INPLASY PROTOCOL

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Corresponding author:
Yuerong Ma

Mayr666@163.com

Author Affiliation:
Chengdu University of TCM

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Conflicts of interest:
The authors declare that they have no competing interests.

The Efficacy of Taking Traditional Chinese Medicine Orally In Renal Interstitial Fibrosis: Protocol for A Systematic Review and Meta-Analysis

Yu, G[1]; Guo, M[2]; Zou, J[3]; Zhou, X[4]; Ma, Y[5].

Review question / Objective: **Is the therapy of taking TCM Orally effective in treating RIF?**
Condition being studied: **Oral treatment of traditional Chinese medicine (TCM)is one of the therapies for RIF. Randomized controlled trials (RCTs) of TCM treatment RIF have been reported, but its effectiveness and safety have yet been systematically investigated. Therefore, through the systematic analysis and meta-analysis, our study will summarize the effectiveness and safety of oral treatment RIF of TCM.**
Information sources: **The following databases will be searched: PubMed, China National Knowledge Infrastructure (CNKI) ,China Scientific Journal Database (VIP) ,Excerpt Medical Database (Embase) ,WanFan Data,Chinese Biomedical Literature Database (CBM),WHO International Clinical Trials Registry Platform.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 August 2020 and was last updated on 10 August 2020 (registration number INPLASY202080042).

INTRODUCTION

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METHODS

Search strategy: A comprehensive search of prominent medical and health science electronic databases: PubMed, China National Knowledge Infrastructure (CNKI) ,China Scientific Journal Database (VIP) ,Excerpt Medical Database (Embase) ,WanFan Data,Chinese Biomedical Literature Database (CBM),WHO International Clinical Trials Registry Platform.

Participant or population: Patients with unlimited race, nationality, age, and sex has a history of CKD or systemic disease involving the kidney.

Intervention: The treatment group was treated with integrated Chinese and western medicine (basic Western medicine + TCM) or TCM only. The TCM was administered orally. The course of treatment is unlimited.

Comparator: The control group was treated with western medicine only or blank or placebo.

Study designs to be included: RCTs of taking TCM orally for RIF in chronic kidney disease. Randomized grouping regardless of whether it is single-blind, double-blind or non-blind.

Eligibility criteria: Exclude other organ fibrosis diseases that affect fibrogenic factors. Excluding non-randomized controlled trials, non-oral administration, the control measures are TCM, and the control measures are not clearly described.

Information sources: The following databases will be searched: PubMed, China National Knowledge Infrastructure (CNKI) ,China Scientific Journal Database (VIP) ,Excerpt Medical Database (Embase) ,WanFan Data,Chinese Biomedical Literature Database (CBM),WHO International Clinical Trials Registry Platform.

Main outcome(s): The efficacy of oral TCM in RIF will be evaluated by serum creatinine concentration (Scr),blood urea nitrogen (BUN), Notch1, Jagged-1 and urine TGF-β1 content and 24-hour urinary protein quantity.

Additional outcome(s): The additional outcomes include the effective rate and adverse reactions.

Data management: We use the Noteexpress software to conduct a preliminary review of the literature, then read the title and abstract of the article for a preliminary screening, and then exclude it by reading the full text and filtered it again until all RCTs are confirmed.

Quality assessment / Risk of bias analysis: The risk of bias included in the RCTs will be evaluated by the bias risk assessment tool provided in the Cochrane System Evaluation Manual 5.1.0 [1], including the generation of random sequence schemes, whether to use allocation hiding, whether to implement blind methods, whether the result data is complete, whether to selectively report results, and other sources of bias. The above six items will be evaluated with "yes" (low bias), "no" (high bias) or "unclear" (lack of relevant information or uncertainty of bias).

Strategy of data synthesis: According to the evaluation manual of the Cochrane intervention system, two researchers will independently extract the data of the research that meet the inclusion criteria, and then check the extracted contents one by one. In case of disagreement, it is solved by re-search the literature and discussion. If the research report is still not available, remove the document. The extracted contents mainly include the basic situation, sample size, design method, intervention measures, intervention time, curative effect index and measurement value of the included study.

Subgroup analysis: We apply a sensitivity analysis by combining the same models to various results to identify the source of heterogeneity and reliability of the various results.

Sensibility analysis: For quality analysis, we will conduct a sensitivity analysis of the main results to explore the influence of the bias of a single study on the results.

Language: English or Chinese-language.

Country(ies) involved: China.

Keywords: Traditional Chinese Medicine, Renal Interstitial Fibrosis, Systematic Review, Meta-Analysis.

Dissemination plans: We will disseminate the results of this systematic review by publishing manuscripts in peer-reviewed journals or publishing relevant findings at relevant conferences.

Contributions of each author:
Author 1 - Guang Yu - was in charge of conceptualization and investigation, drafted the manuscript.
Author 2 - Mao Guo - provided statistical expertise.
Author 3 - Junju Zou - contributed to the development of the selection criteria,and the risk of bias assessment strategy.
Author 4 - Xiaotao Zhou - contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 5 - Yuerong Ma - read , provided feedback and approved the final manuscript.