Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effectiveness and safety between Alpha chain Erythropoietin and Beta chain Erythropoietin produced by Iran in the Remodeling of Anemia in Children with Chronic kidney disease

Protocol summary

Study aim

Comparison of the effectiveness and safety between Alpha chain Erythropoietin and Beta chain Erythropoietin in the Remodeling of Anemia in Children with Chronic Renal Failure

Design

In this clinical trial (phase II), the patients are divided in two parallel groups according to simple randomization based on table of random numbers: 1) Alpha chain erythropietin (PDpoietin, Pooyesh Darou co) 2) Betha chain erythropoietin (Cinapoietin, Cinnagen co) In these two groups, the drugs are prescribed based on KDIGO36 guideline for three months duration to maintain hemoglobin range between 11-12 g/dl. In this study concealment was not carried out.

Settings and conduct

This study is the comparison of efficacy of 2 drugs, PDpoietin and Cinapoietin in remodeling of anemia in chronic kidney disease patients refer to Aliasghar children hospital by simple randomization (without blindness).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Parent consent, Children With under 18 years old, hemoglobin less than 11 gr/dl, Renal failure stage 3-5 ,no iron or B12 deficiency Exclusion Criteria:No consent of parents, Secondary anemia : Uncontrolled hyperparathyroidism, Heart failure, Coagulopathy, thrombocytopnea, leukopenia, Major surgery during the last 6 months ago, Immunesuppressive treatment, History of malignancy, severe drug hypersensitivity, blood transfusion in last 3 months,Primary blood disease, Known resistance to rHuEPO

Intervention groups

The first intervetion group receive Alpha chian Epoietin and Second group receive Beta chain Epoietin.

Main outcome variables

The improve of hemoglobin concentration due to erythropoietin therapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180222038824N1**
Registration date: **2018-06-05, 1397/03/15**
Registration timing: **retrospective**

Last update: **2018-06-05, 1397/03/15**
Update count: **0**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Mohsen Fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

Email address

fathi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-24, 1396/12/05

Expected recruitment end date

2018-03-25, 1397/01/05

Actual recruitment start date

2018-02-24, 1396/12/05

Actual recruitment end date

2018-03-25, 1397/01/05

Trial completion date
empty

Scientific title
Comparison of the effectiveness and safety between Alpha chain Erythropoietin and Beta chain Erythropoietin produced by Iran in the Remodeling of Anemia in Children with Chronic kidney disease

Public title
Comparing the Effectiveness and Safety of PDpoetin and cinapoetin in the Remodeling of Anemia in Children with Chronic Renal Failure

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Parent consent for Research, Children With under 18 years old, children with hemoglobin less than 11 gr/dl, Renal failure with Grade 3-5 ,if that treatment with iron and folic acid and vitamin B12 have not modify the anemia,

Exclusion criteria:
No consent of parents Secondary anemia due to causes other than CKD advanced liver disease Uncontrolled hyperparathyroidism Heart failure (New York Heart Association (NYHA) class III and IV) Discoagulopathy Thrombocytopenia leukopenia Acute or chronic bleeding during the last two month ago Systemic or inflammatory infection Major surgery during the last 6 months ago (except surgery for vessels access) Immune suppressive treatment History of malignancy severe drug hypersensitivity Every reception of blood during the last 3 months ago Every primary blood disorder (Myelodysplasia syndrome, Myeloma, Sickle cell anemia, Malignancy, Multiple Myeloma) Documented resistance to rHuEPO

Age
From **3 months** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **6**
blood sample
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients Randomization is Simple and Unit of randomization is individual and according to table of random number the patients are divided to two groups: 1) Alpha chain Epoietin produced by Pooyesh darou 2) Betha chain Epoietin produced by Cinnagen In these two groups, the drugs are prescribed based on KDIGO36 guideline to maintaine hemoglobin range between 11-12 g/dl. In this study concealment was not carried out.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
efficacy and side effects of these two medication made by Iran has not been compared in children

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Siences

Street address
Modares highway, Vahid dastgerdy st, Aliasghar Children Hospital

City
Tehran

Province
Tehran

Postal code
1919816766

Approval date
2018-02-21, 1396/12/02

Ethics committee reference number
IR.IUMS.FMD.REC 1396.9511359001

Health conditions studied

1

Description of health condition studied
alpha and Betha erythropoietin, Anemia in CKD

ICD-10 code
N18.3

ICD-10 code description
Chronic kidney disease, stage 3 (moderate)

Primary outcomes

1

Description
The improve of hemoglobin concentration due to erythropoietin therapy

Timepoint
at the start of study and then every one month in a period of 3 months

Method of measurement
CBC

Secondary outcomes

1

Description
Compare the rate of pain, hypertension, thrombosis, other side effects
Timepoint
six months
Method of measurement
pain sacle, measure BP, physical exam

2

Description
Comparing the dose of drug to correct anemia and maintain HB
Timepoint
six months
Method of measurement
dose calculation per kg/wk

3

Description
Comparing the Serum electrolytes level between two group
Timepoint
monthly to six months
Method of measurement
K, ca, Ph, PTH level

Intervention groups

1

Description
Intervention group 1:The patient with CKD and anemia in children Up to 18 years old, Number: 20 patients, drug: alpha chain Epoietin, Dosage: 100 unit/kg, interval: 1-3 dose per week, duration: 3 months,The route Presciption: SQ, Company: pooyesh darou
Category
Treatment - Drugs

2

Description
Intervention group 2: Intervention group 1:The patient with CKD and anemia in children Up to 18 years old, Number: 20 patients, drug: Betha chain Epoietin, Dosage: 100 unit/kg, interval: 1-3 dose per week, duration: 3 months,The route Presciption: SQ, Company: CinnaGen
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Aliasghar Childern Hospital
Full name of responsible person
Mohsen Fathi
Street address
No.193, Vahid Dastgerdi St, Modares Highway, Aliasghar Children Hospital
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2

Recruitment center

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kazem Malakoti
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Shahid Hemmat Highway, Iran University of Medical Sciences
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hooman.n@iums.ac.ir
Grant name
none
Grant code / Reference number
خیر
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohsen Fathi
Position
Fellow
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable