Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 (Venofor®) Dosage and Administration: 200 mg intravenous infusion once weekly Five consecutive doses Total cumulative dose: 1000 mgvenous 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
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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

1

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

1

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

1

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

1

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) = (Serum Iron ÷ Total Iron-Binding Capacity) × 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 (Venofor) 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
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Sponsors / Funding sources

1

Sponsor
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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
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Person responsible for updating data

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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