

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

erythropoietin therapy

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 erythropoietin (PDpoietin, Pooyesh Darou co) 2) Beta 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, thrombocytopenia, 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 intervention group receive Alpha chain Epoietin and Second group receive Beta chain Epoietin.

Main outcome variables

The improve of hemoglobin concentration due to

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

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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 scale, 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 Prescription: 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: Beta chain Epoietin, Dosage: 100 unit/kg, interval: 1-3 dose per week, duration: 3 months, The route Prescription: 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

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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

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Grant name

none

Grant code / Reference number

خير

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 scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Consultant , Professor

Latest degree

Subspecialist

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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