Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effectiveness of treatment of iron deficiency anemia with daily vs. every other day oral iron supplementation

Protocol summary

Study aim
Comparison of the effectiveness of iron deficiency anemia treatment with daily protocol and one day in between with oral iron

Design
This study is a phase 3 parallel randomized clinical trial. Individuals are told that they are randomly assigned to one of these two groups of 188people.

Settings and conduct
one group of patients are treated daily and in the second group every other day with oral iron. One week after the start of treatment, changes in the patient's clinical symptoms, at the time of diagnosis and 1.5 months after the start of treatment, the parameters are checked.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age ≥ 15 years and less than 50 years Women with iron deficiency with ferritin less than 30 micrograms per liter No pregnancy and breastfeeding Absence of comorbidities (ckd, DM, IHD, etc.) No history of inflammatory bowel disease and celiac diseas,thalassemia,inherited bleeding disorder Do not take multivitamin and mineral supplements (35 mg or more of essential iron per day) in the 2 weeks prior to randomization No allergy to oral iron Lack of intravenous iron therapy in the last 12 weeks Not receiving anticoagulant therapy No surgery and chemotherapy for the next 12 weeks. Lack of creatinine clearance less than 30 ml per minute and hemoglobin less than 80 g / l with active bleeding Lack of hypermenorrhea Exclusion criteria: Intolerance or non-response to oral iron gluconate, sulfate or fumarate in the last 12 weeks Received frequent anemia treatments and are resistant to anemia treatment. Dissatisfaction to participate in the study or lack of cooperation and consent to continue treatment

Intervention groups
one group of patients will receive 150-200 mg of elemental iron daily and the second group of patients will receive 150- 200 mg of elemental iron every other day

Main outcome variables
Hb, clinical signs, side effects, retic count, TIBC

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210730052015N1**
Registration date: **2021-09-25, 1400/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-25, 1400/07/03**
Update count: **0**

Registration date
2021-09-25, 1400/07/03

Registrant information
Name
Negar Gheytassi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 86 3147 3521
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-21, 1400/06/30
Expected recruitment end date
2022-01-20, 1400/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of treatment of iron deficiency anemia with daily vs. every other day oral iron supplementation

Public title
Comparison of the effectiveness of treatment of iron deficiency anemia with daily vs. every other day oral iron supplementation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≥ 15 years and less than 50 years outpatients Women with iron deficiency with ferritin less than 30 micrograms per liter No pregnancy No breastfeeding right now Absence of comorbidities (ckd, DM, IHD, etc.) Lack of known history of inflammatory bowel disease Lack of known history of celiac disease No known history or thalassemia No known hereditary bleeding disorder Do not take multivitamin and mineral supplements (35 mg or more of essential iron per day) in the 2 weeks prior to randomization. No allergy to oral iron Lack of intravenous iron therapy in the last 12 weeks Do not receive anticoagulants (eg warfarin, apixaban, debigatran, adoxaban, Riveroxban) Lack of creatinine clearance less than 30 ml per minute Lack of hemoglobin less than 80 g / l with active bleeding No chemotherapy planned for the next 12 weeks. No surgery is scheduled for the next 12 weeks.

Exclusion criteria:
Intolerance or non-response to oral iron gluconate, sulfate or fumarate in the last 12 weeks Received frequent anemia treatments and are resistant to anemia treatment. Dissatisfaction to participate in the study or lack of cooperation and consent to continue treatment

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **376**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomized block method was used for randomization. For this purpose, a block of 4 is used. In such a way that first 4 blocks are prepared as BAAB, BABA, BBAA, AABB, ABAB, ABB and then these blocks are arranged randomly and people are assigned to two groups according to A or B and this work is continuous. Will be repeated to reach the desired sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is one-sided blind, which means that none of the participants is aware of how individuals are assigned to the groups. Labels A and B are labeled on the packages, but only the researcher knows the true nature of the supplements.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
University of Medical Sciences, Payambar Azam University Complex. Deputy of research and technology

City
Arak

Province
Markazi

Postal code
3848176341

Approval date
2021-06-27, 1400/04/06

Ethics committee reference number
IR.ARAKMU.REC.1400.074

Health conditions studied

1

Description of health condition studied
Iron deficiency anemia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
hemoglobin

Timepoint
The beginning of the study, two weeks and a month and a half after the intervention

Method of measurement
Using the device

2

Description
Ferritin
Timepoint
At the beginning of the study and one and a half months after the intervention
Method of measurement
Using the device

3

Description
Retic COUNT
Timepoint
First and two weeks after the intervention
Method of measurement
Using the device

4

Description
Serum iron levels
Timepoint
At the beginning of the study and one and a half months after the intervention
Method of measurement
Using the device

5

Description
TIBC
Timepoint
At the beginning of the study and one and a half months after the intervention
Method of measurement
Using the device

Secondary outcomes

1

Description
General clinical symptoms(weakness, fatigue, drowsiness, restlessness, anxiety, etc.)
Timepoint
at the beginning and end of the study
Method of measurement
check list

2

Description
Side effects during the study (nausea and vomiting, black stools / heartburn, etc.)
Timepoint
during the study
Method of measurement
check list

Intervention groups

1

Description
Intervention group: In one group of patients, 150-200 mg of elemental iron is given daily (in the form of ferrofort tablets of Abidi Pharmaceutical Company twice a day).
Category
Treatment - Drugs

2

Description
Intervention group: In the second group, patients are treated every other daybetween 150-200 mg of elemental iron (in the form of ferrufort tablets of Abidi company twice a day every other day).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
درمانگاه تخصصی بیمارستان امیرالمومنیت اراک
Full name of responsible person
Negar Gheytassi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
علیرضا کمالی
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Finance Management, Third Floor, Arak University of Medical Sciences, Alma Al-Huda St., Shahid Shiroodi St.
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Negar Gheytassi

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Position
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Latest degree
Medical doctor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified

individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Students and researchers can use the data of this study.

From where data/document is obtainable

Researchers can contact the study author via email at Drnegar.gheytassi@gmail.com to receive data and information.

What processes are involved for a request to access data/document

Request information and data to the author via email Drnegar.gheytassi@gmail.com

Comments