

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of Intravenous and Oral Iron Administration on Responsiveness to Synthetic Erythropoietin in Hemoglobin Increase of Hemodialysis Patients

Protocol summary

Summary

This study was conducted to compare the effect of intravenous (Venofer) and oral iron on hemoglobin (Hb) rise in response to synthetic erythropoietin in hemodialysis patients. In this controlled single blind clinical trial, 42 hemodialysis patients with < 10 g/dl hemoglobin after seven weeks treatment with 2000 units subcutaneous erythropoietin (three times weekly at the end of each dialysis session) were selected via convenience sampling method. Also at least six months history of hemodialysis was necessary for including to the study. Bone marrow malignancy, evidence of chronic infection, evidence of significant bleeding (decrease in Hb level > 2g/dL during the past 3 months), hemoglobinopathies, myelodysplastic syndrome were lead to exclusion of subjects from the study. One week after the last dose of erythropoietin injection, basic measurement was done for serum levels of hemoglobin, ferritin and iron saturation. Then patients randomly allocated into two oral and intravenous iron groups. For oral iron group patients administered Ferrous Sulfate tablet 50 mg daily, for seven weeks and other group received 100 mg Venofer, three times weekly at the end of each dialysis sessions for seven weeks and during this time, subjects in both groups received 2000 unit subcutaneous erythropoietin (three times weekly at the end of each dialysis sessions). Finally, hemoglobin, ferritin and iron saturation were examined following therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102195864N1**

Registration date: **2011-08-29, 1390/06/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-29, 1390/06/07

Registrant information

Name

Ali Reza Shariati

Name of organization / entity

Golestan Medical Sciences University

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 6900

Email address

shariaty@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan Medical Sciences University

Expected recruitment start date

2010-05-05, 1389/02/15

Expected recruitment end date

2010-07-06, 1389/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Intravenous and Oral Iron Administration on Responsiveness to Synthetic Erythropoietin in Hemoglobin Increase of Hemodialysis Patients

Public title

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Receiving hemodialysis therapy for at least 6 months; having dossier in hemodialysis center; three times hemodialysis weekly and four hours for each session; hemoglobin less than 10 g/dl; history of seven weeks treatment with subcutaneous erythropoietin (2000 units, three times weekly at the end of each dialysis sessions). Exclusion criteria: Bone marrow malignancy; evidence of chronic infection; evidence of significant bleeding (decrease in Hb level > 2g/dL during the past 3 months); hemoglobinopathies; myelodysplastic syndrome.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan Medical Sciences University

Street address

Golestan Medical Sciences University (Falsafi Complex), Shast Kola, 5th km of Gorgan to Sari Road, Gorgan

City

Gorgan

Postal code

Approval date

2011-01-30, 1389/11/10

Ethics committee reference number

2906/ 35/3

Health conditions studied

1

Description of health condition studied

Iron Deficiency Anaemia

ICD-10 code

D50.8, D50

ICD-10 code description

Other iron deficiency anaemias, Iron deficiency anaemia, unspecified

Primary outcomes

1

Description

Hemoglobin

Timepoint

Pre and Post of Intervention

Method of measurement

Blood Exam

2

Description

Ferritin

Timepoint

Pre and Post of Intervention

Method of measurement

Blood Exam

3

Description

Total Iron Binding Capacity

Timepoint

Pre and Post of Intervention

Method of measurement

Blood Exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 100 mg intravenous Venofer, three times weekly at the end of each dialysis sessions for seven weeks

Category

Treatment - Drugs

2

Description

Control group: Ferrous Sulfate tablet 50 mg daily, for seven weeks

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

5th Azar Educational and Therapeutic Center

Full name of responsible person

Ali Reza Shariati

Street address

5th Azar St, Gorgan

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan Medical Sciences University

Full name of responsible person

Dr Mohammad Ali Vakili

Street address

Golestan Medical Sciences University (Falsafi Complex), Shast Kola, 5th km of Gorgan to Sari Road, Gorgan

City

Gorgan

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, Golestan Medical Sciences University

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

Golestan Medical Sciences University

Full name of responsible person

Ali Reza Shariati

Position

Master in Nursing

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