Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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 ≥ 6 months; serum ferritin level of 500 ng/mL or more, transferring 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

پ گ/489/35

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
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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