

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Oral versus Intravenous Iron Therapy in the Treatment of Anemia among Patients with End-Stage Renal Disease: An Open-Label Randomized Controlled Trial at Pakistan Emirates Military Hospital, Rawalpindi, Pakistan

Protocol summary

Study aim

To compare the efficacy and safety of oral ferrous sulfate and intravenous iron sucrose in the treatment of anemia among patients with ESRD.

Design

Single-center, open-label, parallel-group randomized controlled trial.

Settings and conduct

Department of Nephrology, Pakistan Emirates Military Hospital (PEMH), Rawalpindi, Pakistan.

Participants/Inclusion and exclusion criteria

Age 18 years or older. Diagnosed End-Stage Renal Disease. Anemia requiring iron supplementation, according to the treating nephrologist. Ability and willingness to provide written informed consent. Exclusion Criteria Active bleeding. Blood transfusion within the preceding four weeks. Known iron overload disorder. Active systemic infection. Known hypersensitivity to oral or intravenous iron preparations. Pregnancy or lactation. Active malignancy.

Intervention groups

IntraDrug Name: Iron Sucrose (Venofer®) Dosage and Administration: 200 mg intravenous infusion once weekly Five consecutive doses Total cumulative dose: 1000 mg intravenous Iron Therapy

Main outcome variables

Change in hemoglobin concentration (g/dL) from baseline to 12 weeks after initiation of treatment.

General information

Reason for update

Acronym

OIVI-ESRD

IRCT registration information

IRCT registration number: **IRCT20260617069855N1**

Registration date: **2026-06-26, 1405/04/05**

Registration timing: **retrospective**

Last update: **2026-06-26, 1405/04/05**

Update count: **0**

Registration date

2026-06-26, 1405/04/05

Registrant information

Name

muhammad sulman

Name of organization / entity

National university of medical sciences, rawalpindi

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-01, 1403/06/11

Expected recruitment end date

2025-09-01, 1404/06/10

Actual recruitment start date

2024-09-15, 1403/06/25

Actual recruitment end date

2025-10-30, 1404/08/08

Trial completion date

2026-01-31, 1404/11/11

Scientific title

Oral versus Intravenous Iron Therapy in the Treatment of Anemia among Patients with End-Stage Renal Disease:

An Open-Label Randomized Controlled Trial at Pakistan Emirates Military Hospital, Rawalpindi, Pakistan	
Public title	Comparison of Oral and Intravenous Iron Therapy for the Treatment of Anemia in Patients with End-Stage Renal Disease
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Age 18 years or older. Diagnosed End-Stage Renal Disease. Diagnosed End-Stage Renal Disease anemia requiring iron supplementation according to treating nephrologist Ability and willingness to provide written informed consent. Exclusion criteria: Active bleeding Blood transfusion within the preceding four weeks Known iron overload disorder Known hypersensitivity to oral or intravenous iron preparations. Pregnancy or lactation. Active systemic infection
Age	From 18 years old to 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 250 Actual sample size reached: 163
Randomization (investigator's opinion)	Randomized
Randomization description	Participants will be randomized using a computer-generated randomization sequence. 93 in the intravenous group and 69 in the oral group. Allocation Concealment Sequentially numbered opaque sealed envelopes.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	Prospective, single-center, open-label, parallel-arm randomized controlled trial with two intervention groups (oral iron versus intravenous iron) and 12-week follow-up. Outcome assessment includes hematological response, iron status parameters, and treatment-related adverse events.
Secondary Ids	empty
Ethics committees	

<u>1</u>
Ethics committee
Name of ethics committee
PEMH,Rawalpindi ,Pakistan
Street address
abid majeed road
City
Rawalpindi
Postal code
46000
Approval date
2023-09-01, 1402/06/10
Ethics committee reference number
ERC/552/23

Health conditions studied

<u>1</u>
Description of health condition studied
Anemia in patients with End-Stage Renal Disease (ESRD)
ICD-10 code
D63.1
ICD-10 code description
Anemia in chronic kidney disease

Primary outcomes

<u>1</u>
Description
Change in hemoglobin concentration (g/dL) from baseline following iron therapy.
Timepoint
Baseline and 12 weeks (3 months) after initiation of treatment
Method of measurement
Hemoglobin concentration (g/dL) will be measured using an automated hematology analyzer as part of routine laboratory investigations. The primary outcome will be calculated as the difference between baseline and 12-week hemoglobin values and compared between the oral iron and intravenous iron groups

Secondary outcomes

<u>1</u>
Description
Change in serum ferritin concentration (ng/mL).
Timepoint
Baseline and 12 weeks (3 months) after initiation of treatment
Method of measurement
Serum ferritin will be measured using a validated immunoassay in the hospital laboratory. The change from baseline to 12 weeks will be compared between treatment groups.

2

Description

Change in transferrin saturation (TSAT, %).

Timepoint

Baseline and 12 weeks (3 months) after initiation of treatment

Method of measurement

TSAT (%) will be calculated using the formula $TSAT = \frac{\text{Serum Iron}}{\text{Total Iron-Binding Capacity}} \times 100$. Serum iron and TIBC will be measured using standard biochemical assays, and the change from baseline will be compared between groups.

3

Description

Requirement for erythropoiesis-stimulating agents (ESA)

Timepoint

Baseline and 12 weeks (3 months) after initiation of treatment

Method of measurement

The proportion of participants requiring ESA therapy and the cumulative ESA dose administered during follow-up will be recorded from medical records.

4

Description

Requirement for blood transfusion.

Timepoint

Throughout the 12-week follow-up period.

Method of measurement

The number of participants requiring blood transfusion and the number of units transfused will be obtained from hospital records

Intervention groups

1

Description

Intervention group: Participants will receive intravenous iron therapy with iron sucrose (Venofer) 200 mg administered intravenously once weekly for 5 consecutive weeks (total cumulative dose: 1000 mg), in addition to standard care for end-stage renal disease.

Category

Treatment - Drugs

2

Description

Control group: Participants will receive oral ferrous sulfate 200 mg once daily for 3 months, in addition to standard care for end-stage renal disease.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

PEMH, Rawalpindi

Full name of responsible person

Muhammad Sulman

Street address

HOUSE NO 07, Street 64, SECTOR F, DHA PHASE 5,

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Rawalpindi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

PEMH, Rawalpindi

Full name of responsible person

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shaffaqzaman@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

PEMH, Rawalpindi

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

PEMH, Rawalpindi

Full name of responsible person

Muhammad Sulman

Position

internal medicine registrar

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Pemh , rawalpindi

Full name of responsible person

Shafaq Zaman

Position

consultant

Latest degree

Specialist

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Ear, Nose, and Throat

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified individual participant data underlying the published results, including baseline demographic characteristics, laboratory parameters (hemoglobin, serum ferritin, transferrin saturation), intervention allocation, and outcome measures.

When the data will become available and for how long

Beginning 6 months after publication of the primary study results and remaining available for 5 years

To whom data/document is available

Qualified researchers conducting scientifically sound research, subject to approval by the Principal Investigator and the Institutional Ethics Committee

Under which criteria data/document could be used

To verify published results, perform secondary analyses, and conduct systematic reviews or meta-analyses.

From where data/document is obtainable

Data will be shared upon reasonable request to the principal investigator after execution of a data-sharing agreement and approval by the institutional ethics committee.

What processes are involved for a request to access data/document

Data will be shared upon reasonable request to the principal investigator after execution of a data-sharing agreement and approval by the institutional ethics committee.

Comments