

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Fatemeh 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)

Phone

+98 81 1821 3770

Email address

b.basiri@umsha.ac.ir

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 Erythropoietin 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= \leq 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

Dr.Behnaz Basiri

Position

Neonatologist

Other areas of specialty/work

Street address

NICU, Fatemieh Hospital, Pasdaran Street

City

Hamadan

Postal code

6517789975

Phone

+98 81 1827 7082

Fax

Email

b.basiri@umsha.ac.ir
behnazbasiri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr.Behnaz Basiri

Position

Neonatologist

Other areas of specialty/work

Street address

NICU, Fatemieh Hospital, Pasdaran Street

City

Hamadan

Postal code

6517789975

Phone

+98 81 1827 7082

Fax

Email

b.basiri@umsha.ac.ir

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