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 Recieving 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.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137776788

Phone

+98 51 3229 1969

Fax

+98 51 3229 1960

Email

montaserie@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Quraishi Building, Daneshgah Ave, Headquarters of the University

City

Mashhad

Province

Razavi Khorasan

Postal code

3316- 913791

Phone

+98 51 3841 2081

Fax

+98 51 3882 3251

Email

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.

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

Email

mazlomr@mums.ac.ir

Person responsible for scientific

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.

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3229 1970

Fax
+98 51 3859 7313

Email
Mazlomr@mums.ac.ir

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

Street address
No.15, West Eghbal Lahoory Ave

City
Mashhad

Province
Razavi Khorasan

Postal code
9115625890

Phone
+98 51 3502 9275

Fax

Email
sheidaeia1@mums.ac.ir

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