

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

+98 28 3379 0611

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

+98 28 3368 1570

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

Saadat Blv

City

Qazvin

Province

Qazvin

Postal code

3415766858

Phone

+98 28 3368 1570

Email

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

Person responsible for scientific 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

Saadat Blv

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Email

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

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Taheri

Position

Medical Student

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General Practitioner

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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