

INPLASY PROTOCOL

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Efficacy and safety of traditional Chinese medicine enema in the treatment of diabetic nephropathy

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None declared.

Review question / Objective: To evaluate the efficacy and safety of traditional Chinese medicine enema in the treatment of diabetic nephropathy.

Condition being studied: The epidemiological survey of diabetic nephropathy shows that diabetic nephropathy is the leading cause of end-stage renal disease in the world. At present, western medicine treatment of diabetic nephropathy and no effective means to prevent the progression of diabetic nephropathy. Studies have shown that traditional Chinese medicine enema has a therapeutic effect on diabetic nephropathy and is widely used in clinic. Therefore, it was decided to carry out this study.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 April 2021 and was last updated on 12 April 2021 (registration number INPLASY202140072).

INTRODUCTION

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METHODS

Participant or population: 1. inclusion criteria (1) The study type was randomized controlled experiment (2) the subjects met who diagnostic criteria (3) symptoms and signs of diabetic nephropathy (4) urinary albumin excretion rate, 24h urine protein quantification or serum creatinine increase. 2. Exclusion criteria 1. The research object does not meet the diagnostic criteria or has no diagnostic criteria; 2. Non clinical trial research; 3. Only one repetitive literature is selected; 4. Complete data and literature with obviously unreasonable data are not provided. 5. There is no randomized controlled trial, the treatment group contains the clinical research of drugs other than traditional Chinese medicine enema and drugs used in the control group; 6. The observation indexes do not contain the literature of main and secondary indexes. 7. Severe cardiovascular disease and primary kidney and liver disease 8. Unclear prescription.

Intervention: Traditional Chinese medicine enema.

Comparator: The treatment group was treated with Enema with Chinese medicine on the basis of the treatment of the control group, and the control group was treated with routine treatment.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: According to the bias risk of RCT in Cochrane system reviewer's Handbook (version 5.1), the evaluation tool was used to evaluate the bias risk of the included studies. Two researchers independently evaluated each item with "high", "low" and "unclear" by using Cochrane evaluation tool.

Information sources: We searched PubMed, MEDLINE, EMBASE, Cochrane Central Register of controlled trials (central), Chinese National Knowledge Infrastructure (CNKI), wanfane database, Chinese scientific and technical periodic database (VIP) for all randomized controlled trials.

Main outcome(s): 24-hour urine protein, urea nitrogen, serum creatinine and total effective rate of disease.

Quality assessment / Risk of bias analysis: According to the bias risk of RCT in Cochrane system reviewer's Handbook (version 5.1), the evaluation tool was used to evaluate the bias risk of the included studies. Two researchers independently evaluated each item with "high", "low" and "unclear" by using Cochrane evaluation tool.

Strategy of data synthesis: Revman 5.3 software was used for meta analysis. The count data were analyzed by odds ratio (or) and 95% CI was reported. The measurement data were analyzed by weighted mean difference (WMD) and 95% CI was reported. When the measurement units were different, the standardized mean difference (SMD) was selected and 95% CI was reported. The results of meta-analysis were represented by forest map, and the heterogeneity among the studies was tested by χ^2 test. When $p > 0.10$ and $I^2 \leq 50\%$, fixed effect model was used. When there was statistical heterogeneity among the studies, i.e. $P < 0.10$, $I^2 > 50\%$, subgroup analysis or sensitivity analysis was performed according to the possible heterogeneity factors to eliminate the heterogeneity. If the heterogeneity still exists, but there is clinical homogeneity, it can be combined, and the random effect model is used for meta analysis. Funnel plot was used to analyze publication bias.

Subgroup analysis: None.

Sensitivity analysis: None.

Country(ies) involved: China.

Keywords: diabetic nephropathy, meta analysis, system review, traditional Chinese medicine enema.

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