

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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*