# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 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)

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+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

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Jahrom

**Province**

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**Postal code**

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**Phone**

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**Email**

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## 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

**Phone**

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info@jahrom.ac.ir

**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**

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**Position**

Faculty Subspecialist

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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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Motahari Blvd

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**Province**
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71586794

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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.