Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Effect of high versus low dose of human recombinant erythropoietin on the Anemia of prematurity

Protocol summary

Summary

Anemia of prematurity appears after the second week of life and its intensity is in the second month. Erythropoietin accelerates erythropoietin response and the presence of sensitive red cells so it is described for treatment of anemia of prematurity. This is a prospective study that evaluates two methods of high dose versus low dose of erythropoietin in treatment of anemia of prematurity in newborns that are admitted in NICU of Emamreza hospital. Premature infants randomly divide in two groups. High dose group receive 500 u/kg erythropoietin twice weekly and low dose group receive 500 u/kg erythropoietin weekly. All newborns are breast milk and receive supplemental iron. Hemotocrite and reticulocyte count at the beginning, third day from the start day and one week after the end of treatment will be checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711201162N13**
Registration date: **2009-06-07, 1388/03/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-06-07, 1388/03/17

Registrant information

Name

Ashraf Mohammadzadeh

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 1121

Email address

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Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2001-05-04, 1380/02/14

Expected recruitment end date

2002-05-04, 1381/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high versus low dose of human recombinant erythropoietin on the Anemia of prematurity

Public title

Effect of high versus low dose of human recombinant erythropoietin on the Anemia of prematurity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age less than 34 weeks, breast milk feeding, hematocrit <30% when infant age is between 2 to 3 weeks or HCT<25% when infant age is more than 3 weeks. Exclusion criteria: Infants with hemolytic anemia, active bleeding or congenital malformation.

Age

No age limit

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research of Mashhad University of medical sciences
Street address
Ghoreshi building, Daneshgah street
City
Mashhad
Postal code
13131-91379
Approval date
2002-07-05, 1381/04/14
Ethics committee reference number
1427 ت

Health conditions studied

1

Description of health condition studied
anemia of prematurity
ICD-10 code
P61.2
ICD-10 code description
Anaemia of prematurity

Primary outcomes

1

Description
Hemotocrite and reticulocyte count
Timepoint
the beginning, third day and one week after the end of treatment
Method of measurement
venous sampling and laboratory measurement

Secondary outcomes

empty

Intervention groups

1

Description
Group 1 received erythropoietin 500 unite/kg twice in week along with supplemental iron
Category
empty

2

Description
Group 2 received erythropoietin 500 unite/kg once in week along with supplemental iron
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU Emaereza hospital
Full name of responsible person
Dr.Ashraf mohammadzadeh
Street address
NICU- Emamreza hospital
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad university of medical sciences
Full name of responsible person
Dr jalil tavakol afshari
Street address
Ghoreshi bulding-daneshgah street
City
Mashhad
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
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
Neonatal Research Center
Full name of responsible person
Dr. Ashraf mohammadzadeh
Position
Neonatologist, professor
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

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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