

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of intravenous vitamin c in decreasing ferritin level in patients with ESRD under dialysis

#### Protocol summary

##### Study aim

Evaluation of the effect of intravenous vitamin C c in decreasing ferritin level in patients with ESRD under dialysis in Velayat hospital in Qazvin province in 2020

##### Design

This study was performed on 32 hemodialysis patients with inclusion criteria. Patients were randomly divided into intervention groups(A,N=16) and control groups(B,N=16) using Winpepi software.the study will be triple-blind.

##### Settings and conduct

This study is a clinical trial with the aim of determining the effect of intravenous vitamin C in decreasing ferritin level in patients with ESRD under dialysis in velayat hospital in Qazvin province in 2020.This study was performed on 32 patients with hemodialysis and inclusion criteria. ) And control B (N = 16) are divided. The study will be Triple-blind

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing hemodialysis with iron deficiency anemia with Hb <11 g / dl and serum ferritin level (> 500 ng / ml) and transferrin saturation (TSAT ≤ 20%) Exclusion criteria: 1-Patients with infection. 2- Patients with inflammation. 3- Patients with a history of receiving venoffer in the last 2 months. 4- Patients who refuse to participate in the study. 5- Patients who do not seek treatment for any reason.

##### Intervention groups

Patients were randomly divided into intervention group A and control group B. Group A intravenous ascorbic acid 500 mg three times a week after each dialysis session for 3 months with erythropoietin and group B as much distilled water as placebo three times a week after each hemodialysis Erythropoietin IV is given by a colleague for 3 months.

##### Main outcome variables

Serum ferritin level,Hemoglobin,TIBC(Total Iron binding capacity ),Transferrin saturation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191112045426N1**

Registration date: **2020-01-07, 1398/10/17**

Registration timing: **prospective**

Last update: **2020-01-07, 1398/10/17**

Update count: **0**

##### Registration date

2020-01-07, 1398/10/17

##### Registrant information

##### Name

Mohammad Taheri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3368 1570

##### Email address

m.t.a.h.e.r.i@yandex.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-11, 1399/01/23

##### Expected recruitment end date

2020-05-12, 1399/02/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of intravenous vitamin c in decreasing ferritin level in patients with ESRD under dialysis

#### Public title

Effect of intravenous vitamin c in decreasing ferritin level in patients with ESRD under dialysis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients undergoing hemodialysis with iron deficiency anemia with Hb <11 g / dl and serum ferritin level (> 500 ng / ml) and transferrin saturation (TSAT ≤ 20%)

##### Exclusion criteria:

#### Age

No age limit

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

#### Sample size

Target sample size: 32

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The sampling is done in an available way. Patients were randomly divided into intervention group A and control B using Winpepi software By a methodologist.

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

As the intervention prescribed by the researchers is injected by the project executive, in addition to the patients who administer the intervention and evaluate the results, they are also blind to the type of intervention administered, so the study will be a triple-blind study.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

#### Street address

Shahid Beheshti, Ave' 3415613911 Qazvin' IRAN

#### City

Qazvin

#### Province

Qazvin

#### Postal code

3415613911

#### Approval date

2019-12-30, 1398/10/09

#### Ethics committee reference number

IR.QUMS.REC.1398.252

### Health conditions studied

#### 1

##### Description of health condition studied

Chronic kidney disease (CKD)

##### ICD-10 code

D63.1

##### ICD-10 code description

Anemia in chronic kidney disease

### Primary outcomes

#### 1

##### Description

Age

##### Timepoint

before intervention

##### Method of measurement

Form

#### 2

##### Description

Gender

##### Timepoint

before intervention

##### Method of measurement

Form

#### 3

##### Description

marital status

##### Timepoint

before intervention

##### Method of measurement

Form

#### 4

##### Description

Serum ferritin level

##### Timepoint

before intervention and after three months

##### Method of measurement

Paraclinic

## 5

### **Description**

Hemoglobin

### **Timepoint**

before intervention and after three months

### **Method of measurement**

Paraclinic

## 6

### **Description**

TIBC(Total Iron binding capacity )

### **Timepoint**

before intervention and after three months

### **Method of measurement**

Paraclinic

## 7

### **Description**

Transferrin saturation

### **Timepoint**

before intervention and after three months

### **Method of measurement**

Paraclinic

## 8

### **Description**

Intervention group

### **Timepoint**

before intervention and after three months

### **Method of measurement**

software

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The intervention group received intravenous ascorbic acid 500 mg three times a week after each dialysis session for 3 months with erythropoietin IV.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: The control group received distilled water as placebo three times a week after each hemodialysis for 3 months and erythropoietin IV.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

بیمارستان ولایت قزوین

##### **Full name of responsible person**

Dr Seyed Saeed Farzam

##### **Street address**

Taavon Square, 22 Bahman Blvd, Elahieh, Qazvin, Iran

##### **City**

قزوین

##### **Province**

Qazvin

##### **Postal code**

3419759811

##### **Phone**

+98 28 3379 0620

##### **Fax**

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##### **Email**

m.t.a.h.e.r.i@yandex.com

##### **Web page address**

<http://hosvelayat.qums.ac.ir>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Qazvin University of Medical Sciences

##### **Full name of responsible person**

Mohammad Taheri

##### **Street address**

Saadat Blv

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3415766858

##### **Phone**

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##### **Email**

m.t.a.h.e.r.i@yandex.com

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

No

##### **Title of funding source**

researchers

##### **Proportion provided by this source**

100

##### **Public or private sector**

Private

##### **Domestic or foreign origin**

Domestic

##### **Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Persons

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Mohammad Taheri

**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Mohammad Taheri

**Position**

Medical Student

**Latest degree**

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**Other areas of specialty/work**

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**Contact**

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**Full name of responsible person**

Mohammad Taheri

**Position**

Medical Student

**Latest degree**

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**Other areas of specialty/work**

General Practitioner

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**Province**

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**Postal code**

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**Phone**

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**Email**

m.t.a.h.e.r.i@yandex.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The results of this research will be shared after the end of the research.

**When the data will become available and for how long**

The results of this research will be shared after the end of the research.

**To whom data/document is available**

Medical universities will have access to the documentation.

**Under which criteria data/document could be used**

For use in treating patients

**From where data/document is obtainable**

Qazvin University of Medical Sciences

**What processes are involved for a request to access data/document**

Send your request to Qazvin University of Medical Sciences Medical School and it will be answered after

review.

**Comments**