Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 (<3° 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
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Email address
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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 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 (<3° 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 complaints 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 committe 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sheikh Zayed Medical College / Hospital Rahim Yar Khan
Full name of responsible person
Muhammad Bilal
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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
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Person responsible for updating data

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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 permissionfrom the author via mail
Comments