

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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)

##### Phone

+98 51 4401 1300

##### Email address

khaksarZ89@medsab.ac.ir

##### 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 |                                                                                                                                                                                                                                                                                                                                         |
| <b>Public title</b>                                                                                                                            | 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                                                                                                                                                                                         |
| <b>Purpose</b>                                                                                                                                 | Prevention                                                                                                                                                                                                                                                                                                                              |
| <b>Inclusion/Exclusion criteria</b>                                                                                                            |                                                                                                                                                                                                                                                                                                                                         |
| <b>Inclusion criteria:</b>                                                                                                                     | Infants 4 to 12 months old Gestational age more than 37 weeks Birth weight more than 2500 grams Singleton                                                                                                                                                                                                                               |
| <b>Exclusion criteria:</b>                                                                                                                     | Congenital anomalies History of addiction in mother                                                                                                                                                                                                                                                                                     |
| <b>Age</b>                                                                                                                                     | From <b>4 months</b> old to <b>12 months</b> old                                                                                                                                                                                                                                                                                        |
| <b>Gender</b>                                                                                                                                  | Both                                                                                                                                                                                                                                                                                                                                    |
| <b>Phase</b>                                                                                                                                   | 3                                                                                                                                                                                                                                                                                                                                       |
| <b>Groups that have been masked</b>                                                                                                            | <ul style="list-style-type: none"> <li>Outcome assessor</li> </ul>                                                                                                                                                                                                                                                                      |
| <b>Sample size</b>                                                                                                                             | Target sample size: <b>100</b><br>Actual sample size reached: <b>100</b>                                                                                                                                                                                                                                                                |
| <b>Randomization (investigator's opinion)</b>                                                                                                  | Randomized                                                                                                                                                                                                                                                                                                                              |
| <b>Randomization description</b>                                                                                                               | 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. |
| <b>Blinding (investigator's opinion)</b>                                                                                                       | Single blinded                                                                                                                                                                                                                                                                                                                          |
| <b>Blinding description</b>                                                                                                                    | 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.                                                              |
| <b>Placebo</b>                                                                                                                                 | Not used                                                                                                                                                                                                                                                                                                                                |
| <b>Assignment</b>                                                                                                                              | Parallel                                                                                                                                                                                                                                                                                                                                |
| <b>Other design features</b>                                                                                                                   |                                                                                                                                                                                                                                                                                                                                         |
| <b>Secondary Ids</b>                                                                                                                           | empty                                                                                                                                                                                                                                                                                                                                   |
| <b>Ethics committees</b>                                                                                                                       |                                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                                                                                                                |                                                                                                                                                                                                                                                                                                                                         |
| <b>Ethics committee</b>                                                                                                                        |                                                                                                                                                                                                                                                                                                                                         |
| <b>Name of ethics committee</b>                                                                                                                | Ethics committee of Sabzevar University of Medical Sciences                                                                                                                                                                                                                                                                             |
| <b>Street address</b>                                                                                                                          | Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar Town                                                                                                                                                                                                                                                                      |
| <b>City</b>                                                                                                                                    | Sabzevar                                                                                                                                                                                                                                                                                                                                |
| <b>Province</b>                                                                                                                                | Razavi Khorasan                                                                                                                                                                                                                                                                                                                         |
| <b>Postal code</b>                                                                                                                             | 9613873136                                                                                                                                                                                                                                                                                                                              |
| <b>Approval date</b>                                                                                                                           | 2017-08-15, 1396/05/24                                                                                                                                                                                                                                                                                                                  |
| <b>Ethics committee reference number</b>                                                                                                       | IR.MEDSAB.REC.1369.48                                                                                                                                                                                                                                                                                                                   |
| <b>Health conditions studied</b>                                                                                                               |                                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                                                                                                                |                                                                                                                                                                                                                                                                                                                                         |
| <b>Description of health condition studied</b>                                                                                                 | Infant Growth Index                                                                                                                                                                                                                                                                                                                     |
| <b>ICD-10 code</b>                                                                                                                             | P61.3                                                                                                                                                                                                                                                                                                                                   |
| <b>ICD-10 code description</b>                                                                                                                 | Congenital anaemia from fetal blood loss                                                                                                                                                                                                                                                                                                |
| <b>Primary outcomes</b>                                                                                                                        |                                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                                                                                                                |                                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                                                                                                                             | The weight of the infants                                                                                                                                                                                                                                                                                                               |
| <b>Timepoint</b>                                                                                                                               | Weight measurement at birth and 2, 4, 6, 9 and 12 months                                                                                                                                                                                                                                                                                |
| <b>Method of measurement</b>                                                                                                                   | Baby scales with a capacity of 20 kg with a precision of 20 g to 20 kg                                                                                                                                                                                                                                                                  |
| <b>Secondary outcomes</b>                                                                                                                      |                                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                                                                                                                |                                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                                                                                                                             | The height of infant                                                                                                                                                                                                                                                                                                                    |
| <b>Timepoint</b>                                                                                                                               | Measuring height at birth and 2, 4, 6, 9 and 12 months                                                                                                                                                                                                                                                                                  |
| <b>Method of measurement</b>                                                                                                                   | Meters with millimeter precision                                                                                                                                                                                                                                                                                                        |
| <b><u>2</u></b>                                                                                                                                |                                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                                                                                                                             | Infant head circumference                                                                                                                                                                                                                                                                                                               |
| <b>Timepoint</b>                                                                                                                               | Measuring head circumference at birth and 2, 4, 6, 9 and 12 months                                                                                                                                                                                                                                                                      |
| <b>Method of measurement</b>                                                                                                                   | 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

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

5144011604

##### Phone

+98 51 4401 1601

##### 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

##### Street address

Sabzevar University of Medical Sciences, Tohid Blvd.,  
Sabzevar Twon

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913114

##### Phone

+98 51 4401 8319

##### 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

##### Street address

Sabzevar University of Medical Sciences, Tohid Blvd.,  
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## Person responsible for scientific 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 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

**Street address**

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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