Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 mounts 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, ferrtin and iron saturation. Then patients randomly allocated into two oral and intravenous iron groups. For oral iron group patients administrated 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, ferrtin 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

The Treatment of Hemodialysis Patients' Anemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Receiving hemodialysis therapy for at least 6 months; having dossier in hemodialysis ceneter; three time 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

Ethic 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/پگ

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

Ferrtin

Timepoint

Pre and Post of Intervention

Method of measurement

Blood Exam

3

Description

Total Iron Bonding Capasity

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

Treatment - Drugs

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

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

City
Gorgan

Postal code

Phone
+98 17 1442 6900

Fax
+98 17 1442 5171

Email
shariati1382@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Golestan Medical Sciences University

Full name of responsible person
Ali Reza Shariati

Position
Mastar in Nursing

Other areas of specialty/work

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

City
Gorgan

Postal code

Phone
+98 17 1442 6900

Fax
+98 17 1442 5171

Email
shariati1382@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Golestan Medical Sciences University

Full name of responsible person
Ali Reza Shariati

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Master in Nursing

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Fax
+98 17 1442 5171

Email
shariati1382@yahoo.com
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