INPLASY PROTOCOL

To cite: Lv et al. Efficacy and Safety of Zhenwu Decoction in the Treatment of Diabetic Nephropathy: A Systematic Review and Meta-Analysis. Inplasy protocol 202290071. doi: 10.37766/inplasy2022.9.0071

Received: 16 September 2022

Published: 16 September 2022

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Support: **82074400, 82004185.**

Review Stage at time of this submission: **Data analysis.**

Conflicts of interest:
None declared.

Efficacy and Safety of Zhenwu Decoction in the Treatment of Diabetic Nephropathy: A Systematic Review and Meta-Analysis

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Review question / Objective: **The aim of this systematic review and meta-analysis of randomized controlled trials (RCTs) is to compare the efficacy and safety between Zhenwu Decoction combined with conventional Western medicine (CWM) and the conventional therapy alone in treating diabetic nephropathy (DN).**
Condition being studied: **According to the IDF, there will be 578 million people with diabetes worldwide (10.2%) by 2030. With the global prevalence of diabetes, the incidence of DN is increasing. Surveys indicate that about 40% of the type 2 diabetes mellitus (T2DM) may develop into DN. With the in-depth exploration and understanding of various pathological mechanisms of DN, the clinical efficacy of single target therapy is unsatisfactory. As a result of the limitations of its treatment, more studies tend to the combination of traditional Chinese and Western medicine therapy. Zhenwu Decoction (ZWD) has been used in clinical practice for thousands of years in China, due to its effect of strengthening spleen and nourishing yang. Although there are more and more clinical reports on the combination of ZWD and conventional western medicine (CWM) for DN treatment, more evidence of the effectiveness and safety of its combination is needed.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 September 2022 and was last updated on 16 September 2022 (registration number INPLASY202290071).

INTRODUCTION

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METHODS

Participant or population: The patient was clinically diagnosed with Diabetic Nephropathy, meet the diagnostic criteria. There are no limits to the gender or race.

Intervention: The experimental group was treated with Zhenwu Decoction on the basis of the control group, or Zhenwu Decoction alone.

Comparator: The control group was treated with conventional western medicine, including diabetes education, hypoglycemic drugs and hypotensive drugs.

Study designs to be included: Only the randomized controlled trials (RCTs) published in Chinese and English on the effect of ZWD for diabetic nephropathy treatment.

Eligibility criteria: (1) Type of researches: The randomized controlled trials (RCTs) published in Chinese and English on ZWD for diabetic nephropathy.(2) Type of participants: adult patients who met the diagnostic criteria of DN.(3) Intervention measures: the control group was treated with CWM, including diabetes education, hypoglycemic drugs and hypotensive drugs. The experimental group was treated with ZWD on the basis of the control group, or ZWD alone.(4) Outcome indicators: the clinical efficacy (Total Effective Rate), fasting blood glucose (FBG), Blood urea nitrogen (BUN), 24-hour urine protein, Creatinine clearance (Ccr) and serum creatinine (Scr).

Information sources: The literatures will be searched in five databases: PubMed, the China National Knowledge Infrastructure (CNKI), the China Science and Technology Journal Database (VIP), the Chinese Biomedical Literature Database (CBM), and the WanFang databasesPubMed, the China National Knowledge Infrastructure (CNKI), the China Science and Technology Journal Database (VIP), the Chinese Biomedical Literature Database (CBM), and the WanFang databases.

Main outcome(s): Outcome indicators: the clinical efficacy (Total Effective Rate), fasting blood glucose (FBG), Blood urea nitrogen (BUN), 24-hour urine protein, Creatinine clearance (Ccr) and serum creatinine (Scr).

Quality assessment / Risk of bias analysis: We will evaluate the methodological quality of the included RCTs, according to the assessment criteria of the Cochrane Systematic Review Manual, including the following contents: Correctness of random allocation method; Adequacy of allocation concealment; Use of blind method; Patients who lost follow-up or withdrew; Integrity of outcome data and other bias. GRADE pro software will be used to access the strength of the evidence to make the results more credible.

Strategy of data synthesis: The meta-analyses will perform by Review Manager 5.3.3 and Stata 12.0 software. We will use odds ratio (OR) to assess the binary variables. For continuous variables, mean difference (MD, when the units of measure of the results are the same) or standardized

mean difference (SMD, when the units of measure of the results are different) are adopted to represent the difference between groups. 95% confidence interval (CI) will use to represent the results. The heterogeneity will be evaluated by Chi2 test, if P > 0.1 or I2 < 50%, it indicates that the heterogeneity is not obvious, the fixed effect model will select, otherwise, the random effects model will accept. In addition, sensitivity analysis will perform for each outcome to assess stability. We also will complete the Egger test to detect potential publication bias.

Subgroup analysis: If necessary, subgroup analyses will be performed according to the different types of participant characteristics, treatment methods, duration, and so on.

Sensitivity analysis: When there is significant heterogeneity, we will conduct sensitivity analysis. We will determine the robustness of the results by excluding low-quality studies.

Country(ies) involved: China.

Keywords: Diabetic Nephropathy; Zhenwu Decoction; traditional Chinese medicine; Systematic Review.

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