauma and Surgery Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 0000

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of ferric carboxymaltose and oral iron in treatment of chronic iron deficiency anemia in colon cancer patients

Public title

Effect of intravenous iron in the treatment of chronic iron deficiency anemia in colon cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : colon cancer; chronic iron deficiency anemia. Exclusion criteria: severe drug reaction; lost to follow up; low level of consciousness due to underlying disease and death.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Iran University of Medical Science

Street address

Central division of Iran University of Medical Sciences, Hemat gateway

City

Tehran

Postal code**Approval date**

2015-09-23, 1394/07/01

Ethics committee reference number

IR.IUMS.REC.139527216

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

Iron deficiency anaemia

ICD-10 code

D-50

ICD-10 code description

Iron deficiency anaemia

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

Hemoglobin

Timepoint

Pre treatment; 8 weeks following end of treatment

Method of measurement

gram/ deciliter using of blood sample

2**Description**

Ferritin

Timepoint

Pre treatment; 8 weeks following end of treatment

Method of measurement

nanogram/ mililiter using of blood sample

Secondary outcomes

empty

Intervention groups**1****Description**

1500 mg bolus injection of ferric carboxymaltose (Injectafer®)

Category

Treatment - Drugs

2**Description**

65mg/TDS ferrous sulfate (Daru Yab. Co) until two month, 180 tables

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasool Akram Hospital

Full name of responsible person

Naffise Ansari Nejad

Street address

Niayesh St, Tohid Sq.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seeid Ali Javad Mosavi

Street address

Central division of Iran University of Medical Sciences, Hemat gateway

City

Teharn

Grant name**Grant code / Reference number**

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

Yes

Title of funding source

Vice Chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Naffiseh Ansarinejad

Position

MD

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty