

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparison of intravenous versus subcutaneous methods of erythropoietin injection on hemoglobin and hematocrit, complications and satisfaction of patients with Chronic kidney disease undergoing hemodialysis

#### Protocol summary

##### Study aim

Determining the effect of intravenous and subcutaneous injection of erythropoietin on hematocrit, hemoglobin, Systolic hypertension and satisfaction of injection method in patients with chronic kidney disease

##### Design

Quasi - experimental study before and after intervention without blindness (without independent control group).

##### Settings and conduct

Sampling was done among patients with chronic renal failure undergoing hemodialysis, referring to the hemodialysis department of Montsaray hospital in Mashhad, available and non-blind. Evaluation of patients to enter the study done through a research unit selection questionnaire. The injection, for 4 months, was performed by the nurse after each session of the hemodialysis.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability to speak persian language; hemodialysis three times a week; Know the person, time and place; completely satisfactory cooperation; The patients are within the age limit of 18 - 60; Have Chronic kidney disease ; All subjects were given erythropoietin 3 times a week exclusion criteria: Acute bleeding ; severe infection; uncontrolled hypertension ; Pregnancy

##### Intervention groups

Subcutaneous erythropoietin 4000 units, Three times a week for two months and then for the same group, Intravenous erythropoietin 4000 units, Three times a week for another two months. Its manufacturer is JANSSEN-CILGA Switzerland.

##### Main outcome variables

Hematocrit; Hemoglobin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180124038491N1**

Registration date: **2018-12-28, 1397/10/07**

Registration timing: **retrospective**

Last update: **2018-12-28, 1397/10/07**

Update count: **0**

##### Registration date

2018-12-28, 1397/10/07

##### Registrant information

##### Name

Azadeh Sheidaie

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3502 9275

##### Email address

sheidaeia1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-20, 1397/01/31

##### Expected recruitment end date

2018-08-17, 1397/05/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of intravenous versus subcutaneous methods of erythropoietin injection on hemoglobin and hematocrit, complications and satisfaction of patients with Chronic kidney disease undergoing hemodialysis

### Public title

Comparison of two methods of subcutaneous versus intravenous injection of Erythropoietin on hemodialysis patients

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Have Chronic kidney disease Hemodialysis is performed three times a week Receiving Erythropoietin three times in a week The patients are within the age limit of 18 - 60

#### Exclusion criteria:

Suffering from Cardiovascular disease Recently, he has had acute bleeding. Severe infection Not satisfied with participation in the study

### Age

From **18 years** old to **60 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **31**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Quraishi Building, Daneshgah Ave, Headquarters of the University

##### City

Mashhad

### Province

Razavi Khorasan

### Postal code

13944-91388

### Approval date

2018-04-20, 1397/01/31

### Ethics committee reference number

IR.MUMS.REC.1397.049

## Health conditions studied

### 1

#### Description of health condition studied

Chronic kidney disease

#### ICD-10 code

I13.11

#### ICD-10 code description

Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease

## Primary outcomes

### 1

#### Description

Hematocrit

#### Timepoint

Measurement of hematocrit levels at the end of the first month and the second month in both methods

#### Method of measurement

Siys max device

### 2

#### Description

Hemoglobin

#### Timepoint

Measurement of Hemoglobin levels at the end of the first month and the second month in both methods

#### Method of measurement

Siys max device

## Secondary outcomes

### 1

#### Description

patients Satisfaction

#### Timepoint

after tow month of intervention

#### Method of measurement

Satisfaction Questionnaire

## Intervention groups

### 1

#### Description

The intervention group1:They will give 4000 units of

erythropoietin three times a week for two consecutive months in subcutaneous form. At the end of each month, the hematocrit and hemoglobin levels will be measured. Its manufacturer is JANSSEN-CILGA, Switzerland, and the pharmaceutical companies of Oswah, and Iran's drug improvement

**Category**

Treatment - Other

**2****Description**

The intervention group 2: They will give 4000 units of erythropoietin three times a week for two consecutive months in Intravenous form. At the end of each month, the hematocrit and hemoglobin levels will be measured. Its manufacturer is JANSSEN-CILGA, Switzerland, and the pharmaceutical companies of Oswah, and Iran's drug improvement

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Montaserie hospital

**Full name of responsible person**

Ali Asghar Yar Mohammadi

**Street address**

Opposite Saba Building, Imam Khomeini St. 25, mashhad, Razavi Khorasan Province.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

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Quraishi Building, Daneshgah Ave, Headquarters of the University

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Tafaghodim@mums.ac.ir

**Web page address**

<https://ict.tbzmed.ac.ir/>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyed Reza Mazloum

**Position**

professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Avicenna St., Mashhad, Iran.

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

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**Other areas of specialty/work**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Azadeh Sheidaie

**Position**

Employee

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available