Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

"Effect of Daily, Alternate-Day, and Every-Other-Day Oral Iron Supplementation on Gastrointestinal Adverse Effects and Treatment Efficacy in Women Aged 18–45 with Iron Deficiency

Protocol summary

Study aim

"Compare the therapeutic efficacy and gastrointestinal adverse events of oral iron supplementation administered daily, every other day, and every two days in the treatment of iron-deficiency anemia in women."

Design

Phase IV, randomized, three-arm parallel trial, double-blind, N=150; computer-generated allocation stratified by baseline Hb.

Settings and conduct

Outpatient clinics of Jahrom University of Medical Sciences; women aged 18–45; screening, baseline labs, randomisation, 8-week follow-up; participants and outcome assessors blinded.

Participants/Inclusion and exclusion criteria

Eligibility Conditions Women aged 18 to 45 years attending the clinics of Jahrom University of Medical Sciences Diagnosis of iron deficiency anemia based on: Hemoglobin 8–12 g/dL Serum ferritin < 30 ng/mL No use of oral or injectable iron in the past 12 weeks No history of surgery, chemotherapy, or blood donation in the past 12 weeks GFR > 30 mL/min No chronic inflammatory, renal, hepatic, or malignant disease No gastrointestinal disorders affecting iron absorption No history of severe allergy or intolerance to iron supplements Ability to understand study information and provide informed consent Discontinuation Criteria Voluntary withdrawal by the participant at any time Pregnancy occurring during the study period Development of serious adverse events related to iron supplementation Non-adherence, defined as taking < 80% of the prescribed supplement Initiation or continuous use of interfering medications A final diagnosis other than iron deficiency anemia Hospitalization or any clinical deterioration that prevents continuation of participation

Intervention groups

Arm A: Daily oral iron; Arm B: Alternate-day oral iron; Arm C: Every–two-day oral iron;

Main outcome variables

Mean hemoglobin change from baseline to week 8; Frequency and severity of gastrointestinal adverse effects

General information

Reason for update

Acronym

ida-iron

IRCT registration information

IRCT registration number: **IRCT20251122068082N1**
Registration date: **2025-12-01, 1404/09/10**
Registration timing: **prospective**

Last update: **2025-12-01, 1404/09/10**
Update count: **0**

Registration date

2025-12-01, 1404/09/10

Registrant information

Name

ali naderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5684 5311

Email address

naderi.ali8001@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2026-02-19, 1404/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"Effect of Daily, Alternate-Day, and Every-Other-Day Oral Iron Supplementation on Gastrointestinal Adverse Effects and Treatment Efficacy in Women Aged 18–45 with Iron Deficiency

Public title

Effect of Different Oral Iron Dosing Regimens on Side Effects and Treatment Effectiveness in Iron Deficiency Anemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 45 years attending the clinics of Jahrom University of Medical Sciences Diagnosis of iron deficiency anemia based on: Hemoglobin 8–12 g/dLSerum ferritin < 30 ng/mL No use of oral or injectable iron in the past 12 weeks (based on self-report and medical records) No history of surgery, chemotherapy, or blood donation in the past 12 weeks GFR > 30 mL/min No chronic inflammatory, renal, hepatic, or malignant disease No gastrointestinal disorders affecting iron absorption (e.g., celiac disease, Crohn’s disease, intestinal resection) No history of severe allergy or intolerance to iron supplements Ability to understand study information and provide informed consent

Exclusion criteria:

Voluntary withdrawal by the participant at any time Pregnancy occurring during the study period Development of serious adverse events related to iron supplementation (e.g., severe allergic reaction or disabling gastrointestinal side effects) Non-adherence, defined as taking < 80% of the prescribed supplement Initiation or continuous use of interfering medications (e.g., antacids, proton pump inhibitors, or specific antibiotics) A final diagnosis other than iron deficiency anemia (e.g., anemia of chronic disease, thalassemia) Hospitalization or any clinical deterioration that prevents continuation of participation

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to the study groups using variable block randomization based on a computer-generated random sequence. The unit of randomization is the individual eligible participant. To ensure balanced distribution of anemia severity between the groups, stratified randomization will be performed according to baseline hemoglobin levels in two strata (8 to <10 g/dL and 10 to 12 g/dL), with independent block randomization within each stratum. The random allocation sequence will be generated by an individual independent of the study team using statistical software, and variable block sizes will be applied without disclosure to investigators involved in participant enrollment. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes that will be opened only after eligibility has been confirmed for each participant. No quasi-random allocation methods will be used in this study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind Both participants and outcome assessors (clinical staff and data analysts) will remain unaware of group assignments. Blinding will be maintained using matched placebo tablets to ensure identical appearance and dosing schedule across all study arms.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of jahrom University of Medical Sciences

Street address

motahari blvd

City

jahrom

Province

Fars

Postal code

7174935488

Approval date

2025-11-12, 1404/08/21

Ethics committee reference number

IR.JUMS.REC.1404.106

Health conditions studied

1

Description of health condition studied
iron deficiency anemia
ICD-10 code
D50.9
ICD-10 code description
Iron deficiency anemia, unspecified

Primary outcomes

1

Description
Change in Blood Hemoglobin Concentration
Timepoint
Measurement of blood hemoglobin concentration at baseline (before initiation of the intervention) and eight weeks after initiation of the intervention
Method of measurement
Measurement of blood hemoglobin concentration using peripheral blood sampling and analysis with an automated blood cell counter in a university-affiliated clinical laboratory

2

Description
Severity of Gastrointestinal Adverse Effects Related to Iron Supplementation
Timepoint
Assessment of the severity of gastrointestinal adverse effects at baseline (before initiation of the intervention) and then weekly until the end of the eighth week of the intervention
Method of measurement
Assessment of the severity of gastrointestinal adverse effects including nausea, vomiting, abdominal pain, constipation, and diarrhea using a ten-point visual analogue scale completed by the participants

Secondary outcomes

1

Description
Adherence to Oral Iron Supplementation
Timepoint
Assessment of adherence to oral iron supplementation weekly during the intervention period and at the end of the eighth week
Method of measurement
Assessment of adherence to treatment based on pill count and participant self-report recorded in weekly follow-up forms

2

Description
Change in Serum Ferritin Concentration
Timepoint
Measurement of serum ferritin concentration at baseline (before initiation of the intervention) and eight weeks after initiation of the intervention
Method of measurement
Measurement of serum ferritin concentration using blood samples and the immunoassay method in a university-affiliated clinical laboratory

3

Description
Serum Hepcidin Level
Timepoint
Measurement of serum hepcidin level at baseline (before initiation of the intervention) and eight weeks after initiation of the intervention
Method of measurement
Measurement of serum hepcidin level using blood samples and the enzyme-linked immunosorbent assay (ELISA) method in a university-affiliated clinical laboratory

Intervention groups

1

Description
Intervention group: Participants in this group will receive oral iron supplementation in the form of ferrous sulfate tablets. Each tablet contains three hundred and twenty-five milligrams of ferrous sulfate equivalent to sixty-five milligrams of elemental iron. The tablets will be administered on an alternate-day regimen, with one tablet taken every other day, for a total duration of eight weeks. Tablets are to be taken preferably on an empty stomach with a glass of water.
Category
Treatment - Drugs

2

Description
Intervention group: Participants in this group will receive oral iron supplementation in the form of ferrous sulfate tablets. Each tablet contains three hundred and twenty-five milligrams of ferrous sulfate equivalent to sixty-five milligrams of elemental iron. The tablets will be administered every forty-eight hours, with one tablet taken once every forty-eight hours, for a total duration of eight weeks. Tablets are to be taken preferably on an empty stomach with a glass of water.
Category
Treatment - Drugs

3

Description
Control group: Participants in this group will receive oral iron supplementation in the form of ferrous sulfate tablets. Each tablet contains three hundred and twenty-five milligrams of ferrous sulfate equivalent to sixty-five milligrams of elemental iron. The tablets will be administered once daily, one tablet per day, for a total duration of eight weeks. Participants will be instructed to take the tablets preferably on an empty stomach with a

glass of water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Hossein Ali Rostami Pour

Street address

Next to Peymanieh Hospital, Main Street, Imam Reza Clinic

City

Jahrom

Province

Fars

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7514413110

Phone

+98 71 5434 5666

Email

hossainroscawi41@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Hosein Kargar

Street address

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715657898

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Email

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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

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Hossein Ali Rostamipour

Position

Faculty Subspecialist

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hossein Ali Rostamipour

Position

Faculty Subspecialist

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person
Ali Naderi

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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71586794

Phone
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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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The collected data in this study include de-identified participant information, laboratory test results, treatment adherence, and primary and secondary clinical outcomes. All data will be anonymized before sharing. The dataset includes all primary and secondary outcome measures, as well as details of interventions and study groups.

When the data will become available and for how long
Access to the data will be available starting six months after the publication of study results and will continue for five years thereafter.

To whom data/document is available
Active researchers at academic and scientific institutions can request access to the data. Independent researchers with a relevant research proposal and ethical approval may also be granted access.

Under which criteria data/document could be used
Data are permitted solely for scientific research purposes, and commercial use is prohibited. Statistical analyses must follow the submitted research protocol, and any publication must cite the source and ethical approval.

From where data/document is obtainable
Applicants can contact Dr. Hossein Ali Rostamipour at Imam Reza Clinic, adjacent to Peymanieh Hospital, Jahrom. Contact details: Phone: +989177911197, Email: hossainroscawi41@yahoo.com

What processes are involved for a request to access data/document
The applicant must complete and submit a formal request form, provide their research proposal, and ethical approval. After review by the study coordinator, approved data will be provided in a de-identified file. The process typically takes 2 to 4 weeks.

Comments
All data and documents will be stored and shared in accordance with privacy regulations and research ethical standards.