Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 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 30 mg in 24 hours or urine albumin to creatinine ratio (ACR) 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 30 mg in 24 hours or urine albumin to creatinine ratio (ACR) 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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Hamza Nawaz Chattha
Position
Registrar
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Other areas of specialty/work
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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