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INPLASY

Clinical efficacy and safety of XiaoKe decoction in the treatment of diabetic kidney disease: A protocol for systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No Founding.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 November 2024 and was last updated on 12 November 2024.

INTRODUCTION

Review question / Objective This study systematically reviewed RCTs on the efficacy and safety of Xiaoke Decoction, used alone or with antidiabetic medications, in the management of DKD.

Rationale This study systematically searched seven Chinese and English databases, including PubMed, EMBASE, Cochrane Library, CNKI, Wan Fang, and VIP, for eligible randomized controlled trials published between January 2010 and May 2024. The meta-analysis will be performed with RevMan 5.4 and Stata 18.0.

Condition being studied Diabetic nephropathy is a chronic condition that is the most prevalent cause of end-stage kidney disease (ESKD). As the prevalence of diabetes continues to increase, the incidence of chronic kidney disease (CKD) attributable to diabetes has also increased proportionally. A large amount of clinical data indicates that the combination of traditional Chinese medicine and modern Western medicine in treating diabetic nephropathy has been more effective than Western medicine alone. In recent years, Xiaoke Decoction, a traditional Chinese herbal formula, has gained attention for its use in treating diabetic nephropathy in recent years. However, a systematic review of Xiaoke Decoction in the treatment of diabetic nephropathy has yet to be conducted. Therefore, we plan to conduct a systematic review and meta-analysis to evaluate its efficacy and safety, thereby providing robust evidence-based support for clinical applications.

METHODS

Search strategy This study systematically searched seven Chinese and English databases, including PubMed, EMBASE, Cochrane Library, CNKI, Wan Fang, and VIP, for eligible randomized

controlled trials published between January 2010 and May 2024.

Participant or population Patients diagnosed with DKD met the diagnostic criteria established by the 2024 consensus between the American Diabetes Association and Kidney Foundation. Patients with non-diabetic renal impairment were excluded from the study.

Intervention Studies involving Xiaoke decoction or its modified forms will be included without restrictions on the dosage form (decoction, capsule, or pellet), frequency, or dosage; however, only oral administration will be considered. The experimental group was permitted to receive either Xiaoke Decoction alone or in combination with conventional treatment, with no additional traditional Chinese medicine therapies allowed.

Comparator The treatment group received Xiaoke decoction in conjunction with standard therapy, whereas the control group received only standard therapy, with no specific requirements regarding duration, frequency, or form of medication.

Study designs to be included The study will only include RCTs published in Chinese and English that examine the Xiaoke Decoction for treating diabetic nephropathy.

Eligibility criteria This study systematically searched seven Chinese and English databases, including PubMed, EMBASE, Cochrane Library, CNKI, Wan Fang, and VIP, for eligible randomized controlled trials published between January 2010 and May 2024. This study employed a combination of keywords and text terms related to "Oral Diabetes Remedies," " modified Diabetes Remedies," "DKD" and "RCTs" for the search process .The search terms primarily included: "Xiao ke formula," "Xiao ke decoction," "Xiao ke granule," "XKF," "diabetic nephropathy" "diabetic kidney diseases," "diabetic nephropathies," and "RCTs."

Information sources This study systematically searched seven Chinese and English databases, including PubMed, EMBASE, Cochrane Library, CNKI, Wan Fang, and VIP, for eligible randomized controlled trials published between January 2010 and May 2024. This study employed a combination of keywords and text terms related to "Oral Diabetes Remedies," " modified Diabetes Remedies," "DKD" and "RCTs" for the search process .The search terms primarily included: "Xiao ke formula," "Xiao ke decoction," "Xiao ke granule," "XKF," "diabetic nephropathy" "diabetic kidney diseases," "diabetic nephropathies," and "RCTs."

Main outcome(s) Overall response rate, 24-hour urinary protein quantification, and serum creatinine.

Additional outcome(s) Glycated hemoglobin A1c; Fasting blood glucose; Urea nitrogen.

Data management Before study selection, all reviewers will undergo professional training to ensure a thorough understanding of the objectives and procedures of the review. The collected literature was imported into EndnoteX9 for management, and duplicate content was identified and subsequently removed. Initially, two systematic reviewers, (AS) and (ZDM), independently performed a comprehensive screening of primary research articles, evaluating titles and abstracts to identify those that might meet the inclusion criteria, and excluded studies that did not align with these criteria. Subsequently, two reviewers conducted a cross-verification of the included literature and performed a thorough examination of the full text to extract relevant data for classification and synthesis. In the event of a disagreement, a secondary investigator (DXY) was consulted to collaboratively discuss differing opinions or to render a final assessment.

Quality assessment / Risk of bias analysis According to the quality standards set by the Cochrane Collaboration Network, the primary evaluation criteria included random sequence generation, blinding of participants, allocation concealment, providers, outcome assessors, completeness of outcome data, selective reporting, and potential additional biases. Two researchers (AS and DXY) will assess the quality using criteria categorized as low risk, high risk, or unclear. Any discrepancies in the ratings were resolved through consultation with a third researcher (WX). For each item, a response of "yes" indicates a low risk of bias, "no" indicates a high risk, and "unknown" reflected uncertainty.

Strategy of data synthesis Meta-analysis was conducted using RevMan 5.4 software from; Cochrane Collaboration), applying risk ratios (RR) for dichotomous variables and mean differences (MD) for continuous variables. The χ^2 test was used to assess heterogeneity. The χ^2 test was used to assess heterogeneity: when $P > 0.1$ or $I^2 < 50\%$, heterogeneity was considered minimal, and a fixed-effects model (FEM) was applied; otherwise, a random-effects model(REM) was used. A sensitivity analysis was conducted for each

outcome to evaluate stability, and the Egger test was performed to assess potential publication bias.

Subgroup analysis Use subgroup analysis to group different effects as needed, such as different stages of DKD.

Sensitivity analysis To ensure robust results, sensitivity analyses were performed using Stata version 18.0. In cases where significant statistical heterogeneity was identified, we excluded low-quality trials, duplicate studies, and studies with inadequate sample sizes or insufficient data. This approach enabled us to assess each study's impact on the overall findings and confirm the reliability of the results.

Language restriction No limit.

Country(ies) involved China.

Keywords diabetic kidney disease; systematic evaluation; meta-analysis; traditional Chinese medicine; Xiaoke Decoction.

Contributions of each author

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