Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Effect of Oral Erythropoietin on tolerance of oral feeding, Prevention of Complications and reduction of mortality in neonatal with hypoxic ischemic encephalopathy

Protocol summary

Study aim

The effect of oral erythropoietin on oral nutrition tolerance, prevention of complications and reduction of mortality in neonates with ischemic hypoxic encephalopathy

Design

Affected infants will be randomly divided into control and intervention groups. The intervention group will include infants who will be given oral erythropoietin at a dose of 400 units / kg daily within the first 48 hours of birth and for 5 days. The control group will receive standard asphyxia and placebo treatments. Normal saline will be given as a placebo in the same amount of oral or gastric catheter. Finally, the two groups in terms of oral feeding tolerance (feeding start time, 100 cc / kg full feeding time) will be considered as the primary outcome.

Settings and conduct

Neonates with a gestational age greater than and equal to 37 weeks (semesters and near semesters) and without structural anomalies during 1400-1699 in NICU of Imam Reza Hospital with HIE (ischemic hypoxic encephalopathy) grade 2 or 3, which is based on clinical and laboratory criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age more than or equal to 37 weeks, perinatal asphyxia, grade 2 and 3 encephalopathy Exclusion criteria: Birth weight <2200 g, A genetic or congenital disease that affects nerve growth or requires multiple surgeries, Head circumference <30 cm, Polycythemia, The infant should participate in another intervention period during hospitalization, Asphyxia cases without HIE, Metabolic diseases, Confirmed infection

Intervention groups

The intervention group will include infants who will be given oral erythropoietin ampoules at a dose of 400 units / kg daily within a maximum of 48 hours of birth and will be prescribed for 5 days.

Main outcome variables

The two groups in terms of oral feeding tolerance (feeding start time, time to complete feeding 100 cc / kg) as primary outcome will be considered

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140907019076N2**
Registration date: **2021-06-19, 1400/03/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-19, 1400/03/29**
Update count: **0**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 261 7030

Email address

saeedir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Oral Erythropoietin on tolerance of oral feeding, Prevention of Complications and reduction of mortality in neonatal with hypoxic ischemic encephalopathy

Public title

Effect of Oral Erythropoietin in neonatal with hypoxic ischemic encephalopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age more than and equal to 37 weeks prenatal asphyxia Grade 2 and 3 encephalopathy Conscious consent of parents

Exclusion criteria:

Birth weight <2200 g A genetic or congenital disease that affects nerve growth or requires multiple surgeries Head circumference <30 cm Polycythemia The infant should participate in another intervention period during hospitalization Asphyxia cases without HIE Metabolic diseases Confirmed infection

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The study design is done in parallel in which the two groups are compared over time. The simple randomization method is using a table of random numbers using the site www.randomization.com. Concealment is done through sealed envelopes. The method of the envelope is that the envelopes will be prepared and printed by a member of the research team and random numbers with the help of Randomaize.com and placed inside the envelope. The lid of the envelope will be closed and its contents will not be visible from the outside. Then, the purpose of the study is first explained to the person who meets the conditions, and the person, if he wishes, signs the informed consent form and takes an envelope, and then opens it and enters the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects and evaluators will be unaware of the intervention and control groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of MashhadUniversity of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciencs (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-08-18, 1399/05/28

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.342

Health conditions studied

1

Description of health condition studied

Ischemic hypoxic encephalopathy

ICD-10 code

P91.6

ICD-10 code description

Hypoxic ischemic encephalopathy [HIE]

Primary outcomes

1

Description

Effect of Oral Erythropoietin on tolerance of oral feeding, Prevention of Complications and reduction of mortality in neonatal with hypoxic ischemic encephalopathy

Timepoint

In the erythropoietin intervention group, orally within the first 48 hours of birth at a dose of 400 units per kilogram daily for 5 days (days 7,5,3,1,2)

Method of measurement

By mouth or stomach catheter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Erythropoietin is administered orally within the first 48 hours of birth dose 400 units per kg daily for 5 days (days 7, 5, 3, 1, 2) in addition to standard treatment for newborns.
Category
Placebo

2

Description
Control group: newborns receive standard asphyxia treatment, including fluid restriction and placebo. The normal saline placebo will be given in the same amount as the oral or gastric catheter.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Saeedeh Eshkil
Street address
Neonatal Intensive Care Unite, Imam Reza Hospital, Ibn Sina Ave, Mashhad, Iram
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Mashhad
Province
Razavi Khorasan
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9137913316
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+98 51 3852 1121
Email
eshkils@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
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Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3852 1121
Email
ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences
Full name of responsible person
Saeedeh Eshkil
Position
neonatology
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Neonatal intensive care unite, Imam reza hospital, Ibn Sina Ave, Mashhad, Iran
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eshkils@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person

Saeedeh Eshkil

Position
Neonatology

Latest degree
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Person responsible for updating data

Contact

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Full name of responsible person
Saeedeh Eshkil

Position
neonatology

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Email
eshkils@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data can be shared after patients are made unidentified.

When the data will become available and for how long
Data can be accessible 6 months after results are published

To whom data/document is available
data can be accessible through an email to the corresponding author

Under which criteria data/document could be used
Data will be available for researchers in universities and other scientific institution.

From where data/document is obtainable
After sending a request email to the corresponding author, data will be sent in 1 month.

What processes are involved for a request to access data/document
Carrying out analysis on data is permitted

Comments