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

Expected recruitment start date
2009-05-22, 1388/03/01
Expected recruitment end date
2009-07-23, 1388/05/01

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

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
beginning 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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Fatemeh Mirzamohammadi
Position
Medical student
Other areas of specialty/work
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Person responsible for updating data
Contact
Name of organization / entity
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Fatemeh Mirzamohammadi
Position
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Phone
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Email
fateme_mm@yahoo.co.uk
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