Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the Effect of Human Recombinant Erythropoietin on Reducing Need to Blood Transfusion in Very-Low-Birth-Weight Infants

Protocol summary

Summary

Premature infants with very low birth weight often develop anemia that need to transfusion and blood transfusion have its side effects. The exogen human erythropoietin is used for preventing and treating anemia of prematurity. In this research we study the effect of recombinant human erythropoietin in reducing need to transfusion in very-low-birth-weight infants. Material and Methods: This study is performed in NICU of Fatemieh hospital, Hamadan, Iran. Thirty neonate with birth weight less than 1500 grams and gestational age equal or less than 31 weeks, who have hematocrit less than 40% and receive at least 50% of their calories by enteral route, are included and randomly divided to two groups: intervention and control (15 patients in each group). In control group, ferrous sulfate drop (4mg/kg/day) is administered and in intervention group, in addition to ferrous sulfate drop, Eprex 2000 IU- 250 IU/kg three times in a week is administered subcutaneously. Hemoglobin and hematocrit and reticulocyte count and patient's weight are recorded at the first of study and the end of first and second and third weeks of study. Need to transfusion and its times will be recorded in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112265110N2**
Registration date: **2012-03-22, 1391/01/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-03-22, 1391/01/03

Registrant information

Name

Behnaz Basiri

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2008-12-08, 1387/09/18

Expected recruitment end date

2010-03-09, 1388/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Human Recombinant Erythropoietin on Reducing Need to Blood Transfusion in Very-Low-Birth-Weight Infants

Public title

The Effect of Erythropoeitin on Anemia of Prematurity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Neonates with birth weight less than 1500 gram; gestational age less than 31 weeks; post natal age at Least 6 days; received calories at least 50 Kcal/kg, at Least 50% in enteral route; Hct=< 40%.

Exclusion criteria: Severe congenital anomalies, dysmorphic syndromes; hemolytic anemia; severe acute infections.

Age
From **6 years** old to **28 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, Fahmideh Street

City
Hamadan

Postal code
65178/518

Approval date
2011-05-29, 1390/03/08

Ethics committee reference number
783/9/35/16/د/پ

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
Need to transfusion

Timepoint
At the end of treatment

Method of measurement
The number of transfusions

Secondary outcomes

1

Description
Hemoglobin, Hematocrit, Reticulocyte count

Timepoint
Weekly

Method of measurement
CBC

2

Description
Weight of neonate

Timepoint
weekly

Method of measurement
Seca scale

Intervention groups

1

Description
Intervention group: Eprex 2000 IU Ampule 250 IU/kg 3 Times in a Week s/c and ferrous sulfate drop 4 mg/kg/day

Category
Treatment - Drugs

2

Description
Control group: Administration of Ferrous Sulfate Drop 4mg/kg

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital

Full name of responsible person
Dr. Behnaz Basiri

Street address
Pasdaran Street

City

Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Tchnology, Hamadan University of Medical Sciences
Full name of responsible person
Mis. Asgarnia
Street address
Hamadan University Of Medical Science, Fahmideh Street
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Tchnology, Hamadan 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
Hamadan University of Medical Sciences
Full name of responsible person
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Position
Neonatologist
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Web page address

Person responsible for updating data

Contact

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