INPLASY PROTOCOL

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Corresponding author:
Le Liu

707993226@qq.com

Author Affiliation:
Changchun University of Chinese Medicine

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None declared.

Yuquan Pill Enhance the Effect of Western Medicine in Treatment Diabetic Nehropathy： A protocol for systematic review and meta-analysis

Liu, L[1]; Zhang, Y[2]; Zhu, Z[3]; Yu, Z[4]; Bao, P[5]; Nan, Z[6].

Review question / Objective: **This study will analyze multiple outcome indicators such as urine albumin excretion rate, blood creatinine value, urea nitrogen, 24-hour urine protein quantification, fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin, clinical effective rate, and TCM symptom scores into YQP. Provide a reliable basis for the treatment of diabetic nephropathy.**
Condition being studied: **Diabetic nephropathy is glomerular sclerosis caused by diabetic microvascular disease, which is one of the most serious complications of diabetes. At present, the traditional treatment of diabetic nephropathy is mainly based on the control of blood pressure, blood sugar, blood lipids and other basic treatments, using ACEI/ARB Drug therapy.However, the clinical reports of relying solely on ACEI/ARB to delay the course of diabetic nephropathy are not optimistic. Yuquan Pill, as a classic traditional Chinese medicine prescription, has clinical reports that it can effectively assist in the treatment of diabetic nephropathy with small side effects. However, there is no systematic review of Yuquan Pill in the treatment of diabetic nephropathy. This article systematically evaluates the effectiveness and safety of YQP clinical application.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 May 2021 and was last updated on 08 May 2021 (registration number INPLASY202150030).

INTRODUCTION

Review question / Objective: **Diabetic nephropathy is glomerular sclerosis caused by diabetic microvascular disease, which is one of the most serious complications of diabetes. At present, the traditional treatment of diabetic nephropathy is mainly based on the control of blood pressure, blood sugar, blood lipids and other basic treatments, using ACEI/ARB Drug therapy.However, the clinical reports of**

relying solely on ACEI/ARB to delay the course of diabetic nephropathy are not optimistic. Yuquan Pill, as a classic traditional Chinese medicine prescription, has clinical reports that it can effectively assist in the treatment of diabetic nephropathy with small side effects. However, there is no systematic review of Yuquan Pill in the treatment of diabetic nephropathy. This article systematically evaluates the effectiveness and safety of YQP clinical application. Methods: Database search includes 7 databases including PubMed, Embase, Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Wanfang database, etc. In addition, manual searches of related journals in various fields, Magazine as a supplement. The search date was set as a randomized controlled trial from the establishment of the database to April 21, 2021. The main outcome indicators include the patient's urine albumin excretion rate, blood creatinine value, urea nitrogen, 24-hour urine protein quantification, fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin, clinical effectiveness, etc., as well as TCM symptom scores. The analysis software uses RevMan 5.3 software and Stata 15. Results: This study will analyze multiple outcome indicators such as urine albumin excretion rate, blood creatinine value, urea nitrogen, 24-hour urine protein quantification, fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin, clinical effective rate, and TCM symptom scores into YQP. Provide a reliable basis for the treatment of diabetic nephropathy.

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METHODS

Search strategy: Database search includes 7 databases including PubMed, Embase, Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP),

Wanfang database, etc. In addition, manual searches of related journals in various fields, Magazine as a supplement. The search date was set as a randomized controlled trial from the establishment of the database to April 21, 2021. The main outcome indicators include the patient's urine albumin excretion rate, blood creatinine value, urea nitrogen, 24-hour urine protein quantification, fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin, clinical effectiveness, etc., as well as TCM symptom scores. The analysis software uses RevMan 5.3 software and Stata 15.

Participant or population: According to the 2009 ADA Diabetes Diagnostic Criteria and Mogensen staging. Patients who meet the diagnostic criteria of diabetic nephropathy, those with acute metabolic disorders of diabetes, diabetic ketoacidosis, urinary tract infections, and severe heart, lung, and liver diseases except. There are no requirements for gender, race and age.

Intervention: The intervention method of the treatment group was YQP combined with western medicine. The control group was treated with conventional western medicine.There are no requirements for medication time, medication frequency, and drug dosage form.

Comparator: The intervention method of the treatment group was YQP combined with western medicine. The control group was treated with conventional western medicine.There are no requirements for medication time, medication frequency, and drug dosage form.

Study designs to be included: 2.5 Search strategy 2.5.1 Electronic searches The selection of the time for inclusion of the literature will be selected from the establishment of each database to April 21, 2021, by searching PubMed, Embase, Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Wanfang database and other 7 databases. Keywords include“Yuquan Pill”, “diabetic nephropathy”and so on. 2.5.2 Specific search terms The search terms mainly include: 1、Yuquan Pills or Yuquan Wan or Yuquan Decoction or Yuquan capsule.

Eligibility criteria: Evidence quality evaluation Refer to the quality evaluation standards recommended by the Cochrane Collaboration Network for quality evaluation, Mainly include: random sequence generation method; whether allocation concealment is used; whether the subject and the intervention provider are blinded; whether the result evaluator is blind; whether the result data is complete; Whether selective results reporting and other sources of bias. The quality evaluation is carried out by 2 researchers (LL and YZ), and the evaluation criteria include 3 categories (low risk, high risk, and unclear). If the quality audit is different, it will be decided through discussion with the third researcher (ZN). In all items, the answer "yes" means that there is a low risk of bias, the answer "no" is a high risk of bias, and the answer "unknown" means that it is uncertain whether there is a risk of bias.

Information sources: The selection of the time for inclusion of the literature will be selected from the establishment of each database to April 21, 2021, by searching PubMed, Embase, Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Wanfang database and other 7 databases. Keywords include“Yuquan Pill”, “diabetic nephropathy”and so on.

Main outcome(s): Outcome indicators include: urine albumin excretion rate, blood creatinine value, urea nitrogen, 24 h urine protein quantification, fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin, clinical effectiveness, etc.as well as multiple outcome indicators such as TCM symptom scores.

Additional outcome(s): Outcome indicators include: urine albumin excretion rate, blood creatinine value, urea nitrogen, 24 h urine protein quantification, fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin, clinical effectiveness, etc.as well as multiple outcome indicators such as TCM symptom scores.

Data management: Data collection and analysis. Included literature screening Two researchers (Le Liu and Ye Zhang) conducted a literature search. After retrieval, the literature was imported into Endnote X9 software for review. After deleting duplicate literature, read the abstract for preliminary screening, and download all literature after excluding those that obviously did not meet the inclusion criteria. The full text, read carefully, and further review. Finally, the documents that meet the inclusion criteria are screened out, and the data extraction table has been designed for data extraction, and two researchers conduct cross-checking. If the results are different, we will ask the third researcher (Nan Zheng) to assist in the judgment.

Quality assessment / Risk of bias analysis: Refer to the quality evaluation standards recommended by the Cochrane Collaboration Network for quality evaluation, Mainly include: random sequence generation method; whether allocation concealment is used; whether the subject and the intervention provider are blinded; whether the result evaluator is blind; whether the result data is complete; Whether selective results reporting and other sources of bias. The quality evaluation is carried out by 2 researchers (LL and YZ), and the evaluation criteria include 3 categories (low risk, high risk, and unclear). If the quality audit is different, it will be decided through discussion with the third researcher (ZN). In all items, the answer "yes" means that there is a low risk of bias, the answer "no" is a high risk of bias, and the answer "unknown" means that it is uncertain whether there is a risk of bias.

Strategy of data synthesis: This study will use the RevMan 5.0 software (version 5.3) and Stata 15.0 software provided by Cochrane for meta-analysis. The effect index is expressed by odds ratio (OR) and 95% confidence interval (95% CI). If there is statistical homogeneity (I2 <50%) between the studies, the fixed effect model is used. When the heterogeneity between the research results is significant (I2≥50%), sublayer analysis is needed to find the reason for the heterogeneity. If the heterogeneity is too large or the source of the heterogeneity is unknown, use qualitative heterogeneity. When there are many influencing factors and the stratification method is not suitable, meta-regression analysis is required .When the number of articles included in the analysis of effect indicators is ≥10, the funnel chart is used to analyze the risk of publication bias. When the funnel chart is obviously asymmetric, it indicates that there is publication bias.

Subgroup analysis: When there is disagreement in the results, a subgroup analysis needs to be carried out according to different reasons. Heterogeneity is mainly manifested in many aspects such as race, gender, age, drug formulations, different forms of intervention, treatment time, and drug dosages.

Sensitivity analysis: I2 and Chi-square statistics were used to assess the statistical heterogeneity between studies. If I2 is between 50% and 100%, there is statistical heterogeneity, and we will use a random effects model to analyze the data. If the heterogeneity test is not significant (I2≤50%), the fixed effects model is used. In addition, due to differences in heterogeneity, we will conduct subgroup or sensitivity analysis to find potential causes.Sensitivity analysis is used to eliminate studies with high risk of bias or incomplete data and the impact of outliers.

Country(ies) involved: China.

Keywords: Yuquan Pill; Western Medicine; Diabetic Nehropathy; systematic review.

Contributions of each author:

Author 1 - Le Liu.
Author 2 - Ye Zhang.
Author 3 - Zhiyue Zhu.
Author 4 - Zlyang Yu.
Author 5 - Pengjie Bao.
Author 6 - Zheng Nan.