

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

COMPARISON OF ORAL VERSUS INTRAVENOUS IRON THERAPY IN IMPROVING HEMOGLOBIN STATUS IN PATIENTS OF CHRONIC KIDNEY DISEASE

Protocol summary

Study aim

Treatment efficacy of oral versus intravenous iron supplementation in improving the serum iron and hemoglobin status of patients with chronic kidney disease not on hemodialysis or erythropoietin

Design

Single center, parallel group, randomized controlled interventional trial

Settings and conduct

Department of Medicine, PEMH Rawalpindi Participants divided into the intravenous iron supplementation group (Group I) (n=105) and the oral iron supplementation group (Group O) (n=105).

Participants/Inclusion and exclusion criteria

Inclusion criteria included all male and female patients over the age of 18 years not on hemodialysis or erythropoietin diagnosed as anemia with a baseline Hb of less than 13 g/dl in males and less than 12 g/dl in females with established chronic kidney disease with a GFR (glomerular filtration rate) of less than 60ml/min for more than 90 days assessed using the CKD-EPI equation and/or hyper albuminuria with urine albumin $\geq$ 30 mg in 24 hours or urine albumin to creatinine ratio (ACR) $\geq$ 30 mg/g. Exclusion criteria included patients on dialysis, erythropoietin or use of erythropoietin stimulating agents (ESAs) in the last 3 months, patients with advanced liver, cardiac or ESKD (end-stage kidney disease), drug allergies to iron and its supplemental form during therapy or previous known history or unwilling to be included in the study.

Intervention groups

Intravenous iron group (Group I) (n=105) Oral iron group (Group O) (n=105)

Main outcome variables

Primary variables observed were changes in the serum iron, Hb, transferrin and TIBC. Secondary variables observed were the adverse effect profile seen with both

treatment regimes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231003059605N1**

Registration date: **2023-10-31, 1402/08/09**

Registration timing: **retrospective**

Last update: **2023-10-31, 1402/08/09**

Update count: **0**

Registration date

2023-10-31, 1402/08/09

Registrant information

Name

Hamza Nawaz

Name of organization / entity

Armed Forces Postgraduate Medical Institute

Country

Pakistan

Phone

+92 324 5972040

Email address

hamzanawazchattha@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-01, 1401/10/11

Expected recruitment end date

2023-06-30, 1402/04/09

Actual recruitment start date

2023-01-01, 1401/10/11

Actual recruitment end date

2023-06-30, 1402/04/09
Trial completion date
2023-06-30, 1402/04/09

Scientific title
COMPARISON OF ORAL VERSUS INTRAVENOUS IRON THERAPY IN IMPROVING HEMOGLOBIN STATUS IN PATIENTS OF CHRONIC KIDNEY DISEASE

Public title
ORAL VERSUS IV IRON THERAPY IN PATIENTS WITH KIDNEY DISEASE

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria included all male and female patients over the age of 18 years Not on hemodialysis or erythropoietin diagnosed as anemia with a baseline Hb of less than 13 g/dl in males and less than 12 g/dl in females With established chronic kidney disease with a GFR (glomerular filtration rate) of less than 60ml/min for more than 90 days assessed using the CKD-EPI equation and/or hyper albuminuria with urine albumin $\geq$ 30 mg in 24 hours or urine albumin to creatinine ratio (ACR) $\geq$ 30 mg/g.
Exclusion criteria:
Exclusion criteria included patients on dialysis, erythropoietin or use of erythropoietin stimulating agents (ESAs) in the last 3 months Patients with advanced liver, cardiac or ESKD (end-stage kidney disease) Drug allergies to iron and its supplemental form during therapy or previous known history Unwilling to be included in the study.

Age
From **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **210**
Actual sample size reached: **210**

Randomization (investigator's opinion)
Randomized

Randomization description
The RCT included all the assessed participants for eligibility and meeting the inclusion criteria randomized through non-probability consecutive sampling by lottery method through concealed envelopes into the intravenous iron supplementation group (Group I) (n=105) and the oral iron supplementation group (Group O) (n=105).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ERB Pak Emirates Military Hospital, Rawalpindi

Street address

Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2022-12-25, 1401/10/04

Ethics committee reference number

PEMH-RWP-003236

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

D63.1

ICD-10 code description

Anemia in chronic kidney disease

Primary outcomes

1

Description

Serum iron levels

Timepoint

4 weeks after starting therapy

Method of measurement

Blood levels

2

Description

Serum Hb

Timepoint

4 weeks after therapy

Method of measurement

Blood levels

3

Description

Serum Ferritin levels

Timepoint

4 weeks after therapy

Method of measurement

Blood levels

4

Description

Serum transferrin and TIBC levels

Timepoint

4 weeks after therapy

Method of measurement

Blood levels

Secondary outcomes

1

Description

Constipation and diarrhea

Timepoint

During 4 weeks of therapy

Method of measurement

Patient history

2

Description

Allergy to iron supplementation

Timepoint

During 4 weeks of therapy

Method of measurement

Patient assessment weekly during treatment

Intervention groups

1

Description

Intervention group: Intravenous iron supplementation group

Category

Treatment - Drugs

2

Description

Intervention group: Oral iron intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Dr Hamza Nawaz Chattha

Street address

Rawalpindi

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Email

hamzanawazchattha@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Hamza Nawaz Chattha

Street address

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Email

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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

Pak Emirates Military Hospital Rawalpindi

Proportion provided by this source

5

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

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Hamza Nawaz Chattha

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Position
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Medical doctor
Other areas of specialty/work
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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

No - There is not 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

All data sets including output sheets made in SPSS 26 will be shared after permission from the author and acceptance of publication of the manuscript

When the data will become available and for how long

Data will be available indefinitely to academics after the acceptance of the manuscript for publication

To whom data/document is available

Will be available to academics after permission from the primary author

Under which criteria data/document could be used

The data will be allowed to be used for academic and research purposes

From where data/document is obtainable

Will be available online on Google drive and link would be sent after acceptance of the manuscript

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

An official request email from the institute or academic email ID for request of data. The application would be processed within 3 days and data would be available within 2 weeks of acceptance by the primary author

Comments