

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 188 people.

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 \geq 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 diseases, 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 Gheytaasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3147 3521

Email address

drnegar.gheytaasi@gmail.com

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 \geq 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 of 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 day between 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 امیرالمؤمنین اراک

Full name of responsible person

Negar Gheytaasi

Street address

اراک، میدان بسیج (سردشت)، جنب دانشکده پزشکی، بیمارستان امیرالمؤمنین

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Drnegar.gheytaasi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

علیرضا کمالی

Street address

Finance Management, Third Floor, Arak University of Medical Sciences, Alma Al-Huda St., Shahid Shiroodi St.

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dopdarman@gmail.com

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 Gheytaasi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Amir Al-Momenin Hospital, Next to the School of Medicine, Basij Square (Sardasht), Arak

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Negar.Gheytaasi

Position

RESIDENT

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Negar Gheytaasi

Position

RESIDENT

Latest degree

Medical doctor

Other areas of specialty/work

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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.ghetassi@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.ghetassi@gmail.com

Comments