

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Zahra Lotfi

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4316

Email address

lotfiz@sums.ac.ir

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

Street address

central building -Shiraz University of Medical Science - Zand Blvd

City

Shiraz

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

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Zahra Lotfi

Position

Nephrology Fellow

Other areas of specialty/work

Street address

central building-Shiraz university of Medical Science - Zand Blvd-

City

Shiraz

Postal code

1978-71345

Phone

+98 71 1647 4316

Fax

+98 71 1647 4316

Email

zah_lotfi@yahoo.com; lotfi.farideh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mahdi Sagheb

Position

Nephrologist

Other areas of specialty/work**Street address**

Central building, Shiraz university of Medical Science -
Zand Blvd-

City

Shiraz

Postal code

71345-1978

Phone

+98 71 1647 4316

Fax

+98 71 1647 4316

Email

saghebf@gmail.com

Web page address

central building, Shiraz university of Medical Science -
Zand Blvd

City

Shiraz

Postal code

1978-71345

Phone

+98 71 1647 4316

Fax

+98 71 1647 4316

Email

zah_lotfi@yahoo.com; lotfi.farideh@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Zahra Lotfi

Position

Nephrology Fellow

Other areas of specialty/work**Street 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