

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Investigation of the safety and efficacy of Epolyc 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/1.73m² 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 Epolyc on ESRD patients on hemodialysis and comparison with EPREX

Public title

Investigation of the safety and efficacy of Epolyc 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/1.73m² 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

صور تجلیسه 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

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Person responsible for updating data

Contact

Name of organization / entity

Notarkib Biopharmaceutical company

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Position

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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