Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of short-term and low amount of intravenous Ascorbic Acid on reducing ferritin in Hemodialysis Patients without increasing the start dosage of erythropoietin: crossed over double blind randomized controlled trial

Protocol summary

Summary

In this study, we assessed the effect of vitamin C on elimination of the unexplained hyperferritinemia on EPO-hyporesponsive anemia in hemodialysis patients without changing the starting maintenance dosage of rEPO. In a crossed over, single blind randomized controlled trial, thirty HD patients who met the eligibility criteria, patients were randomly assigned into one of following groups. The patients in the intervention group received standard care and adjuvant therapy of 500 mg of intravenous vitamin C (IVAA) along with each dialysis session at the first week of each month (total 1500 mg/month) for three months and in the control group received standard cares only. Then, the patients passed two months wash out period and then they were crossed over for another three months. Hemoglobin, mean corpuscular volume, serum iron, iron-binding capacity, ferritin level, and TSAT were assessed every month. In addition, biointact parathyroid hormone, liver enzymes, albumin, and cholesterol were measured every 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904263325N3**
Registration date: **2010-09-14, 1389/06/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-09-14, 1389/06/23

Registrant information

Name
Majgan Jalalzadeh
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Zanjan University Of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2009-05-22, 1388/03/01

Expected recruitment end date

2009-07-23, 1388/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of short-term and low amount of intravenous Ascorbic Acid on reducing ferritin in Hemodialysis Patients without increasing the start dosage of erythropoietin: crossed over double blind randomized controlled trial

Public title

Effect of intravenous Ascorbic Acid on reducing ferritin in Hemodialysis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: receiving hemodialysis therapy for at least 6 months, administered EPO for 6 months or longer at a dose of 80-360 U/kg/wk or greater, rolling 3-month average Hb level of 11.0 g/dL or less (110 g/L), ferritin level greater than 500 ng/Ml, transferrin saturation (TSAT) of 20% or less and administered maintenance intravenous iron (25-100 mg/week) Exclusion criteria: bone marrow malignancy, myelodysplastic syndrome, evidence of chronic infection, hemochromatosis, hemoglobinopathies, evidence of significant bleeding (decrease in Hb level ≥ 2 g/dL during the past 3 months, mean corpuscular volume greater than 100 fL, biointact parathyroid hormone (bio-PTH) level greater than 500 pg/mL (ng/L)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences

Street address

Faculty of Medicine, Zanjan University of Medical Sciences, Shahrake Karmandan, Zanjan, Iran

City

Zanjan

Postal code

Approval date

2010-04-14, 1389/01/25

Ethics committee reference number

19/3-3/235

Health conditions studied

1

Description of health condition studied

End-stage renal disease

ICD-10 code

N18.0

ICD-10 code description

End-stage renal disease

Primary outcomes

1

Description

ferritin

Timepoint

begining of each phase and after 3 months

Method of measurement

laboratory techniques

2

Description

hemoglobin

Timepoint

beginning of each phase and each months (0-1-2-3)

Method of measurement

laboratory techniques

Secondary outcomes

1

Description

Serum Iron

Timepoint

at the beginning of study and after 3 months

Method of measurement

laboratory techniques

2

Description

TIBC

Timepoint

at the beginning of study and after 3 months

Method of measurement

laboratory techniques

Intervention groups

1

Description

500mg of intravenous vitamin C (IVAA) along with each dialysis session at the first week of each month for three months (total 1500mg/3month)

Category

Treatment - Drugs

2

Description
control group did not receive any intervention
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti hemodialysis center
Full name of responsible person
Zeinolabedin Nourcheshmeh
Street address
City
Zanjan

2

Recruitment center
Name of recruitment center
Valieasr hemodialysis center
Full name of responsible person
Street address
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Samsami
Street address
Zanjan University of Medical Sciences, Azadi boulevard, Zanjan, Iran
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
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
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Fatemeh Mirzamohammadi
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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