

# 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  $\leq 75$  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

**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**

**Street address**

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**Person responsible for scientific inquiries**

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**Position**

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**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*