

# 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 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

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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*