Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Sadughi University of Medical Sciences

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Iran (Islamic Republic of)

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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; paients 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

Yazd

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
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Shahid Sadoughi University of Medical Sciences,Yazd, Iran
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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

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Person responsible for updating data

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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