

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Ferritin ≤ 75 and Serum Ferritin > 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 Ferritin 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 gr showing at least one of the risk factors for in utero Latent Iron Deficiency including maternal diabetes, maternal gestational hypertension, intrauterine growth restriction, and Serum Ferritin 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, 6th 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 Ferritin 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

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Vali e asr Hospital, Imam Khomeini Hospital
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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 updating data

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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