Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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+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 ≤ 500/µl.

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 (50µg/day), 1ml vit A+D /day (1mililiter containing vitamin: A, 1500IU, vitamin D 400U) and 1ml/day vit E.

Category

Prevention

2

Description
Treated infants receive 500 u/kg/wk rhu EPO, 2 times weekly, administer subcutaneously in lateral side of thight. Treatment continue untile 4 weeks after beginning. Criteria for withholding / stopping the study drug included: neutropenia (ANC<500/µl) 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 (50µg/day), 1ml vit A+D /day (1mililiter 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
Street address
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Niknafs P.
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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Neonatologist
Other areas of specialty/work

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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