

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative Study of Intravenous Iron versus Intravenous Ascorbic Acid for Treatment of Anaemic Hemodialysis Patients with High Ferritin and Low Transferrin Saturation

Protocol summary

Summary

This study is a single blind randomized, clinical trial that compares effect of intravenous Iron with intravenous Ascorbic Acid in treatment of functional iron deficiency in 2 hemodialysis centers. Population of study is 40 hemodialysis patients divided into two groups (20 patients in each groups). Inclusion criteria are ferritin level ≥ 500 ng/ml and TSAT $\leq 25\%$, hemodialysis therapy for ≥ 3 months, Hemoglobin level < 11 gr/dl and age ≥ 18 years and < 70 years. Exclusion criteria are blood transfusion or blood loss or administration of intravenous Iron during 3 months ago, acute infection, chronic inflammatory disease, active liver disease hemoglobinopathy such as sickle cell disease. The goal for response to treatment is Hb > 11 g/dl. We randomly divide 40 patients into two groups. In group I patients will receive IV infusion of 100 mg Iron sucrose, postdialysis, twice a week, during the first 5 weeks of the study. In group II 20 patients will receive 300 mg intravenous Ascorbic acid postdialysis, twice a week for 5 consecutive weeks. Fasting, predialysis blood samples will be taken to measure hemoglobin, serum iron, ferritin, total iron binding capacity (TIBC) before the start of study as baseline and at the end of study after 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112248501N1**
Registration date: **2012-01-21, 1390/11/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-21, 1390/11/01

Registrant information

Name

Omid Sedighi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-03-10, 1390/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of Intravenous Iron versus Intravenous Ascorbic Acid for Treatment of Anaemic Hemodialysis Patients with High Ferritin and Low Transferrin Saturation

Public title

Comparative Study of Intravenous Iron versus Intravenous Ascorbic Acid for Treatment of Functional Iron Deficiency in Hemodialysis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Ferritin level ≥ 500 ng/ml and TSAT $\leq 25\%$; 2) Hemodialysis therapy for ≥ 3 months; 3) Duration of recombinant human Erythropoietin (rHVEPO) treatment ≥ 6 months at least 6000 u/week; 4) Hemoglobin level < 11 gr/dl and Stable hemoglobin levels for four consecutive weeks; 5) The Hemodialysis patients ≥ 18 years and < 70 years. Exclusion criteria: 1) Blood transfusion during 3 months ago; 2) Blood loss during 3 months ago; 3) Acute infection; 4) Chronic inflammatory disease; 5) Active liver disease; 6) Hemoglobinopathy such as sickle cell disease; 7) Administration of intravenous Iron during 3 months ago.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Department of Research and Technology, Moallem Square

City

Sari

Postal code

Approval date

2010-09-08, 1389/06/17

Ethics committee reference number

89-70

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

2

Description of health condition studied

Iron deficiency anaemia

ICD-10 code

D50.9

ICD-10 code description

Iron deficiency anaemia, unspecified

Primary outcomes

1

Description

Hemoglobin

Timepoint

Before the drug administration and at the 12 weeks after the start of drug administration

Method of measurement

computerized coulter counter (Abbot Machine made in USA)

Secondary outcomes

1

Description

Serum Ferritin

Timepoint

Before the drug administration and at the 12 weeks after the start of drug administration

Method of measurement

In ng/ml and will measure by LIAZON kit (made in Italy)

2

Description

Serum Iron

Timepoint

Before the drug administration and at the 12 weeks after the start of drug administration

Method of measurement

In ng/ml and will measure by Pars Azmoon kit (made in Iran) and Hitachi analyzer (Model 911, made in Japan)

3

Description

Total Iron Binding Capacity (TIBC)

Timepoint

Before the drug administration and at the 12 weeks after the start of drug administration

Method of measurement

In mg/dl and will measure by Pars Azmoon kit (made in

Iran) and Hitachi analyzer (Model 911, made in Japan)

4

Description

Transferrin Saturation(TSAT)

Timepoint

Before the drug administration and at the 12 weeks after the start of drug administration

Method of measurement

In Percent and will calculate by dividing serum Iron by TIBC x 100.

Intervention groups

1

Description

Iron sucrose (Venofor st . Gallen/Switzerland) 100 mg diluted in 100 ml of Normal Saline, postdialysis, twice a week , during the first 5 weeks of the study in case group.

Category

Treatment - Drugs

2

Description

Ascorbic acid 300 mg Intravenous postdialysis, twice a week for 5 consecutive weeks in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis Center of Imam Khomeini Hospital in Sari

Full name of responsible person

Omid Sedighi

Street address

Imam Khomeini Hospital, Amirmazandarani Blvd

City

Sari

2

Recruitment center

Name of recruitment center

Hemodialysis Center of Fatemeh Zahra Hospital in Sari

Full name of responsible person

Omid Sedighi

Street address

Artesh Bolvard

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmad Ali Enayati

Street address

Moalem Square, Department of Research and Technology

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Omid Sedighi

Position

Nephrologist\Faculty Member

Other areas of specialty/work

Street address

Unit 3, No. 26, Peyvand 13 Alley, Peyvandi Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Omid Sedighi

Position

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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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