

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of early erythropoietin administration on erythropoiesis in preterm infants

Protocol summary

Summary

Objective: The effect of early erythropoietin administration on erythropoiesis in preterm infants.
Sample size: This study is doing on the 44 infants that they will born in the Afzalipour hospital, Kerman, Iran.
Inclusion Criteria: premature infants with birth weight<1800g and gestational age<34week that their cardiorespiratory condition are stable. Exclusion Criteria: a major congenital malformation, severe asphyxia, a positive direct antiglobulin test with clinical symptom of hemolytic anemia, surgical problems, exchange transfusion, dependent on mechanical ventilation.
Intervention: Treated infants receive 500 u/kg/wk rhu EPO, 2 times weekly, administered subcutaneously in lateral side of thigh. Infants in control group don't receive placebo. Treatment continues until 4 weeks after beginning. Treated and control infants receive 3 mg/kg/day iron (ferrous sulfate) single dose enterally. All patients receive enteral supplements of folic acid (50µg/day), 1ml vit A+D /day and 1ml vit E/day.
Transfusion information will be recorded in both groups of infants from birth to study completion. Complete blood cells counts with differentials and reticulocyte counts will be performed by Coulter counter in both groups in the beginning and end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008091380N2**
Registration date: **2010-10-30, 1389/08/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-30, 1389/08/08

Registrant information

Name

Mahmood Noori-Shadkam

Name of organization / entity

Shahid Sadoghi university

Country

Iran (Islamic Republic of)

Phone

+98 35 1724 7074

Email address

noori@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2010-11-21, 1389/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of early erythropoietin administration on erythropoiesis in preterm infants

Public title

The effect of erythropoietin on the erythropoiesis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: premature infants with birth weight<1800g and gestational age<34week that their cardiorespiratory condition were stable. Exclusion criteria: a major congenital malformation, evidence of coagulopathy, severe asphyxia, intraventricular

hemorrhage grade 3-4, a positive direct antiglobulin test with clinical symptom of hemolytic anemia, surgical problems, exchange transfusion, severe cardiopulmonary disease required > 40% head box oxygen or dependent on mechanical ventilation, systolic blood pressure > 100mm Hg , an absolute neutrophil counts (ANC) of $\leq$ 500/ μ l.

Age

To 1 year old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 44

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**

Kerman University of Medical Sciences

Street address

Islamic Republic Blv.

City

Kerman

Postal code**Approval date**

2010-05-20, 1389/02/30

Ethics committee reference number

k/89/43

Health conditions studied**1****Description of health condition studied**

Anaemia of prematurity

ICD-10 code

P61.2

ICD-10 code description

Anaemia of prematurity

Primary outcomes**1****Description**

hematocrit

Timepoint

at the beginning and end of study

Method of measurement

with colter counter

Secondary outcomes**1****Description**

pack cell transfusion

Timepoint

at the end of study

Method of measurement

ml

2**Description**

Ferritin

Timepoint

begining and end of study

Method of measurement

Radioimunoassay

3**Description**

Reticulocyte

Timepoint

begining and end of study

Method of measurement

Microscope

4**Description**

Mean daily weight gain

Timepoint

begining and end of study

Method of measurement

Weigher

Intervention groups**1****Description**

Infants in control group don't receive placebo. Control infants receive 3 mg/kg/day elemental iron once a day enterally. In all infants minimal the enteral intake at the end of first week of age is 50ml/ kg, and all patients receive enteral supplements of folic acid (50 μ g/day), 1ml vit A+D /day (1mililiter containing vitamin: A, 1500IU, vitamin D 400U) and 1ml/day vit E.

Category

Prevention

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Description

Treated infants receive 500 u/kg/wk rhu EPO, 2 times weekly, administer subcutaneously in lateral side of thigh. Treatment continue until 4 weeks after beginning. Criteria for withholding / stopping the study drug included: neutropenia (ANC<500/ μ l) or hypertension (defined as a systolic blood pressure > 100mmHg during the first 2 post natal weeks and > 120 mmHg thereafter). Drug is restarted when these conditions resolve. Treatment stops when clinical seizures occur or when hypertension or neutropenia persist. Treated infants receive 3 mg/kg/day iron (ferrous sulfate) single dose enterally. In all infants minimal the enteral intake at the end of first week of age is 50ml/ kg and all patients receive enteral supplements of folic acid (50 μ g/day), 1ml vit A+D /day (1mliliter containing vitamin: A, 1500IU, vitamin D 400U) and 1ml/day vit E.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Noori-Shadkam M.

Street address

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Malekpour-Afshar R.

Street address

Kerman University of Medical Sciences

City

Kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Noori-Shakam M.

Position

Neonatologist

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

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Full name of responsible person

Niknafs P.

Position

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Other areas of specialty/work

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Postal code

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pniknafs@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Noori-Shadkam M.

Position

Neonatologist

Other areas of specialty/work

Street address

City

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Postal code

Phone

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Email

noori@ssu.ac.ir

Web page address

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