

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effects of iron supplementation on neurocognitive development of children

Protocol summary

Study aim

The study's main objective is to perform randomized control trial to determine the effect of iron supplementations on the neurocognitive development of infants.

Design

A concealed, randomized, single blinded, clinical trial with a parallel group design of 204 patients, enrolled between April 2023 and October 2023, and followed up after one year post conceptional age.

Settings and conduct

The study will be conducted one year after approval of the synopsis from the research and ethics committee (REC) of Sheikh Zaid Hospital Rahim Yar Khan and UHS Lahore.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients born between 34 and 36weeks gestational age. 2. Infants older than 1 month of age and tolerating enteral feeds. 3. Parental permission was obtained prior to the start of the study. Exclusion criteria: 1. Significant intrauterine growth limitation, birth weight less than 2000 g, or tiny for maternal age (<3rd centile) 2. Congenital illnesses, presumed disorders, or severe congenital malformation. 3. Birth asphyxia 4. Neurological and neuro-sensory disorders, cerebral anomalies, or hematologic disorders. 5. Infants having a history of any blood transfusion will be excluded. 6. Parents gave no consent, 7. Unable to return for follow-up evaluation at 1 year of age.

Intervention groups

Using a computer-generated randomization process, the infants will be randomly allocated into two groups (Group 1: iron group; Group 2: Placebo).

Main outcome variables

Primary Outcome: 1. Neurodevelopmental outcome in infants at twelve months of age using scale "Portage guide to early education (PGEE)." Secondary Outcome: 1. Iron deficiency: 2. Weight: 3. Length:

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210205050253N1**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **prospective**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Muhammad Bilal

Name of organization / entity

Sheikh zayed college/hospital Rahim yar kan

Country

Pakistan

Phone

+92 21 86705503

Email address

Info@szmc.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-01, 1402/01/12

Expected recruitment end date

2023-10-01, 1402/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of iron supplementation on neurocognitive development of children

Public title

Effects of iron supplementation on neurocognitive development

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Patients born between 34 and 36 weeks gestational age. 2. Infants older than 1 month of age and tolerating enteral feeds 3. Parental permission was obtained prior to the start of the study.

Exclusion criteria:

1. Significant intrauterine growth limitation, birth weight less than 2000 g, or tiny for maternal age (<3rd centile) 2. Congenital illnesses, presumed disorders, or severe congenital malformation 3. Birth asphyxia 4. Neurological and neuro-sensory disorders, cerebral anomalies, or hematologic disorders. 5. Infants having a history of any blood transfusion will be excluded. 6. Parents gave no consent 7. Unable to return for follow-up evaluation at 1 year of age.

Age

From **1 month** old to **1 month** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a computer-generated randomization process, the infants will be randomly allocated into two groups (Group 1: iron group; Group 2: Placebo). Group A (iron group) will receive iron supplementation at 2mg/kg/day when the infant is on enteral feeds and at least one month old. It will be continued till 6 months of post-conception age. Group B will receive a placebo. At the six-month assessment, children who have not taken the research medicine more than 80% of the prescribed days will be categorized as poor complainers and removed from the research. Before participating in the randomization, all registered newborns will get a complete blood count examination at one month of age to rule out anemia. According to Jopling et al. (2009) primary parameter, the cutoff for anemia at one month of age will be hemoglobin 11 g/dL for infants 35-36 gestational age and 10.5 g/dL for infants 34 gestational age. At 6 months and 12 months post-conception, a general medical examination will be carried out to ensure conformity with the medication protocol and assessment of anthropometric measures. Haemoglobin 10.5 g/dL will be the cutoff for anemia at the 6- and 12-month assessments. All patients will be assessed for the psychomotor outcome at 12

months of age using a scale named "Portage guide to early education (PGEE)." This scale contains 5 parameters, i.e., cognition, self-help, motor, socialization, and language. The test will be stopped if the child does not fulfill seven consecutive behaviors from a PGEE scale parameter. For each scale, a mental age and a developmental quotient will be provided (DQ). The mean of the developmental quotients obtained in each of the five subscales will be used to compute the overall development quotient. If the developmental quotient is higher than 85%, between 85% and 70%, or less than 70%, it will be deemed "borderline" and indicative of developmental problems

Blinding (investigator's opinion)

Single blinded

Blinding description

Group A (iron group) will receive iron supplementation at 2mg/kg/day when the infant is on enteral feeds and at least one month old. It will be continued till 6 months of post-conception age. Group B will receive a placebo. As this is single blinded study so participants will be blinded only.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical review committee Sheikh Zayed Hospital

Street address

Hospital Road, Sheikh zayed Hospital Rahim yar khan

City

Rahim Yar khan

Postal code

64200

Approval date

2021-02-13, 1399/11/25

Ethics committee reference number

195/IRB/SZMC/SZH

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

1. Neurodevelopmental outcome

Timepoint

12 months of age. 6 months after intervention

Method of measurement

All patients will be assessed for the psychomotor outcome at 12 months of age using a scale named "Portage guide to early education (PGEE)." This scale contains 5 parameters, i.e., cognition, self-help, motor, socialization, and language. The test will be stopped if the child does not fulfill seven consecutive behaviors from a PGEE scale parameter.

2

Description

1. Iron deficiency

Timepoint

1 month, 6th month and 12th month

Method of measurement

CBC

3

Description

Length

Timepoint

1 month, 6th month and 12th month

Method of measurement

Measuring tape

4

Description

Weight

Timepoint

1 month, 6th month and 12th month

Method of measurement

Weight machine

Secondary outcomes

empty

Intervention groups

1

Description

After getting informed consent from the parents, patients will be divided into two groups. A total of 204 cases will be included in the study for research. Group A (iron group) will receive iron supplementation at 2mg/kg/day. It will be continued till 6 months of post-conception age. Group B will receive a placebo. All patients will be assessed for the psychomotor outcome at 12 months of age using a scale named "Portage guide to early education (PGEE)." This scale contains 5 parameters, i.e., cognition, self-help, motor, socialization, and language.

The test will be stopped if the child does not fulfill seven consecutive behaviors from a PGEE scale parameter.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikh Zayed Hospital

Full name of responsible person

Muhammad Bilal

Street address

Hospital Road Rahim Yar Khan

City

Rahim yar khan

Postal code

64200

Phone

+92 300 7641636

Email

dr.muhammadbilal@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sheikh Zayed Medical College / Hospital Rahim Yar Khan

Full name of responsible person

Muhammad Bilal

Street address

Hospital road

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Rahim Yar Khan

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dr.muhammadbilal@yahoo.com

Grant name

NA

Grant code / Reference number

NA

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sheikh Zayed Medical College / Hospital Rahim Yar Khan

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**

Sheikh Zayed Hospital RYK

Full name of responsible person

Muhammad Bilal

Position

Post graduate Trainee

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

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

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Full name of responsible person

Muhammad Bilal

Position

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Latest degree

Medical doctor

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

Sheikh Zayed Medical College / Hospital Rahim Yar Khan

Full name of responsible person

Muhammad Bilal

Position

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Effects of iron supplementation on neurocognitive development of children

When the data will become available and for how long

2025

To whom data/document is available

to all.

Under which criteria data/document could be used

Portage guide to early education scale data will be shared, along with weight, length and CBC data.

From where data/document is obtainable

IRCT or via email from the author

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

Prior permission from the author via mail

Comments