

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of the effectiveness of liposomal and ferrous iron in the treatment of iron deficiency in infants and children

Protocol summary

Study aim

With due attention to the importance and serious complications of iron deficiency and the need to treat it and find an easy method in children with maximum effectiveness, this clinical trial is conducted to compare the effectiveness of liposomal iron with previous formulations in children with iron deficiency.

Design

In a randomized, double-blind clinical trial, phase 4, children at 6 months to 2 years of age will be enrolled in the study. Infants with iron deficiency will be randomly assigned to two groups by simple lottery method.

Settings and conduct

Children between 6 months to 2 years of age with iron deficiency who refer to the pediatrics clinic at Amir Al-Momenin hospital or maternal and child health care centers of Semnan will be randomly assigned to two groups, the first group will receive liposomal iron and the second group will receive ferrous supplements. A complete blood cell count and measurement of iron, ferritin and TIBC levels are performed before the intervention and at the end of the fourth and twelfth weeks after intervention and at the end of the twelfth week, the occurrence of any side effects after intervention will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: infants with iron deficiency. Non-inclusion criteria: history of taking iron supplements; hemoglobinopathy; severe anemia; asthma; malignancy; active infection; renal dysfunction.

Intervention groups

Intervention group: the first group receives liposomal iron equivalent to 6 mg of elemental iron per kilogram of body weight, at a maximum dose of 200 mg daily. Control group: the second group receives ferrous iron equivalent to 6 mg of elemental iron per kilogram of body weight, at a maximum dose of 200 mg daily.

Main outcome variables

The main outcome variables are included changes in

hematology index, hemoglobin, hematocrit, iron, ferritin and TIBC levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N17**

Registration date: **2023-04-15, 1402/01/26**

Registration timing: **prospective**

Last update: **2023-04-15, 1402/01/26**

Update count: **0**

Registration date

2023-04-15, 1402/01/26

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7844

Email address

mehrdadzahmatkesh@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of liposomal and ferrous iron in the treatment of iron deficiency in infants and children

Public title

Effectiveness of liposomal and ferrous iron in the treatment of iron deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with iron deficiency and iron deficiency anemia

Exclusion criteria:

A history for use of iron supplements Hemoglobinopathy

Severe anemia or anemia due to other causes Asthma

Malignancy Active infection Renal dysfunction

Age

From **6 months** old to **2 years** old

Gender

Both

Phase

4

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, at first stage, 60 spheres from one to 60 are considered and following that will randomly divided into two equal parts, including "1" (Intervention1) and group 2 (Intervention2), and then using a lottery container, the ball of each group taken out and the intended sequence will be recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding of the study is such that the care provider, outcome assessor and biostatistician do not know the content of the intervention. For administration, the drug will be given to the clinical care provider for administration by mentioning the administration method. The outcome assessor records the outcome based on the patient's identity number according to the randomization table, and the data collected based on the number and mention of the first and second intervention is provided to the biostatistician for analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Basidj Blvd.

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-12-28, 1400/10/07

Ethics committee reference number

IR.SEMUMS.REC.1400.231

Health conditions studied

1

Description of health condition studied

Iron deficiency

ICD-10 code

E61.1

ICD-10 code description

Iron deficiency

2

Description of health condition studied

Iron deficiency anemia

ICD-10 code

D50.8

ICD-10 code description

Other iron deficiency anemias

Primary outcomes

1

Description

Serum Iron

Timepoint

Before and 4 and 12 weeks after intervention

Method of measurement

Biochemical test

2

Description

Ferritin

Timepoint

Before and 4 and 12 weeks after intervention

Method of measurement

Biochemical test

3**Description**

Total Iron-Binding Capacity

Timepoint

Before and 4 and 12 weeks after intervention

Method of measurement

Biochemical test

4**Description**

Hemoglobin

Timepoint

Before and 4 and 12 weeks after intervention

Method of measurement

Hematological test

5**Description**

Hematocrit

Timepoint

Before and 4 and 12 weeks after intervention

Method of measurement

Hematological test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The liposomal iron, equivalent to 6 mg/kg/day of elemental iron is prescribed with a maximum dose of 200 mg/day.

Category

Treatment - Drugs

2**Description**

Control group: The ferrous iron equivalent to 6 mg/kg/day of elemental iron is prescribed with a maximum dose of 200 mg/day.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir-Al-Momenin hospital

Full name of responsible person

Maryam Nomani

Street address

No. 9771, Shahid Mostafa Khomeini Blvd.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

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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

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Maryam Nomani

Position

دستیار کودکان

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Mehrdad Zahmatkesh

Position

Research Expert

Latest degree

Bachelor

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Mehri Ayati

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person**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

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be presented anonymously.

When the data will become available and for how long

After publishing of the results, the data will be delivered upon request and after verification.

To whom data/document is available

The data will be available only for academic researchers.

Under which criteria data/document could be used

In order to conduct similar studies.

From where data/document is obtainable

Direct request from the scientific responsible.

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

After request and authentication, the data will be provided.

Comments