Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

The evaluation of the effect of administration time of oral Iron preparations on hemoglobin response in patients with Iron deficiency anemia

Protocol summary

Study aim
The evaluation of the effect of the time of administration of oral iron product on the amount of hemoglobin increase in patients with iron deficiency anemia

Design
A double-blind, placebo-controlled, randomized clinical trial will be performed in parallel on 196 patients. Blocked randomization method was used for randomization

Settings and conduct
Screening and confirmation of study inclusion criteria by a physician from among the patients referred to the clinics of Imam Reza and Ghaem hospitals, then allocation of patients to two groups A and B based on the randomization list.

Participants/Inclusion and exclusion criteria
The diagnosis of iron deficiency anemia based on iron evaluation indices including serum iron level, ferritin and transferrin saturation capacity Hemoglobin level less than or equal to 11 mg/dL

Intervention groups
In the intervention group, iron tablets are prescribed in the morning at 10 o'clock and placebo in the evening at 6 o'clock.

Main outcome variables
Increase in hemoglobin level, and iron profile

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210503051166N2**
Registration date: **2023-02-01, 1401/11/12**
Registration timing: **prospective**

Last update: **2023-02-01, 1401/11/12**
Update count: **0**

Registration date
2023-02-01, 1401/11/12

Registrant information
Name
Omid Arasteh
Name of organization / entity
Country
Iran (Islamic Republic of)
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arasteho@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-21, 1402/02/01
Expected recruitment end date
2024-05-21, 1403/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of the effect of administration time of oral Iron preparations on hemoglobin response in patients with Iron deficiency anemia

Public title
The effect of administration time of oral iron preparations on hemoglobin response
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with iron deficiency anemia based on iron profile study such as serum iron, ferritin, and transferrin saturation percent Hemoglobin level less than 11 mg/dl Not suffering from chronic liver disease (normal bilirubin, LFT<2 times normal), or other chronic inflammatory diseases based on initial evaluation Not suffering from active malignancy based on initial evaluation Not suffering from active infection based on initial evaluation Not suffering from any of the malabsorption syndromes based on the initial evaluation Patients with cardiovascular risk factors

Exclusion criteria:

Suffering from any chronic kidney disease, liver disease, all types of cancer, infections and autoimmune diseases The patient's lack of consent to participate in the plan Having dyspepsia and intolerance to iron food products High CRP levels at study entry

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **196**

Randomization (investigator's opinion)

Randomized

Randomization description

A replacement block using the site https://www.sealedenvelope.com with the explanation that each block has 4 and 6 members and the shape of the blocks can be as follows: [ABAB], [ABBA, [AABB], [BBAA], [BABA][BAAB] Code A corresponds to the intervention group and code B corresponds to the control group. The aforementioned site randomly selects nineteen blocks from four blocks and twenty blocks from six blocks. So, finally 196 patients are included in the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Triple Blinded The patients of the control and intervention groups are randomly divided into two groups based on the codes that were designed by the random block method. These codes are designed by another person who is not aware of the study and are provided to the participants using closed letters. The researcher, patients, physicians responsible for the patients and the person who is responsible for statistical analysis do not know about the codes related to the control and intervention groups until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

No. 16, 21th Edalat avenue., Ahmadabad blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9176614889

Approval date

2022-12-31, 1401/10/10

Ethics committee reference number

IR.MUMS.REC.1401.337

Health conditions studied

1

Description of health condition studied

Iron deficiency anemia

ICD-10 code

D50

ICD-10 code description

Iron deficiency anemia

Primary outcomes

1

Description

Increase in hemoglobin level

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Hemoglobin concentration in complete blood count test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, Iron tablets made by abidi company (Ferofort duodenal) which included 80 mg elemental iron are prescribed in the morning at 10 o'clock and placebo tablets are prescribed in the evening at 6 o'clock. Patients use these pills every day for a month. Hemoglobin level testing is done for patients before the start of the study and after one month.

Category
Treatment - Drugs

2

Description
Control group: In the intervention group, placebo tablets are prescribed in the morning at 10 o'clock and Iron tablets made by abidi company (Ferofort) which included 80 mg elemental iron are prescribed in the evening at 6 o'clock. Patients use these pills every day for a month. Hemoglobin level testing is done for patients before the start of the study and after one month.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Omid Arasteh
Street address
Azadi Square, University Campus, Faculty of Pharmacy
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2

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Khalil Abnous
Street address
میدان آزادی ،پردیس دانشگاه ، دانشکده داروسازی
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Omid Arasteh
Position

Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Clinical Pharmacy

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Full name of responsible person
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Position
Assistant Professor

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Person responsible for updating data

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Assistant Professor of Clinical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
All participants' information will be kept strictly confidential during and after the study

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

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

Informed Consent Form
No - There is not a plan to make this available

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

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

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