

# 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

##### Name of organization / entity

Zanjan University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 1426 6934

##### Email address

jmojgan@zums.ac.ir

#### 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  $\geq$  2 g/dL during the past 3 months, mean corpuscular volume greater than 100 fL, bioactive 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****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****Street address**

No:8, block: 5, Zeitoon apartment, street 13,  
shahrake karmandan, Zanjan, Iran

**City**

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**Postal code****Phone**

+98 24 1426 6934

**Fax****Email**

fateme\_mm@yahoo.co.uk

**Web page address**

## Person responsible for scientific 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****Street address**

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## Person responsible for updating data

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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*