Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Effect of pentoxyphilin on reducing erythropoietin needs in peritoneal dialysis patiente with anemia

Protocol summary

Summary

The purpose of this study was evaluation of effect of pentoxy phylin on hemoglobin level and erythropoietin dose changing in hemodialysis patients with anemia. This study was done in hemodialysis centers in Isfahan (Zahraye Marziye) and Khomeini Shahr (Saei). Patients who were on hemodialysis for at least one month and without infection or bleeding in the last month were assigned in one of the following groups after full satisfaction of participation in research. The patients received pentoxyphylin tablet, 400mg or placebo. Blood levels of Hemoglobin, Iron, Ferritin, serum iron binding capacity, and need to erythropoietin were measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101012417N6**
Registration date: **2011-01-13, 1389/10/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-13, 1389/10/23

Registrant information

Name

Firouzeh Moeinzadeh

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2010-09-06, 1389/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pentoxyphilin on reducing erythropoietin needs in peritoneal dialysis patiente with anemia

Public title

Effect of pentoxyphilin on reducing erythropoietin needs in peritoneal dialysis patiente with anemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient’s satisfaction, hemodialysis for at least 1 month prior to the study, hemoglobin concentration less than 10g/dL in at least 2 episodes, Erythropoietin use more than 12000 units per week, no bleeding over the last month prior to the intervention, no infection resulting admission over the last month prior to the intervention, vitamin C consumption 250mg twice a week Exclusion criteria: drug intolerance, bleeding during the study period, infection resulting admission

Age

From **18 years** old to **90 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
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
Vice Chancellor for Research, Isfahan University of Medical Sciences
Street address
Isfahan 1000 jarib
City
Isfahan
Postal code
Approval date
2010-02-20, 1388/12/01
Ethics committee reference number
287028

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease
ICD-10 code
N18.0
ICD-10 code description
End-stage renal disease

Primary outcomes

1

Description
serum hemoglobin level
Timepoint
Baseline, monthly, at the end of the study
Method of measurement
g/dL

2

Description
serum albumin
Timepoint
Baseline, monthly, at the end of the study
Method of measurement
g/dL

3

Description
Erythropoietin use
Timepoint
monthly
Method of measurement
International unit

Secondary outcomes

1

Description
serum Iron level
Timepoint
Baseline, 3rd month, at the end of study
Method of measurement
µg/dL

2

Description
Total iron binding capacity
Timepoint
Baseline, 3rd month, at the end of study
Method of measurement
µg/dL

Intervention groups

1

Description
Pentoxyphylin, 400mg orally daily for 6 months
Category
Treatment - Drugs

2

Description
Placebo daily for 6 months orally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Peritoneal dialysis center. Alzahra hospital
Full name of responsible person

Mrs. Karimi
Street address
Alzahra hospital, Sofe Ave, Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Isfahan University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research
Street address
Hezarjarib, Isfahan
City
Isfahan
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, Isfahan University of Medical Sciences
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
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Full name of responsible person
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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