

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 venooffer 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)

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+98 28 3368 1570

Email address

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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	
<u>1</u>	
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

Paralclinic

6

Description

TIBC(Total Iron binding capacity)

Timepoint

before intervention and after three months

Method of measurement

Paralclinic

7

Description

Transferrin saturation

Timepoint

before intervention and after three months

Method of measurement

Paralclinic

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

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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

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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

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Full name of responsible person

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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