# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of iron supplement effects on neonatal growth indexes, initiated from first 4th and 6th months of life: A randomized clinical trial

## Protocol summary

**Study aim**

The purpose of this study was to evaluate the effect of initiation of iron supplementation at the end of 4 months, compared to 6 months of age, on growth indices in infants.

**Design**

Randomized, blinded, sham controlled clinical trial with a parallel group design of 100 infants, 50 patients in the intervention group (starting an iron drop from 4 months) and 50 in the control group (starting the iron drop from 6 months of age ).

**Settings and conduct**

The aim of this study was to investigate the effect of early onset of iron supplementation on growth indices in infants (height, weight and head circumference) in specialty and postgraduate specialty clinic of Heshamateyeh Hospital in Sabzevar city. In this study, only those who evaluated the outcome in infants were unaware of how infants were grouped. Infants are randomly assigned to the intervention group (the start of iron drop at the end of 4 months of age at dosage of 2 mg/kg) and the control (starting the iron drop at the end of 6 months of age at dosage of 2 mg/kg). Growth index will be compared in two groups by the end of the 12th month.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria consisted infants aged 4 to 12 months, gestational age greater than 37 weeks, birth weight more than 2500 grams and without congenital anomalies.

**Intervention groups**

Starting iron supplementation at the end of 4 months as an intervention group and from 6 months as a control group.

**Main outcome variables**

Infant growth indices (height, weight and head circumference) by the end of the 12th month

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180305038958N1**
Registration date: **2018-08-20, 1397/05/29**
Registration timing: **retrospective**

Last update: **2018-08-20, 1397/05/29**
Update count: **0**

**Registration date**

2018-08-20, 1397/05/29

**Registrant information**

**Name**

Zahra Khaksar

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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+98 51 4401 1300

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2017-04-21, 1396/02/01

**Expected recruitment end date**

2018-04-21, 1397/02/01

**Actual recruitment start date**

2017-04-21, 1396/02/01

**Actual recruitment end date**

2018-06-11, 1397/03/21

**Trial completion date**

empty

**Scientific title**

Comparison of iron supplement effects on neonatal growth indexes, initiated from first 4th and 6th months of life: A randomized clinical trial

**Public title**
Comparison of initiation of iron supplementation at the end of 4 months and 6 months of age on height, weight and head circumference of infants
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Infants 4 to 12 months old Gestational age more than 37 weeks Birth weight more than 2500 grams Singleton
**Exclusion criteria:**
Congenital anomalies History of addiction in mother
**Age**
From **4 months** old to **12 months** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **100**
Actual sample size reached: **100**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Block randomization based on permutation. Accordingly, 25 blocks were allocated to patients, in each block, 2 from A treatment group and 2 from B treatment group were placed. Eventually, after completion of the blocks, group A was treated with iron drops from 4 months of age and Group B received iron drops at 6 months of age.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Each person in the study will be assigned code A and B, that the researcher will only be known of the type of groups and the outcome evaluator is unaware of the groups. It should be noted that the participants can not be blinded to the intervention or control group.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Sabzevar University of Medical Sciences
**Street address**
Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar Town
**City**
Sabzevar
**Province**
Razavi Khorasan
**Postal code**
9613873136
**Approval date**
2017-08-15, 1396/05/24
**Ethics committee reference number**
IR.MEDSAB.REC.1369.48

## Health conditions studied

### 1

**Description of health condition studied**
Infant Growth Index
**ICD-10 code**
P61.3
**ICD-10 code description**
Congenital anaemia from fetal blood loss

## Primary outcomes

### 1

**Description**
The weight of the infants
**Timepoint**
Weight measurement at birth and 2, 4, 6, 9 and 12 months
**Method of measurement**
Baby scales with a capacity of 20 kg with a precision of 20 g to 20 kg

## Secondary outcomes

### 1

**Description**
The height of infant
**Timepoint**
Measuring height at birth and 2, 4, 6, 9 and 12 months
**Method of measurement**
Meters with millimeter precision

### 2

**Description**
Infant head circumference
**Timepoint**
Measuring head circumference at birth and 2, 4, 6, 9 and 12 months
**Method of measurement**
Meters with millimeter precision

## Intervention groups

### 1

**Description**
Intervention group: Starting an iron ferrous sulfate drop (Iranian Simorgh Darou Attar Company) from the end of 4 months with a dose of 2 mg/kg until the end of 24 months of infancy
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Starting an iron ferrous sulfate drop (Iranian Simorgh Darou Attar Company) from the 6 months of ages with a dose of 2 mg/kg until the end of 24 months of infancy
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Heshamati Hospital Clinic
**Full name of responsible person**
Seyed Mohsen Emami
**Street address**
Heshamati Hospital, Asadabad Ave., Sabzevar Twon
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5144011604
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**Email**
Mohsenemami007@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Sabzevar University of Medical Sciences
**Full name of responsible person**
Omid Gholami
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Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Twon
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**Email**
omid693@yahoo.com
**Web page address**
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Sabzevar 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**
Sabzevar University of Medical Sciences
**Full name of responsible person**
Seyed Mohsen Emami
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Pediatrics
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## Person responsible for scientific inquiries

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**Position**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Sabzevar University of Medical Sciences

**Full name of responsible person**
Zahra Khaksar

**Position**
Medical student

**Latest degree**
Medical doctor

**Other areas of specialty/work**
General Practitioner

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**Email**
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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**
No more information

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

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

**Clinical Study Report**
No - There is not a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available