

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

A Comparative Study of the Effect of Iron Supplements in Ferrous Sulfate and Ferrous Gluconate on Prophylaxis of Iron Deficiency in 6-24 Months Children Referring to Amirkabir Hospital in Arak

Protocol summary

Blood indexes, ferritin, anorexia, diarrhea, constipation

Study aim

Comparison of ferrous sulfate and ferrous gluconate supplementation with iron supplementation in prophylaxis of iron deficiency in children 6 to 18 months old referred to Amir Kabir hospital in Arak

Design

This study is a randomized clinical trial that will be conducted as a single blind. Are blind. In this study, 120 healthy 6- to 18-month-old children (two groups of 60 each) were recruited using the easy-to-select based on the pair-wise and individual-based clinic design and divided into two groups of amlodipine and control groups.

Settings and conduct

This study is a randomized clinical trial that will be performed as single blind on all healthy children 6 to 18 months old referred to Amir Kabir Hospital in Arak. The statistician who manages the data analysis is blind to the groups, and the pediatrician, interns responsible for the study, and the families of the children participating in the study are aware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children referred to Amir Kabir Hospital in Arak who are 6 months to 18 months old with birth weight above 2500 gr and gestational age 42-37 weeks are fully term. Exclusion criteria: Children with underlying hematological disease or any anemia, birth weight less than 2500 grams and gestational age below 37 weeks, or infants who have not been breastfed since birth.

Intervention groups

In this study 120 healthy children 6 to 18 months of age were divided into two groups of 60 and iron supplemented for 6 months with 15 mg daily ferrous sulfate iron in one group and 15 mg ferrous gluconate iron in the other group.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190902044674N1**

Registration date: **2019-11-07, 1398/08/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-07, 1398/08/16**

Update count: **0**

Registration date

2019-11-07, 1398/08/16

Registrant information

Name

Sanaz Khodabakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 1878

Email address

s.khodabakhshi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study of the Effect of Iron Supplements in Ferrous Sulfate and Ferrous Gluconate on Prophylaxis of Iron Deficiency in 6-24 Months Children Referring to Amirkabir Hospital in Arak

Public title

The effect of ferrous sulfate and ferrous gluconate on the prevention of iron deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6 months to 18 months. Children with birth weight above 2500 gr and gestational age 42-37 weeks and full term

Exclusion criteria:

Children with underlying hematologic disease or any anemia Children weighing less than 2500 grams and gestational age below 37 weeks Infants who have not been breastfed since birth. Children who have started iron supplementation earlier than 6 months due to birth defects or anemia.

Age

From **6 months** old to **24 months** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 120 patients were recruited using the easy-to-select based on the pair-wise and individual-based clinic design and divided into two groups of amlodipine and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blindness is due to being single-blind so the statistician who analyzes the data is blind to the groups, and the pediatrician, interns in charge of the study, and the families of the children participating in the study are aware of the groups under study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Sardasht Sq., Peyambar-e-azam Complex

City

اراک

Province

Markazi

Postal code

3819693345

Approval date

2019-04-07, 1398/01/18

Ethics committee reference number

IR.ARAKMU.REC.1398.016

Health conditions studied

1

Description of health condition studied

Iron Deficiency

ICD-10 code

E61.1

ICD-10 code description

Iron deficiency

Primary outcomes

1

Description

ferritin serum level

Timepoint

Before intervention and 6 months later

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Take 15 mg ferrous gluconate daily for 6 months

Category

Treatment - Drugs

2

Description

Control group: Take 15 mg ferrous sulfate daily for 6 months

Category
Treatment - Drugs

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir Hospital
Full name of responsible person
Sanaz Khodabakhshi
Street address
Parastar Sq., Shiroudi St.
City
Arak
Province
Markazi
Postal code
۳۸۱۹۶۹۳۳۴۰
Phone
+98 86 3313 4715
Email
info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Payambar-e-azam Complex, Sardasht Sq.
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3417 3639
Email
research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Sanaz Khodabakhshi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
No. 3, Sam Apartment, Arghavan Alley, Bagh-e-daryache St.
City
Isfahan
Province
Isfahan
Postal code
8176763331
Phone
+98 31 3786 1878
Email
s.khodabakhshi@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Sanaz Khodabakhshi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
No. 3, Sam Apartment, Arghavan Alley, Bagh-e-daryache St.
City
Isfahan
Province
Isfahan
Postal code
8176763331
Phone
+98 31 3786 1878
Email
s.khodabakhshi@arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Sanaz Khodabakhshi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No. 3, Sam Apartment, Arghavan Alley, Bagh-e-daryache St.

City

Isfahan

Province

Isfahan

Postal code

8176763331

Phone

+98 31 3786 1878

Email

s.khodabakhshi@arakmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

Undecided - It is not yet known if there will be 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