

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 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

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 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 Children Hospital

#### Full name of responsible person

Mohsen Fathi

#### Street address

No.193, Vahid Dastgerdi St, Modares Highway, Aliasghar Children Hospital

#### City

Tehran

#### Province

Tehran

#### Postal code

1919816766

#### Phone

+98 21 2304 6253

#### Email

hooman.n@iums.ac.ir

### 2

#### Recruitment center

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Kazem Malakoti

##### Street address

Shahid Hemmat Highway, Iran University of Medical Sciences

##### City

Tehran

##### Province

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##### Postal code

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##### Phone

+98 21 86701

##### Email

hooman.n@iums.ac.ir

#### 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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dr.fathi51@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Nakysa Hooman

**Position**

Consultant , Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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N197, Ali-asghar children hospital, vahid dasgerdi st

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

Fellow

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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**Email**

fathi.m@iums.ac.ir

**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