Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study of the Effects of Perinatal Iron Deficiency and Its Treatment on Auditory Brainstem Evoked Response in Neonates at Risk of Latent Iron Deficiency in the Vali-e Asr Hospital Maternity Ward

Protocol summary

Summary

In the first phase, a prospective cohort study shall be conducted wherein maternal and cord blood samples will be taken after birth and will be sent to the laboratory for measurement of ferritin levels. Study infants will be divided into two groups, Serum Feritin≤75 and Serum Feritin>75 ng/mL. For initial assessment of nervous system development in the auditory pathway, bilateral monaural ABR shall be utilized within the first 48 hours after birth by an audiologist. The test is repeated three times and an average of the waves from two out of three of the tests is used for analysis. The ABR data is analyzed by an audiologist that is unaware of the iron levels. ABR results of the strongest ear, i.e. the ear with lowest latency of wave V in ABR, are utilized in the final analysis. Absolute latencies of waves I, III, and V and inter peak latencies (IPL) I-III, III-V, I-V are recorded as the outcomes indicating neurodevelopment. The second phase of the study will be a clinical trial using the same infants from the first phase of the study. In this phase, infants with Feritin concentrations corresponding to aforementioned definition of Latent Iron Deficiency, i.e. 11-75 ng/mL, will be administered with 1 mg/kg iron drops (ferrous sulfate) from the start of the third week after birth until the end of the infant's first month of life. At the end of the first month, ABR will be performed again and compared with the initial ABR.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709019568N18**
Registration date: **2017-09-30, 1396/07/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-30, 1396/07/08

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center,Tehran University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2357

Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Maternal Fetal and Neonatal Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effects of Perinatal Iron Deficiency and Its Treatment on Auditory Brainstem Evoked Response in Neonates at Risk of Latent Iron Deficiency in the Vali-e Asr Hospital Maternity Ward

Public title
Effects of Iron administration on Auditory Brainstem Evoked Response in neonates at Risk of Latent Iron Deficiency
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Neonates with gestational ages>35 weeks and weight over 2,500 grshowing at least one of the risk factors for in utero Latent Iron Deficiency including maternal diabetes, maternal gestational hypertension, intrauterine growth restriction, and Serum Feritin levels between 11-75 ng/mL. Exclusion criteria: Neonates with craniofacial anomalies, chromosome abnormalities, hemolytic diseases, history of infectious disease in the third trimester, clinical evidence of chorioamnionitis, 5-minute Apgar scores<5, evidence of TORCH infections, clinical or laboratory diagnosed sepsis, history of hospitalization in the NICU due to any medical issue.
Age
From **14 days** old to **30 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Ethics committee of Tehran University of Medical Sciences,6 th floor of Tehran University of Medical Sciences,ghods St., Keshavarz blv,Tehran, Iran
City
Tehran
Postal code
Approval date
2017-05-22, 1396/03/01
Ethics committee reference number
1396.3377

Health conditions studied

1

Description of health condition studied
Neonatal hearing impairment
ICD-10 code
H90.5
ICD-10 code description
Sensorineural hearing loss, unspecified

2

Description of health condition studied
Iron deficiency anemia
ICD-10 code
D-50
ICD-10 code description
anaemia

Primary outcomes

1

Description
neonatal hearing assessment
Timepoint
at birth and one month later
Method of measurement
ABR test

Secondary outcomes

empty

Intervention groups

1

Description
infants with Feritin concentrations corresponding to aforementioned definition of Latent Iron Deficiency, will be administered with 1 mg/kg iron drops (ferrous sulfate) from the start of the third week after birth until the end of the infant’s first month of life. At the end of the first month, ABR will be performed again and compared with the initial ABR.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Delivery Room, Vali e asr Hospital
Full name of responsible person

Dr. Elaheh Amini

Street address

Vali e asr Hospital,Imam Khomeini Hospital complexex, Keshavarz blv,14914, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maternal, Fetal & Neonatal Research Center, Tehran University of Medical Sciences

Full name of responsible person

Mamak Shariat

Street address

Vali e asr Hospital,Imam Khomeini Hospital complexex, Keshavarz blv,14914, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Maternal, Fetal & Neonatal Research Center, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Maternal Fetal and Neonatal Research Center

Full name of responsible person

Dr. Elaheh Amini

Position

Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Elaheh Amini

Position

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Person responsible for updating data

Contact

Name of organization / entity

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Dr. Elaheh Amini

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associate professor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty