

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 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, 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

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 center; 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/ک

## 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 Bonding 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

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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**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*