

INPLASY PROTOCOL

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Clinical efficacy and safety of astragalus injection combined with ACEI/ARB in the treatment of diabetic kidney disease: A protocol for systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: Diabetic kidney disease (DKD) is one of the most common complications of diabetes mellitus. Astragalus injection is widely used in the treatment of diabetic kidney disease. In this study, we want to perform a meta-analysis to evaluate the efficacy and safety of astragalus injection in the treatment of DKD patients.

Condition being studied: Diabetic kidney disease is now considered to be the major cause of end-stage renal disease (ESRD). Current therapy for diabetic kidney disease still primarily relies on the antiproteinuric, antihypertensive and nephroprotective effects of renin-angiotensin system (RAS) blockers. However, these standard therapies are insufficient to prevent progression to ESRD in a substantial number of patients with residual proteinuria. Nowadays, Astragalus injection is widely used in the treatment of diabetic kidney disease, it can reduce the excretion of urinary protein and reduce the level of inflammatory factors in diabetic nephropathy animal models, thereby reducing renal disease. At present, there are some reports about the treatment of DKD with astragalus injection combined with ACEI/ARB, but the conclusions are not consistent, and most of the research samples are small, which can not provide enough test efficiency.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 September 2021 and was last updated on 07 September 2021 (registration number INPLASY202190014).

INTRODUCTION

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METHODS

Participant or population: Participants were those who had been diagnosed as diabetic kidney disease regardless of age, gender, nationality and race.

Intervention: The experimental group used astragalus injection combined with ACEI/ARB treatment.

Comparator: The control intervention included simple western medicine, such as ACEI/ARB.

Study designs to be included: This study will only consider randomized controlled trials (RCTs) of astragalus injection combined with ACEI/ARB for the treatment of patients with DKD. However, other studies, such as animal studies, reviews, case studies, non-controlled studies, and quasi-RCTs, were excluded.

Eligibility criteria: Studies recruiting patients with DKD, as diagnosed with any

recognized diagnostic criteria, will be included in our study, regardless of gender, ethnic background or nationality. However, subjects with infection, fever, cancer, kidney transplantation, liver disease, and severe cardiopulmonary disease will be excluded.

Information sources: We will search the following databases from their inception to August 31, 2021: EMBASE Database, Web of Science, PubMed, the Cochrane Library, China National Knowledge Internet, Wanfang Database, China Biological Medicine Database, VIP database, and Ongoing Clinical Trials Database.

Main outcome(s): The primary outcome measures set in our study included urinary albumin excretion rates, 24 hours urinary protein quantification, and renal function (blood urea nitrogen, serum creatinine concentration).

Quality assessment / Risk of bias analysis: Each of the included RCTs needs to be assessed for risk of bias, which was done independently by the two author using the Cochrane Risk of bias tool, and the disputed part resolves the disagreement through negotiation or a third author.

Strategy of data synthesis: We performed this meta-analysis using Revman 5.4 software (Cochrane Collaboration) for all statistical data analyses, using 95% confidence interval (CI) and risk ratio (RR) to calculate categorical variables, and using 95% CI and mean differences (MDs) to calculate continuous variables. We used the χ^2 value test and inconsistency index (I^2) to assess the heterogeneity across each study. A value of $P < 0.1$ or $I^2 > 50\%$ was deemed to have significant heterogeneity, a random-effect model was then used to analyze the data. Otherwise, the fixed-effect model was used. We adopted the Egger funnel plot and Egger's test to test publication bias with Stata15.0 (StataCorp LP, College Station, TX, US), with $P < 0.05$ indicating significant asymmetry.

Subgroup analysis: We will investigate the source of heterogeneity using subgroup

analysis based on different interventions, controls, and outcomes. Subgroup analysis was used to find potential source of heterogeneity.

Sensitivity analysis: We will carry out a sensitivity analysis to investigate the robustness and stability of outcome results by removing low methodological quality studies. The main analysis points included the impact of method quality, sample size, and missing data on the study.

Country(ies) involved: China.

Keywords: astragalus injection; ACEI/ARB; diabetic kidney disease; meta-analysis.

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