

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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

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Person responsible for updating data

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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