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)

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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 devision 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
Hemiglobin
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
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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
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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