

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of pentoxifylline on improving of anemia hyporesponsive to recombinant human erythropoietin among patients with ESRD on chronic hemodialysis; a randomized, double blind clinical trial

Protocol summary

Summary

In this randomized double-blind, placebo-controlled clinical trial, 60 patients with chronic hemodialysis who had hemoglobin level less than 11 gr/dL despite receiving 100-200 IU/Kg/W recombinant erythropoietin at least 3 months before starting the study were included. Patients were randomly assigned according to a computer-generated list into the control or case group (30 patients in each group). In the case group patients treated with Pentoxiphyllin 400 mg daily and Patients in the control group took a placebo tablet daily for 4 months. hemoglobin, ESR, CRP and serum iron profile including ferritin and TIBC (monthly) was recorded in a questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042117380N1**
Registration date: **2014-05-12, 1393/02/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-12, 1393/02/22

Registrant information

Name

Farzane Najafi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

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Iran (Islamic Republic of)

Phone

+98 35 1822 4000

Email address

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research- Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-05-15, 1393/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pentoxifylline on improving of anemia hyporesponsive to recombinant human erythropoietin among patients with ESRD on chronic hemodialysis; a randomized, double blind clinical trial

Public title

The effect of pentoxifylline on improving of anemia in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with chronic hemodialysis who had hemoglobin level less than 11 gr/dL despite receiving 100-200 IU/Kg/W recombinant erythropoietin at least 3 months before starting the study. Exclusion criteria: age < 18 years old; pregnancy; past history of allergy or intolerance to Pentoxiphyllin; the use of hemodialysis catheter in a recent month; patients with active ulcer disease or dyspepsia; major surgery within 3

months ago; blood transfusion in past month; history of myocardial infarction, stroke and brain hemorrhage in 3 months ago; suboptimal dialysis in recent 2 months (KT/V < 1.2); PTH > 300 pg/mL; Iron deficiency (ferritin level < 100 µg/L or TIBC < 20%); any hospitalization in past month ; the previous history of hematological problems such as hemoglobinopathies.

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Sadoughi University of Medical Sciences,Yazd, Iran

Street address

Shahid Sadoughi University of Medical Sciences,Yazd, Iran

City

Yazd

Postal code**Approval date**

2013-07-21, 1392/04/30

Ethics committee reference number

75377/1/17/پ

Health conditions studied**1****Description of health condition studied**

Anemia in patients with hemodialysis

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

Primary outcomes**1****Description**

mean changes in hemoglobin concentrations

Timepoint

4 times, monthly

Method of measurement

with CBC

Secondary outcomes**1****Description**

Erythrocyte Sedimentation Rate

Timepoint

each 2 months

Method of measurement

with lab tests

2**Description**

C Reactive Protein

Timepoint

each 2 months

Method of measurement

with lab tests

Intervention groups**1****Description**

case group:400 mg of pentoxifylline daily for 4 months

Category

Treatment - Drugs

2**Description**

control group: 1 placebo tablet daily

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hemodialysis Center, Shahid Rahnemon Hospital

Full name of responsible person

Dr Mohsen Gholinataj

Street address

Shahid Sadoughi Hospital, Yazd

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research -Shahid Sadoughi
University of Medical Science

Full name of responsible person

Dr. Hassan Mozaffari

Street address

Shahid Sadoughi University of Medical Sciences, Yazd,
Iran

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Yazd

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

Yes

Title of funding source

Vice-chancellor for research -Shahid Sadoughi University
of Medical Science

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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Mohsen Gholinataj

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MD, internal medicine resident

Other areas of specialty/work
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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