INPLASY PROTOCOL

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Review Stage at time of this submission: Preliminary searches.

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Efficacy and safety of Chinese Herbal Medicine for advanced diabetic nephropathy: A protocol of systematic review and meta-analysis

Yu, Z[1]; Zhang, W[2]; Li, R[3]; Bao, P[4]; Wang, F[5]; Sun, J[6]; Song, G[7]; Yin, L[8].

Review question / Objective: This study is intended to evaluate the efficacy and safety of Chinese Herbal Medicine for advanced diabetic nephropathy.

Condition being studied: Diabetic nephropathy (DN), one of the most serious complications in the development of diabetes mellitus, has become the main cause of end-stage renal disease and one of the main causes of death in diabetic patients. As the epidemic of diabetes spreads, the number of patients at risk for developing DN are increasing, which occurs in 20% to 40% of all diabetic patients. The main characteristics of DN include proteinuria, decline in glomerular filtration, hypertension, and high risk of cardiovascular morbidity and mortality. However, at present, the research on the pathogenesis of diabetic nephropathy in Western medicine is still in progress, which is not very clear yet, and no drugs have been found to significantly delay or control the progression of DN. TCM has a long history of understanding and treatment of this disease, and clinical studies have shown that TCM is effective in improving symptoms and alleviating pathological progress of kidney tissue.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 May 2021 and was last updated on 26 May 2021 (registration number INPLASY202150094).

INTRODUCTION

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METHODS

Participant or population: Participants who were definitely diagnosed with advanced diabetic nephropathy would be included, there will be no limitation about sex, ages, and other factors.

Intervention: The intervention included both prescription and Chinese herb medicines.

Comparator: Intervention: placebo; no treatment; pharmacological compounds (for example such as irbesartan); non-pharmacological interventions (for example diet, exercise).

Study designs to be included: RCTs.

Eligibility criteria: Patients suffering from advanced diabetic nephropathy.

Information sources: The Cochrane Library, PubMed, EMBASE, Allied and Complementary Medicine Database (AMED), Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure Database (CNKI), Chinese Science and Technique Journals Database (VIP), and the Wanfang Database, and databases of ongoing trials were also searched.

Main outcome(s): 1.24-hour urine protein quantitation, 2.urinary albumin excretion rate, 3.glomerular filtration rate, 4.fasting blood glucose,

Additional outcome(s): Total urinary protein and glycosylated hemoglobin.

Quality assessment / Risk of bias analysis: Two investigators will independently evaluate the methodological quality of the included literature by using the Cochrane Collaboration's ROB tool which includes 7 items: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias) incomplete outcome data (attrition bias), selective reporting (reporting bias), other bias. According to the relevant standards in the Cochrane Intervention System Evaluation Manual, it will be divided into low risk high risk and unclear.

Strategy of data synthesis: Data concerning details of study population, intervention and outcomes will be extracted independently by two reviewers using a standard data extraction form. The standard data extraction form will include at least the following items: general information: General information ; Trial information; Participant characteristics; Study intervention; Categories of intervention.

Subgroup analysis: Sub-group analyses were carried out by region, sample size and types of DN for there was significant heterogeneity across the included studies.

Sensitivity analysis: To eliminate heterogeneity as much as possible, sensitivity analysis or subgroup analysis is applied to explore the source of heterogeneity. If one considers the impact of multiple covariates, a meta-regression analysis is applied to explore the source of heterogeneity.

Country(ies) involved: China.

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