Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ≥ 500ng/ml and TSAT≤ 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 ≥ 500ng/ml and TSAT≤ 25%; 2) Hemodialysis therapy for ≥ 3 months; 3) Duration of recombinant human Erythropoietin (rHYEPO) treatment ≥ 6 months at lest 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) Adminstration 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 adminstration and at the 12 weeks after the start of drug adminstration

Method of measurement
computerized coulter counter(Abbot Machine made in USA)

Secondary outcomes

1

Description
Sreum Ferritin

Timepoint
Before the drug adminstration and at the 12 weeks after the start of drug adminstration

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

2

Description
Serum Iron

Timepoint
Before the drug adminstration and at the 12 weeks after the start of drug adminstration

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 adminstration and at the 12 weeks after the start of drug adminstration

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 adminstration and at the 12 weeks after the start of drug adminstration
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
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Unit 3, No. 26, Peyvand 13 Alley, Peyvandi Street
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Person responsible for scientific inquiries

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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