

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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  $\geq 500\text{ng/ml}$  and TSAT  $\leq 25\%$ , hemodialysis therapy for  $\geq 3$  months, Hemoglobin level  $< 11\text{ gr/dl}$  and age  $\geq 18$  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  $> 11\text{ g/dl}$ . 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)

##### Phone

+98 15 1325 7230

##### Email address

osedighi@mazums.ac.ir

#### 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  $\geq 500\text{ng/ml}$  and TSAT $\leq 25\%$ ; 2) Hemodialysis therapy for  $\geq 3$  months; 3) Duration of recombinant human Erythropoietin (rHVEPO) treatment  $\geq 6$  months at least 6000 u/week; 4) Hemoglobin level  $< 11\text{ gr/dl}$  and Stable hemoglobin levels for four consecutive weeks; 5) The Hemodialysis patients  $\geq 18$  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 (Venofer 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

###### **City**

Sari

###### **Postal code**

###### **Phone**

+98 15 1311 5225

###### **Fax**

###### **Email**

omid\_sadighi2007@yahoo.com

###### **Web page address**

## **Person responsible for scientific inquiries**

##### **Contact**

###### **Name of organization / entity**

Mazandaran University of Medical Sciences

###### **Full name of responsible person**

Omid Sedighi

**Position**

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**Email**

omid\_sadighi2007@yahoo.com

**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*