Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Randomized, double blind, placebo controlled Trial of effect of vitamin c supplement on anemia in peritoneal dialysis patients in Imam Reza center - Shiraz

Protocol summary

Summary

The first objective of this study was to determine plasma Vitamin C level in CAPD (Continuous Ambulatory Peritoneal Dialysis) patients in Imam Reza center -Shiraz. The second objective of the study was to investigation of (i) Prevalence of vitamin C deficiency, (ii) Its association with hemoglobin concentration and (iii) effect of 250 mg daily oral Vitamin C supplementation on Hemoglobin concentration. The study was a prospective, single-center, double-blind, randomized, placebo-controlled trial. All patients who met the selection criteria were attempted for their agreement to join. Inclusion criteria was: patients on maintenance long–term peritoneal dialysis (PD) therapy (defined as having PD treatment for at least 3 months.), were more than 18 years of age, had hemoglobin concentration less than 12 mg/dl, had no acute medical illness over the 3 months prior to determining vitamin C levels. Exclusion criteria was: history of recurrent bleeding or hemolysis, clinically unstable, medical history of cancer, need for transfusion , previous diagnosis of primary hyperoxaluria. Intervention: Sixty-six medically stable PD patients were primarily chosen to enroll in this study. For determination of vitamin C status in patients ,plasma level of vitamin C and several other clinical parameters including Hb, Ferritin, TIBC, serum iron, CRP , transferrin saturation were measured. Vitamin supplements containing vitamin C and any supplements of vitamin C (IV-Oral) were discontinued within 3 weeks before sample collection. Forty-three of 66 PD patients were selected with serum vitamin C level below 4 microgram /ml to enroll in this study. Subjects were given 42 tablets in orders to take one tablet daily for 6 weeks. Active (250 mg ascorbic acid) and placebo (starch) tablets were equal in the form. Both the subjects and investigators were blinded as to allocation until after the last subject terminated the study, and all follow-up records had been collected. Oral dosing was used because intravenous dosing proposed no benefit for hemodialysis subjects and was considered impossible for PD patients. The EPO dose used by each patient was the usual weekly dose ordered during the month before collection whole blood for vitamin C measurement. They received folic acid 5 mg per day. The adjustment of EPO dose was done on a monthly basis to keep Hb range of 11.0 – 12.g/dL, which was the target Hb at the time of the study. Determination of total weekly Kt/V urea was made using standard methodology. Subjects didn’t take tetracycline, cholestyramin or antacid. Blood samples were repeated for Hb –Ferritin-TIBC-CRP-Vitamin C after 6 weeks of treatment at the end of the study. Vitamin C level was measured by Smart line series of Knauer HPLC system include quaternary pump, column oven and Uv detector (20). Serum iron and total iron-binding capacity were determined by spectrophotometric methods with Bio-La-Tests (PLIVA_Lachema AS, Brno, Czech Republic), Serum ferritin was determined by chemiluminescent enzyme immunometric assay using Immulite Ferritin kit (Diagnostic Products Corp, Los Angeles, CA). Outcomes and data collection: The primary outcome was evaluation of serum level of vitamin C in PD patients. The second outcome was evaluation of alteration in mean hemoglobin concentration (gram per deciliter) following oral vitamin C tablets. The third outcomes was evaluation of the change in mean EPO dose (units per kilogram per week), change in mean ferritin concentration (micrograms per liter), change in transferrin saturation (percentage). Compliance was assessed by analyzing changes in plasma ascorbate levels. Ascorbate levels were measured by high-performance liquid chromatography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205089674N1**
Registration date: **2014-01-01, 1392/10/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2014-01-01, 1392/10/11

Registrant information

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Recruitment status
Recruitment complete
Funding source
Shiraz University Of Medical Science -Research Departement

Expected recruitment start date
2012-02-11, 1390/11/22
Expected recruitment end date
2012-03-11, 1390/12/21
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Randomized, double blind, placebo controlled Trial of effect of vitamin c supplement on anemia in peritoneal dialysis patients in Imam Reza center - Shiraz

Public title
Effect of vitamin c supplement on anemia in peritoneal dialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1. Long-term treatment of PD (at least more than three months) 2. Hemoglobin less than 11 milligrams per liter 3. Age over 18 years - Exclusion criteria of the study: 1. Acute illness (including infectious diseases and cancer) within 3 months prior to determining the level of vitamin C 2. Any recent blood transfusion, recurrent bleeding or hemolysis 3. Supplementation with vitamin C during the 3 weeks prior to the determination of serum levels 4. Consumption of tetracycline, antacid and Cholestyramine
Age
From **18 years** old to **80 years** old
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Science
Street address
central building Shiraz university of Medical Science - Zand Blvd
City
Shiraz
Postal code
71345-1978
Approval date
2012-02-07, 1390/11/18
Ethics committee reference number
CT-90-5933

Health conditions studied

1

Description of health condition studied
Anemia
ICD-10 code
D53.2
ICD-10 code description
Scorbutic Anemia

Primary outcomes

1

Description
Hemoglobin
Timepoint
Before and 6 weeks after intervention
Method of measurement
Lab Method

2

Description
Vit C Level
Timepoint
Before and 6 weeks after intervention
Method of measurement
HPLC

Secondary outcomes

1

Description
C Reactive Protein
Timepoint
Before and 6 week after intervention
Method of measurement
Lab Method

Intervention groups

1

Description
Group A,(consist of 22 person)- vitamin C supplement orally up to 250 mg per day for 6 weeks was prescribed. Plasma levels of vitamin C and other clinical parameters including hemoglobin, ferritin, TIBC, iron and CRP were measured at the beginning and end of the study.
Category
Treatment - Drugs

2

Description
Placebo prescribed to Group B. Plasma levels of vitamin C and other clinical parameters including hemoglobin, ferritin, TIBC, iron and CRP were measured at the beginning and end of the study.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Peritoneal dialysis Clinic in Imam Reza center - Shiraz
Full name of responsible person
Dr.Zahra-Lotfi
Street address
Namazi-Hospital-Nephrology Ward
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Department- University of Medical Science -
Full name of responsible person
Dr .Gholam Reza Khatam
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central building -Shiraz University of Medical Science - Zand Blvd
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Grant name
Grant code / Reference number
90-5933
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Department- University of Medical Science -
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

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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