

INPLASY PROTOCOL

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None declared.

INTRODUCTION

Review question / Objective: This study is the protocol for a systematic review to evaluate the efficacy and safety of colonic dialysis combined with Traditional Chinese medicine (TCM) retention enema in the

Efficacy and safety of colonic dialysis combined with Traditional Chinese medicine retention enema in the treatment of chronic renal failure: A protocol for systematic review and meta-analysis

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Review question / Objective: This study is the protocol for a systematic review to evaluate the efficacy and safety of colonic dialysis combined with Traditional Chinese medicine (TCM) retention enema in the treatment of chronic renal failure. we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs) of such combined therapy in the treatment of chronic renal failure,It provides a reliable scientific basis for clinicians to use this approach to treat chronic renal failure.

Information sources: We conducted a systematic search for relevant documents in the Chinese and English databases, and the search time is limited to October 23, 2021. The following eight databases are included: PubMed, EMBASE, Web of Science, The Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database.Relevant journals were searched to trace the references included in the study. Other resources will be searched if necessary.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 October 2021 and was last updated on 29 October 2021 (registration number INPLASY2021100116).

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clinicians to use this approach to treat chronic renal failure.

Condition being studied: Chronic renal failure (CRF) is not an independent disease, is caused by various causes of kidney damage and progressive deterioration. When it reaches the end stage, renal function is close to 10%~15% of normal, a series of clinical symptoms appear Lesions often present progress, gradually developing end-stage renal disease (ESRD) after renal replacement therapy, made a tremendous threat to human health, and seriously affect the quality of human survival and cause more burden to the society and family With the development of the society, the human way of life change, the incidence of chronic kidney disease (CKD) is increasing According to statistics, the prevalence of chronic kidney disease in American adults has been as high as 15.1%, and the prevalence of ESRD is 1738 per million population. Some reports in China show that the prevalence rate of chronic kidney disease is about 10.8%, and the incidence rate of male and female is 55% and 45% respectively. Western medicine mainly treats this disease on the principle of treating basic diseases, preventing complications or invasive kidney replacement therapy, and its therapeutic effect is limited How to delay the further development of kidney disease, kidney disease patients quality of life, is the medical profession at home and abroad on topics of mutual interest Related literature at home and abroad, the modern nephropathy scholars on the relationship between the intestinal tract and kidney made a number of studies, and proposed im - kidney axis theory to explain the mechanism of chronic kidney disease These studies indicate that intestinal microbiota is the main source of uremia toxins, and changes in intestinal microbiota can lead to a series of abnormal changes in kidney disease and various complications, and emphasize that intestinal microbiota is the central link of the gut-kidney axis. Under normal circumstances, human metabolites and toxins mainly pass through the urine intestinal tract Skin and

respiratory excretion, among which urine and intestinal tract.

METHODS

Search strategy: We conducted a systematic search for relevant documents in the Chinese and English databases, and the search time is limited to October 28, 2021. The following eight databases are included: PubMed, EMBASE, Web of Science, The Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database.Chronic renal failure, chronic renal insufficiency, chronic kidney disease, CRF and CKD were selected as key words or theme words respectively. Secondary search included colon dialysis and enema, colon dialysis and Traditional Chinese medicine.

Participant or population: ALL patients who have been diagnosed with chronic renal failure, without regard to region, race, sex, age, education, course of disease, or duration of treatment, will be included.

Intervention: All patients enrolled in the study received conventional treatment for chronic renal failure. On this basis, the intervention group was given colonic dialysis combined with traditional Chinese medicine retention enema.

Comparator: All patients included in the study received routine treatment for chronic renal failure.

Study designs to be included: The only randomized controlled trial was included. Non-randomized controlled trials and uncontrolled clinical trials will be excluded.Whether single-blind, double-blind, or unblinded.

Eligibility criteria: Evidence from the International Evidence-based Medicine / Cochrane Collaboration Volume design: (1) randomized controlled trials were used in this study Trial,RCT), with or without assignment hiding and blinding; (2)The

control group received conventional western medicine treatment, The treatment group took basal This treatment plus colonic dialysis combined with traditional Chinese medicine retention enema. Basic treatment includes salt restriction Low fat high quality protein diet, control blood pressure, regulate fat, prevent infection, maintain hydroelectricity Quality balance, avoiding the use of nephrotoxic drugs and other symptomatic treatment; (3) conform to the public Recognized and authoritative diagnostic criteria for CRF. Exclusion criteria (1) Do not meet or have no diagnostic criteria; (2) No According to the group, or the test design is flawed, or the statistical method is improper; (3) Not available Literature on outcome indicators; (4) Animal experiment, review, experience summary, case report, Case review and retrospective study.

Information sources: We conducted a systematic search for relevant documents in the Chinese and English databases, and the search time is limited to October 23, 2021. The following eight databases are included: PubMed, EMBASE, Web of Science, The Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database. Relevant journals were searched to trace the references included in the study. Other resources will be searched if necessary.

Main outcome(s): The primary outcome is the Serum creatinine (Scr), Urea nitrogen (BUN), Total effective rate, Uric acid(UA), Creatinine clearance (CCr). Secondary outcome: TCM syndrome score, Glomerular filtration rate(GFR), Hemoglobin(Hb), Adverse reactions and adverse events.

Data management: Data extraction was conducted independently by 2 reviewers in accordance with the preset standardized data extraction form. If there is any disagreement or doubt, the decision should be made after discussion or third party opinion should be consulted. The extracted

information includes the following contents: the basic information included in the study, such as the research title, first author, published journal, etc; baseline characteristics of the study subjects and intervention measures; the key elements of bias risk assessment; outcome indicators and outcome measurement data concerned.

Quality assessment / Risk of bias analysis: Two searchers searched the literature independently and checked one by one Include the study. If there is disagreement about the inclusion of the study, consult the expert to decide Decide whether to include it and try to avoid missed detection. Cochrane systems reviewers were used Volume 5.1 Bias risk Assessment tool, the included literature was qualifies from the following six aspects Quantitative evaluation: (1) whether random sequence generation is sufficient;(2) Whether the allocation is hidden; (3) Whether blind method is used;(4) Whether the result data is complete;(5) Selective reporting; (6) Whether there is publication bias.

Strategy of data synthesis: Two authors will independently appraise the methodological quality of each trial in six dimensions: selection bias, performance bias, detection bias, attrition bias, reporting, and other biases. Any disagreements will be resolved through discussions between the two authors or consultation with a third researcher. Articles not made available with complete clinical data will be excluded after several attempts have been made to contact the authors of those studies.

Subgroup analysis: Due to potential heterogeneity that may adversely impact results of this study, The influence of different dosage forms, intervention forms and treatment methods should be considered. If a meta-analysis cannot be performed, we will conduct a descriptive analysis instead.

Sensitivity analysis: A sensitivity analysis will be performed to assess the robustness of the final set of results. If the results are

found to be unstable, studies with a high risk of bias will be excluded.

Country(ies) involved: China.

Keywords: Colon dialysis, TCM retention enema, chronic renal failure, systematic evaluation, and Meta-analysis.

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