

Clinical observation of Yishen Jiangzhuo therapy in the treatment of non-dialysis renal anemia patients with stage 3–4 chronic kidney disease

Submission date 14/07/2026	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 15/07/2026	Overall study status Completed	☐ Protocol
Last Edited 15/07/2026	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Principal investigator, Scientific, Public

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Study information

Scientific Title

A prospective randomized controlled trial comparing conventional western medical therapy alone versus conventional western medical therapy combined with kidney-tonifying turbidity-reducing herbal therapy for improving anemia status, iron metabolism, renal function and inflammatory levels, reducing weekly erythropoietin dosage and evaluating safety among non-dialysis adults with stage three to four chronic kidney disease and renal anemia

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 29/09/2021, Hebei Provincial Hospital of Traditional Chinese Medicine (389 Zhongshan East Road, Chang 'an District, Shijiazhuang, 050011, China; +86 311-69095606; cpwg732@126.com), ref: HBZY2021-KY-052-01

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Treatment of renal anemia in non-dialysis adult patients with stage 3–4 chronic kidney disease

Interventions

Group Allocation Method

All eligible participants will be assigned at a 1:1 ratio to either the treatment group or the control group via block randomisation with a block size of 4 combined with a random number table. An independent statistician will generate the random sequence and seal it in opaque envelopes; researchers will open envelopes sequentially according to participant enrolment order to complete group allocation.

Control Group Intervention (Usual Western Medicine Care, 8-week full treatment course)

Every participant in the control group will receive standard conventional Western medical therapy throughout the trial:

1. Recombinant human erythropoietin injection (Yibi'ao, Shenyang Sansheng Pharmaceutical): 3000 IU administered subcutaneously three times per week (Monday, Wednesday, Friday). Clinicians will adjust dosage dynamically: reduce to twice weekly if haemoglobin exceeds 120 g/L, suspend injection if haemoglobin rises above 130 g/L, and resume the original dose once haemoglobin drops below 120 g/L
2. Ferrous succinate tablets (Suliferr, Jinling Pharmaceutical): 0.2 g taken orally three times daily after meals to relieve gastrointestinal irritation
3. Unified basic kidney protective management: medical staff will control participants' blood pressure below 130/80 mmHg, glycated haemoglobin under 7.0%, and low-density lipoprotein cholesterol less than 2.6 mmol/L; angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers and statins will be prescribed appropriately, and all nephrotoxic drugs will be prohibited

Treatment Group Intervention (Identical Western Medicine plus Yishen Jiangzhuo Herbal Decoction, 8-week full treatment course)

Each participant in the treatment group will receive the exact same conventional Western medical therapy as the control group, with the additional oral administration of Yishen Jiangzhuo herbal decoction:

1. Herbal formula composition: Astragali Radix 30 g, Codonopsis Radix 15 g, Angelicae Sinensis Radix 12 g, Rehmanniae Radix Preparata 15 g, Salviae Miltiorrhizae Radix et Rhizoma 15 g, Spatholobi Caulis 15 g
2. Preparation and administration: The hospital pharmacy will uniformly decoct all qualified authentic medicinal materials, concentrate the liquid into 150 mL vacuum-sealed sachets. Participants will take 150 mL warm decoction twice daily, one hour after breakfast and dinner, continuously for 8 weeks

Unified Trial Procedures for All Participants

1. A telephone follow-up will be conducted at week 4 of treatment to record medication compliance and any adverse events
2. Fasting venous blood samples will be collected in the early morning at baseline and week 8 (± 3 days) to test primary and secondary efficacy indicators as well as safety biomarkers
3. Researchers will record cumulative erythropoietin consumption and all adverse reactions throughout the 8-week intervention period

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Recombinant human erythropoietin (rHuEPO) (Yibi'ao), ferrous succinate (Suliferr), Jiangzhuo formula (astragali radix, codonopsis radix, angelicae sinensis radix, rehmanniae radix praeparata, salviae miltiorrhizae radix et rhizoma, spatholobi caulis)

Primary outcome(s)

1. Change in hemoglobin (Hb) level measured using fasting venous blood hemoglobin concentration via Sysmex XN-9000 automatic hematology analyzer, unit: g/L at baseline (week 0), week 8

2. Change in reticulocyte hemoglobin content (CHr) measured using reticulocyte mean fluorescence intensity by Sysmex XN flow cytometry and convert to CHr value, unit: pg at baseline (week 0), week 8

3. Change in soluble transferrin receptor (sTfR) measured using immunoturbidimetry assay on Roche Cobas c702 analyzer with matched reagents, unit: mg/L at baseline (week 0), week 8

Key secondary outcome(s)

Completion date

30/06/2024

Eligibility

Key inclusion criteria

1. Aged 21 to 69 years old, no gender limitation
2. Diagnosed with stage 3–4 chronic kidney disease with estimated glomerular filtration rate of 15–59 mL/min/1.73 m² and not receiving dialysis
3. Meet the diagnostic criteria for renal anemia: hemoglobin level less than 120 g/L for males and less than 110 g/L for females
4. No recombinant human erythropoietin or intravenous iron agents administered within four weeks before enrollment
5. Serum ferritin higher than 100 ng/mL and transferrin saturation above 20% to rule out absolute iron deficiency
6. Voluntarily participate and sign written informed consent

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

21 Years

Upper age limit

69 Years

Sex

All

Total final enrolment

157

Key exclusion criteria

1. Anemia caused by gastrointestinal hemorrhage, hemolysis and hematological diseases including aplastic anemia, myelodysplastic syndrome and thalassemia
2. Patients complicated with severe infection, hepatic insufficiency with alanine transaminase /aspartate transaminase levels exceeding three times the upper limit of normal values, malignant tumors or active autoimmune diseases

3. Individuals with allergies to ingredients of investigational drugs such as ferrous succinate, erythropoietin and components of traditional Chinese herbal prescriptions
4. Pregnant or lactating women
5. Participants enrolled in other ongoing clinical trials
6. Subjects with poor treatment compliance or those deemed ineligible for enrolment by researchers for other reasons

Date of first enrolment

01/01/2022

Date of final enrolment

31/12/2023

Locations

Countries of recruitment

China

Sponsor information

Organisation

Hebei Provincial Administration of Traditional Chinese Medicine

Funder(s)

Funder type**Funder Name**

Hebei Provincial Administration of Traditional Chinese Medicine

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available