

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The investigation of oral and intravenous ascorbic acid effectiveness on Erythropoietin-hyporesponsive anemia in hemodialysis patients referred to Gorgan 5th Azar educative & therapeutic center

#### Protocol summary

##### Summary

(1) Objective: The study was conducted to investigation of ascorbic acid effectiveness on Erythropoietin-hyporesponsive anemia in hemodialysis patients. (2) Design: randomized controlled trial (RCT). (3) Setting and conduct: seventy five haemodialysis patients were selected from Gorgan 5th Azar educative & therapeutic center via convenience methods. They were randomly allocated into controls (n = 25), oral ascorbic acid (POAA) group (n = 25) and intravenous ascorbic acid (IVAA) group (n = 25). (4): Participants including major eligibility criteria: Inclusion criteria were: at least 6 months history of hemodialysis, more than 6 months treatment duration with rHuEPO, serum ferritin level of 500 ng/mL or more and transferring saturation less than 20%. Exclusion criteria were: History of infection or inflammation within 3 months; C-reactive protein (CRP) level>2 mg/dL; Bleeding or hemolysis within 3 months; Folate level<4 ng/mL; Vitamin B12 level<200 pg/mL; (5) Intervention: Was administered postdialysis (three time weekly) 300mg intravenous vitamin C in IVAA group and orally 500mg vitamin C in POAA group for 8 weeks. (6) Main outcomes variables: Hemoglobin, hematocrit, serum iron, total iron binding capacity (TIBC) and serum oxalate was examined before and following therapy.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201306115864N3**  
Registration date: **2013-07-14, 1392/04/23**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-14, 1392/04/23

##### 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

2012-10-22, 1391/08/01

##### Expected recruitment end date

2013-01-19, 1391/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The investigation of oral and intravenous ascorbic acid effectiveness on Erythropoietin-hyporesponsive anemia in hemodialysis patients referred to Gorgan 5th Azar educative & therapeutic center

##### Public title

Oral and intravenous ascorbic acid effectiveness on erythropoietin-hyporesponsive anemia in hemodialysis

patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria Age between 18-70 years; At least 6 months history of hemodialysis; Having dossier in hemodialysis center; Three time hemodialysis in week and four hours for each session; duration of rHuEPO treatment  $\geq$  6 months; serum ferritin level of 500 ng/mL or more, transferrin saturation  $<$ 20%. Exclusion criteria History of infection or inflammation within 3 months; C-reactive protein (CRP) level  $>$ 2 mg/dL; Bleeding or hemolysis within 3 months; Folate level  $<$ 4 ng/mL; Vitamin B12 level  $<$ 200 pg/mL; simultaneous participation in another study; Pregnant women.

## Age

From **17 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **75**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not 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

2011-05-25, 1390/03/04

#### Ethics committee reference number

489/35/گ پ

## Health conditions studied

### 1

#### Description of health condition studied

anemia

#### ICD-10 code

D63.8

#### ICD-10 code description

Anaemia in other chronic diseases classified elsewhere

## Primary outcomes

### 1

#### Description

Hemoglobin

#### Timepoint

Before and 8 weeks after intervention

#### Method of measurement

Blood examination (g/dl)

### 2

#### Description

Hematocrit

#### Timepoint

Before and 8 weeks after intervention

#### Method of measurement

Blood examination (%)

### 3

#### Description

Serum iron

#### Timepoint

Before and 8 weeks after intervention

#### Method of measurement

Blood examination (ng/ml)

### 4

#### Description

Ferritin

#### Timepoint

Before and 8 weeks after intervention

#### Method of measurement

Blood examination (ng/dl)

### 5

#### Description

Total iron binding capacity

#### Timepoint

Before and 8 weeks after intervention

#### Method of measurement

Blood examination (%)

## Secondary outcomes

1

**Description**

Serum oxalate

**Timepoint**

Before and 8 weeks after intervention

**Method of measurement**

Blood examination mg/dl

**Intervention groups**

1

**Description**

In intravenous ascorbic acid (IVAA) group, 300mg intravenous vitamin C(three time weekly)for 8 weeks after each dialysis session

**Category**

Treatment - Drugs

2

**Description**

In oral ascorbic acid (POAA) group, 500mg vitamin C (three time weekly)for 8 weeks after each dialysis session

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Gogan 5th Azar educative & therputic center

**Full name of responsible person**

Alireza Shariati

**Street address**

**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 Jafar Golalipour

**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**

Alireza Shariati

**Position**

MS 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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Golestan Medical Sciences University

**Full name of responsible person**

Alireza Shariati

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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*