

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Investigation of the safety and efficacy of Epolycres on ESRD patients on hemodialysis and comparison with EPREX

#### Protocol summary

##### Summary

The present trial aimed to evaluate the efficacy of EPOLYREC in the management of renal anemia in End Stage Renal Disease patients on hemodialysis. 160 patients (aged between 10-60 years) who were those with end stage renal disease who were under hemodialysis were assigned to receive EPOLYREC subcutaneously at a dose of 80-100 IU/kg in 2-3 divided doses after each dialysis session for 3 months. Hemoglobin, hematocrit and CBC/DIFF together with biomarkers of iron status, renal function and trace elements were evaluated at baseline and during the course of trial. Patients had a Glomerular filtration rate less than 14 ml/min/1.73m<sup>2</sup> together with a hematocrit less than 30% or hemoglobin less than 10g/dl; Presence of adequate Iron store (serum Ferritin more than 100mg/L and transferrin saturation more than 20%) was also among the inclusion criteria. Exclusion Criteria were CRP more than 10mg/dl; uncontrolled hypertension; Symptomatic ischemic heart disease; History of cerebrovascular events; Graft rejection; Polycystic kidney disease; Myeloma; Malignancies. This study was a multi-center prospective clinical trial investigating the efficacy of EPOLYREC in the elevation of hemoglobin level and hematocrit in anemic End Stage Renal patients who were under dialysis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014120120172N1**  
Registration date: **2015-02-11, 1393/11/22**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-02-11, 1393/11/22

#### Registrant information

##### Name

Maryam Fayazi

##### Name of organization / entity

Notarkib Biopharmaceutical Company

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6656 1850

##### Email address

fayazi@recpharma.com

#### Recruitment status

##### Recruitment complete

#### Funding source

Notarkib Biopharmaceutical Co.

#### Expected recruitment start date

2015-03-21, 1394/01/01

#### Expected recruitment end date

2016-03-20, 1395/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Investigation of the safety and efficacy of Epolycres on ESRD patients on hemodialysis and comparison with EPREX

#### Public title

Investigation of the safety and efficacy of Epolycres in comparison to Eprex in the management of renal anemia.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: End Stage Renal Disease patients who were under hemodialysis and had a Glomerular filtration

rate less than 14 ml/min/1.73m<sup>2</sup> together with a hematocrit less than 30% or hemoglobin less than 10g/dl; Presence of Iron store (serum Ferritin) more than 100mg/L and transferrin saturation more than 20%); Patients aged between 10 to 60 years Exclusion Criteria: CRP more than 10mg/dl; uncontrolled hypertension; Symptomatic ischemic heart disease; History of cerebrovascular event; Graft rejection; Polycystic kidney disease; Myeloma; Malignancies

#### Age

From **10 years** old to **60 years** old

#### Gender

Both

#### Phase

4

#### Groups that have been masked

No information

#### Sample size

Target sample size: **160**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Baghiatalah Hospital

##### Street address

Baghiatalah Hospital, Molasadra street, Vanak Sq.

##### City

Tehran

##### Postal code

#### Approval date

2012-12-26, 1391/10/06

#### Ethics committee reference number

صورتجلسه شماره 32

## Health conditions studied

### 1

#### Description of health condition studied

ESRD patients on hemodialysis

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

### 1

#### Description

hemoglobin

#### Timepoint

Before using medicine and every 2 weeks till end of investigation

#### Method of measurement

Blood test

### 2

#### Description

Hematocrit

#### Timepoint

Before using the medicine and every 2 week till end of investigation

#### Method of measurement

Blood test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In Children 500 Unit/kg/week subcutaneous injection after hemodialysis for 3 months

#### Category

Treatment - Drugs

### 2

#### Description

Subcutaneous injection after dialysis 80 IU/kg/w for 3 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baghiatallah Hospital

##### Full name of responsible person

Dr. Younes Panahi

##### Street address

Baghiatallah Hospital, Mollasadra Street, Vanak Sq.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Notarkib Biopharmaceutical Co.

**Full name of responsible person**

Seyed Ali Tabatabaei Nasab

**Street address**

Unit10, No.13, west Nosrat, Tohid Square

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Notarkib Biopharmaceutical Co.

**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**

Baghiatalah Hospital

**Full name of responsible person**

Dr. Younes Panahi

**Position**

Pharmacotrapy PhD

**Other areas of specialty/work****Street address**

Baghiatalah Hospital, Molasadra Street, Vanak Sq.

**City**

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**Postal code****Phone**

+98 21 8248 2502

**Fax****Email**

yunespanahi@yahoo.com

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Baghiatalah Hospital

**Full name of responsible person**

Dr Younes Panahi

**Position**

pharmacotrapy PHD

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Notarkib Biopharmaceutical company

**Full name of responsible person**

Maryam Fayazi

**Position**

Pharmacist

**Other areas of specialty/work****Street address**

Unit 10, No.13, west Nosrat st., Tohid square

**City**

Tehran

**Postal code****Phone****Fax****Email**

fayazi@recpharma.com

**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*