

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The association between intravenous iron and prescribe recombinant erythropoietin and cardiovascular events in hemodialysis patients

Protocol summary

Study aim

The association between intravenous iron and prescribe recombinant erythropoietin and cardiovascular events in hemodialysis patients

Design

60 patients with chronic kidney disease in hemodialysis will included in the study via simple random non-probability Sampling method consecutively. After that patients will randomly be divided into two similar groups (low Iron regimen group and high Iron regimen group) with random digits table. All data will remain private with encoding method.

Settings and conduct

Patient recruitment will be perform in Sina and 29 Bahman hospitals between 98-99 years. Thus, patients' data will be collected before study beginning and Ferritin level and Iron saturation rate, incidence of acute myocardial ischemia, cerebral stroke, heart failure, mortality rate, and the required monthly prescribed dose of erythropoietin will be monthly measured in both two groups of intravenous Iron receiving during 6 months clinical trial.

Participants/Inclusion and exclusion criteria

1- Be volunteer to participate in the study 2- Patients with end-stage renal disease that have undergone six months of their dialysis 3- Age group of 18-80 years

Intervention groups

Intervention group: high regimen of Iron: Including patients with <700 ferritin and/or <40% Iron saturation that will receive monthly 400 mg intravenous Iron for 6 months. Control group: low regimen of Iron: Including patients with <200 ferritin and/or <20% Iron saturation that will receive weekly 100 mg intravenous Iron for 6 months.

Main outcome variables

Decreasing the required weakly dose of Erythropoietin, Reducing cardiovascular events

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049311N1**

Registration date: **2020-12-16, 1399/09/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-16, 1399/09/26**

Update count: **0**

Registration date

2020-12-16, 1399/09/26

Registrant information

Name

Seyyedeh Mina Hejzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

Email address

smhjl.biotech@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The association between intravenous iron and prescribe recombinant erythropoietin and cardiovascular events in hemodialysis patients

Public title

The association between intravenous iron and cardiovascular complications in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Be volunteer to participate in the study Patients with end-stage renal disease that have undergone six months of their dialysis Age group of 18-80 years

Exclusion criteria:

>700 Ferritin level and/or >40% Iron saturation Having an active infection

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization will be by blocking method and groups division will be perform with an equal number of patients individually. Patients will divided by random digit table. Thus, the statistical population and sample size will be determined first and they will be respectively given a code or serial number. Then, the entered codes will be selected randomly from the table. All participants in this study were blinded unilaterally. Randomly allocation concealment will also go on with the method of not determining study groups before selecting patients and included individuals will be randomly grouped after sampling in this study.

Blinding (investigator's opinion)

Single blinded

Blinding description

All names and personal data of patients will encode during gathering data and will remain totally private. In addition, none of the participants will be grouped at the beginning of study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committees of Islamic Azad university of Tabriz

Street address

Tabriz Branch of Islamic Azad University, Pasdaran highway, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5157944533

Approval date

2020-09-15, 1399/06/25

Ethics committee reference number

IR.IAU.TABRIZ.REC.1399.083

Health conditions studied

1

Description of health condition studied

chronic kidney disease

ICD-10 code

D63.1

ICD-10 code description

Anemia in chronic kidney disease

Primary outcomes

1

Description

Decreasing the required weakly dose of Erythropoietin

Timepoint

Monthly during 6 month prescription of intravenous Iron

Method of measurement

Performing blood test and ELISA method

2

Description

Reducing cardiovascular events

Timepoint

Monthly during 6 month prescription of intravenous Iron

Method of measurement

Investigating the incidence of chronic myocardial ischemia, cerebral stroke, heart failure and mortality rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: High regimen of Iron: Including patients with <700 ferritin and/or <40% Iron saturation that will receive monthly 400 mg intravenous Iron for 6 months.

Category

Treatment - Drugs

2

Description

Control group: Low regimen of Iron: Including patients with <200 ferritin and/or <20% Iron saturation that will receive weekly 100 mg intravenous Iron for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr. Farahnoosh Farnood

Street address

Sina training and Research Center, Azadi Street, Tabriz

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Postal code

5163639888

Phone

+98 41 3541 2101

Email

farnood_farahnoosh@yahoo.com

2

Recruitment center

Name of recruitment center

29 Bahman hospital

Full name of responsible person

Dr. Farahnoosh Farnood

Street address

29 Bahman hospital, 29 Bahman Blvd, Tabriz

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5166617894

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farnood_farahnoosh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Personal expense

Full name of responsible person

Dr. Farahnoosh Farnood

Street address

Kidney Research Center, one floor, Imam Reza training and Research Center, Golgasht Street, Tabriz

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5166614756

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farnood_farahnoosh@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Personal expense

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Farahnoosh Farnood

Position

Subspecialty physician

Latest degree

Subspecialist

Other areas of specialty/work

Nephrology

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Person responsible for scientific inquiries

Contact

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Latest degree
Subspecialist

Other areas of specialty/work
Nephrology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable