Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 referr 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

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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
Hemoglubin
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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
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