

INPLASY PROTOCOL

To cite: Yang et al. Clinical Efficacy and Safety of Chinese Herb Medicine for the Treatment of Patients With Early Diabetic Nephropathy : A Protocol for Systematic Review and Meta-analysis. Inplasy protocol 202040139. doi: 10.37766/inplasy2020.4.0139

Received: 22 April 2020

Published: 22 April 2020

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Support: Horizontal Scientific Research

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

Conflicts of interest: None.

Clinical Efficacy and Safety of Chinese Herb Medicine for the Treatment of Patients With Early Diabetic Nephropathy : A Protocol for Systematic Review and Meta-analysis

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Review question / Objective: Clinical Efficacy and Safety of Chinese Herb Medicine for the Treatment of Patients With Early Diabetic Nephropathy : A Protocol for Systematic Review and Meta-analysis.

Condition being studied: Diabetic nephropathy (DN) is among the common and serious complications of diabetes and is also a major cause of end-stage kidney disease. Early diabetic nephropathy is also called diabetic microalbumin period, the main treatment is in the control of blood sugar on the basis of kidney protection and urine lowering protein. There are few effective methods of western medicine treatment, and most of them are accompanied by adverse reactions. But some studies have shown that traditional Chinese medicine has achieved the curative effect and has certain superiority. However, there are few systematic reviews on the treatment of traditional Chinese herb medicine for early diabetic nephropathy currently. Therefore, this paper conducted a systematic review of clinical efficacy and safety of Chinese herb medicine for the treatment of patients with early DN, aim to comprehensively analyze the role of traditional Chinese herb medicine in the treatment of early DN.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 April 2020 and was last updated on 22 April 2020 (registration number INPLASY202040139).

INTRODUCTION

Review question / Objective: Clinical Efficacy and Safety of Chinese Herb

Medicine for the Treatment of Patients With Early Diabetic Nephropathy : A Protocol for Systematic Review and Meta-analysis.

Condition being studied: Diabetic nephropathy (DN) is among the common and serious complications of diabetes and is also a major cause of end-stage kidney disease. Early diabetic nephropathy is also called diabetic microalbumin period, the main treatment is in the control of blood sugar on the basis of kidney protection and urine lowering protein. There are few effective methods of western medicine treatment, and most of them are accompanied by adverse reactions. But some studies have shown that traditional Chinese medicine has achieved the curative effect and has certain superiority. However, there are few systematic reviews on the treatment of traditional Chinese herb medicine for early diabetic nephropathy currently. Therefore, this paper conducted a systematic review of clinical efficacy and safety of Chinese herb medicine for the treatment of patients with early DN, aim to comprehensively analyze the role of traditional Chinese herb medicine in the treatment of early DN.

METHODS

Search strategy: We will search 3 English database including PubMed, Embase, Cochrane Library Central Register of Controlled Trials and 4 Chinese databases including China National Knowledge Infrastructure (CNKI) database, Wanfang Data Knowledge Service Platform, the VIP information resource integration service platform (cqvip), China Biology Medicine Disc (Sino Med) with a language limitation of English and Chinese from 2010 to February 2020. We will search 3 English database including PubMed, Embase, Cochrane Library Central Register of Controlled Trials and 4 Chinese databases including China National Knowledge Infrastructure (CNKI) database, Wanfang Data Knowledge Service Platform, the VIP information resource integration service platform (cqvip), China Biology Medicine Disc (Sino Med) with a language limitation of English and Chinese from 2010 to February 2020.

Participant or population: Participants who were definitely diagnosed with early DN would be included, but except for patients with other serious disease. There will be no limitation about sex, ages, and other factors.

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

Comparator: The control intervention included simple western medicine, such as placebo or ACEI/ARB. Hypoglycemic therapy was used as a cointervention in both of the arms, including oral hypoglycemic drugs, insulin, and exercise, or did not get any treatment as a blank control would be adopted.

Study designs to be included: This study will include all the RCTs that relate to Chinese herb medicine therapy in treating early DN.

Eligibility criteria: For the included trials, the investigators need to precisely report the stochastic methods, Chinese herb medicine treatment details and parameters, diagnostic criteria and efficacy evaluation they based on. No limitation to whether it is published or not. The experiment is limited to humans. Language is limited to Chinese and English.

Information sources: We will search 3 English database including PubMed, Embase, Cochrane Library Central Register of Controlled Trials and 4 Chinese databases including China National Knowledge Infrastructure (CNKI) database, Wanfang Data Knowledge Service Platform, the VIP information resource integration service platform (cqvip), China Biology Medicine Disc (Sino Med) with a language limitation of English and Chinese from 2010 to February 2020. We will search 3 English database including PubMed, Embase, Cochrane Library Central Register of Controlled Trials and 4 Chinese databases including China National Knowledge Infrastructure (CNKI) database, Wanfang Data Knowledge Service Platform, the VIP information resource integration service platform (cqvip), China

Biology Medicine Disc (Sino Med) with a language limitation of English and Chinese from 2010 to February 2020.

Main outcome(s): The main outcome included 24-hour urine protein quantitation, urinary albumin excretion rate, fasting blood glucose and glycosylated hemoglobin.

Additional outcome(s): The second outcome measure is based on TCM syndrome evaluation criteria. Healing: the clinical symptoms and signs of TCM disappear or almost disappear, and the syndrome score is reduced by $\geq 90\%$; Urine protein excretion rate, creatinine clearance rate all returned to normal. Significant effect: the clinical symptoms and signs of TCM are obviously improved, and the syndrome score is reduced by $\geq 60\%$, $< 90\%$; Urine protein excretion rate decreased $\geq 50\%$, $< 70\%$; creatinine clearance was normal. Effective: Chinese medicine clinical symptoms and signs have improved, syndrome scores decreased by $< 60\%$, but $\geq 30\%$; urinary protein excretion rate decreased by $\geq 20\%$, $< 50\%$; creatinine clearance was normal. Invalid: the clinical symptoms and signs of TCM were not improved, even worse, and the syndrome score was reduced by $< 30\%$. Integral variation formula (nimodipine method): $[(\text{pretreatment score} - \text{posttreatment score}) \div \text{pretreatment score}] \times 100\%$.

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: Two investigators independently extracted information from the included literature. The extracted content includes year of publication, research design, random hiding and blinding, basic information of the included cases, intervention methods, observation indicators and test results of the treatment group and the control group. The extracted literature data will be filled in a unified data statistics table. If there is not enough data in a study, we will contact the corresponding author for more detailed data. If the methodological details are not told in papers, we will contact for more explanation.

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.

Sensibility analysis: we will conduct a sensitivity analysis for the outcomes to investigate the stability of the results. We will exclude each study 1 by 1 which is included in the analysis, and then re-analyze and pooled the data and compare the difference between the re-obtained effects and the original effects. In this way, we will be able to assess the impact of individual studies on the overall results and whether the results are strong.

Country(ies) involved: China.

Keywords: Chinese medicine, traditional Chinese medicine, Chinese herb medicine, Early Diabetic nephropathy, Early-stage Diabetic nephropathy.