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Meta-Analysis of Modified Shenqi Dihuang Decoction for the Treatment of Chronic Renal Failure

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ADMINISTRATIVE INFORMATION

Support - No.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202570028

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 July 2025 and was last updated on 7 July 2025.

INTRODUCTION

Review question / Objective Dihuang Decoction significantly improve renal function and inflammation markers in patients with chronic renal failure compared to conventional treatments?

Rationale Chronic renal failure (CRF) is a progressive disease with a long course, high cost, and poor prognosis. While conventional Western treatments such as dialysis offer symptom control, they are associated with economic burden and limited efficacy in slowing disease progression. Shenqi Dihuang Decoction, a classical traditional Chinese medicine (TCM) formula, has shown promise in clinical settings for enhancing renal function and reducing inflammatory markers in CRF patients. However, individual studies often involve small sample sizes and vary in methodology, resulting in inconsistent outcomes. To date, no comprehensive meta-analysis has synthesized the evidence regarding its efficacy and safety. Therefore, this systematic review aims to critically evaluate current randomized controlled trials to provide more robust evidence for clinical practice and future research.

Condition being studied Chronic renal failure (CRF), also known as chronic kidney failure, is a progressive loss of kidney function over time. This review focuses on patients diagnosed with CRF who are undergoing treatment with modified Shenqi Dihuang Decoction.

METHODS

Search strategy Databases searched: CNKI, VIP, Wanfang, PubMed, Cochrane Library, Web of Science (from inception to April 2025). Keywords: “Shenqi Dihuang Decoction”, “CRF”, “RCT” and their Chinese equivalents. Boolean operators used. No language restrictions.

Participant or population Patients diagnosed with chronic renal failure (CRF), regardless of gender, age, region, or stage of disease, who participated in randomized controlled trials evaluating the

efficacy of Shenqi Dihuang Decoction (modified or not).

Intervention Modified Shenqi Dihuang Decoction (with or without minor herbal adjustments) administered alone or in combination with conventional treatment for chronic renal failure.

Comparator Placebo, conventional western medicine, or other non-TCM interventions used in control groups of the included RCTs.

Study designs to be included Randomized controlled trials (RCTs) only.

Eligibility criteria Inclusion: RCTs involving CRF patients treated with modified Shenqi Dihuang Decoction; outcomes include Scr, BUN, Ccr, TNF-α, IL-6, or clinical effectiveness.
Exclusion: Non-RCTs, reviews, case reports, conference abstracts, animal studies, and duplicate publications.

Information sources Electronic databases: CNKI, VIP, Wanfang, PubMed, Cochrane Library, and Web of Science (from inception to April 2025).

Main outcome(s)
Serum creatinine (Scr)
Blood urea nitrogen (BUN)
Clinical effectiveness rate.

Additional outcome(s)
Creatinine clearance rate (Ccr)
Tumor necrosis factor-alpha (TNF-α)
Interleukin-6 (IL-6)
Adverse events/safety indicators.

Data management Two independent reviewers will screen articles, extract data, and input it into Excel for standardization. Discrepancies will be resolved by discussion or third-party adjudication.

Quality assessment / Risk of bias analysis Risk of bias will be assessed using the Cochrane Collaboration's Risk of Bias Tool, including random sequence generation, allocation concealment, blinding, incomplete data, selective reporting, and other sources of bias.

Strategy of data synthesis Meta-analysis will be conducted using RevMan 5.3 and Stata 16.0. OR and SMD will be used for dichotomous and continuous outcomes, respectively, with 95% confidence intervals. Heterogeneity will be assessed by I^2 and P-value.

Subgroup analysis Subgroup analyses will be conducted based on treatment modality (TCM alone vs. TCM + Western medicine), duration of treatment, and sample size.

Sensitivity analysis Sensitivity analysis will be performed by sequentially excluding individual studies to test the robustness of the results.

Language restriction No language restrictions will be applied during the literature search.

Country(ies) involved China.

Other relevant information This systematic review is currently in progress. The protocol has been completed and preliminary literature screening has been conducted. Registration will be submitted and made public on the INPLASY platform. The study has been designed and written in strict accordance with the PRISMA 2020 statement. A PRISMA flow diagram and checklist will be included in the appendix to ensure transparency and reproducibility of the review process.

Keywords Shenqi Dihuang Decoction; chronic renal failure; chronic kidney disease; meta-analysis; traditional Chinese medicine; randomized controlled trials.

Dissemination plans The findings will be submitted to a peer-reviewed journal for publication and shared through academic conferences and institutional repositories.

Contributions of each author
Author 1 - The sole author (Qing Wang) was responsible for the conception and design of the study, literature search and selection, data extraction and analysis, risk of bias assessment, drafting and revision of the manuscript, and final approval of the version to be submitted.