

INPLASY PROTOCOL

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The authors have no conflict of interests to disclose.

Traditional Chinese medicine on treating splenomegaly due to portal hypertension in cirrhosis: A protocol for systematic review and meta-analysis

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Review question / Objective: The aim of this protocol for systematic review and meta-analysis of randomized controlled trials is to evaluate the efficacy of Traditional Chinese medicine in the treatment of cirrhosis with splenomegaly.

Condition being studied: Liver cirrhosis is a common clinical chronic progressive disease. Due to the obstruction of blood flow after cirrhosis, it leads to long-term congestion of splenic sinus, hyperplasia of fibrous tissue and proliferation of splenic myeloid cells, resulting in hepatocirrhosis and splenomegaly. At present, western medicine still uses splenectomy and interventional therapy are the main treatment, but the adverse reactions are more and the curative effect is not good. Many clinical trials have proved that Traditional Chinese medicine has a great therapeutic effect on Hepatocirrhosis with splenomegaly, which can effectively delay the development of the disease and improve the survival rate of patients. This systematic review aims to evaluate the efficacy and safety of Traditional Chinese medicine in the treatment of hepatocirrhosis with splenomegaly.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 November 2020 and was last updated on 27 November 2020 (registration number INPLASY2020110121).

INTRODUCTION

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METHODS

Participant or population: All the patients who have been diagnosed with hepatocirrhosis with splenomegaly will be included.

Intervention: TCM is used as the main intervention.

Comparator: The control group received conventional western medicine or surgical treatment, including nucleotide drugs, intravenous drip of albumin, or oral amino acid, splenectomy.

Study designs to be included: We will search all the studies that TCM is used as the main intervention for hepatocirrhosis with splenomegaly, Non-RCTs quasi-RCTs, series of case reports, and cross research will be excluded. Full article not available will be excluded. No language restrictions.

Eligibility criteria: 1. Types of studies. We will search all the studies that TCM is used as the main intervention for hepatocirrhosis with splenomegaly, Non-RCTs quasi-RCTs, series of case reports, and cross research will be excluded. Full article not available will be excluded. No language restrictions. 2. Types of participants. All the patients who have been diagnosed with hepatocirrhosis with splenomegaly will be included. There are no restrictions on age, gender, regional, national, belief, ethnic, sources, and courses of disease. 3. Types of interventions. There is no requirement for

the intervention course, the specific contents of the control group and the experimental group are as follows. 3.1. Control intervention. The control group received conventional western medicine or surgical treatment, including nucleotide drugs, intravenous drip of albumin, or oral amino acid, splenectomy. Specific drugs, doses and methods are not limited. If the control group was treated with Traditional Chinese medicine, the study was excluded. 3.2. Experimental interventional. The experimental group is treated with TCM on the basis of conventional western medicine treatment in the control group. The use of TCM is limited to prescription and Chinese patent medicines. Prescription drugs require a clear dose, but there are no restrictions on the composition, dosage form and dosage. For the dosage, such as decoctions, granules, pills, powders, etc. Other types of TCM treatments such as TCM injections, acupuncture, moxibustion, massage, cupping, and others will be excluded.

Information sources: The databases of PubMed, CENTRAL (The Cochrane Central Register of Controlled Trials), Excerpt Medica Database (Embase), China National Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform (WANFANG Data), Weipu Information Chinese Periodical Service Platform (VIP), and China Biomedical Literature Service System (SinoMed) will be searched online. The manual is search mainly for ongoing experiments, and grey literature. We will look for abstracts and conference papers related to Traditional Chinese medicine and hepatocirrhosis with splenomegaly. Ongoing experiments which have been registered on World Health Organization International Clinical Trials Registry Platform (ICTRP) or Chinese Clinical Trial Registry. Try to contact the researchers to inquire about the progress of the trial and provide the latest test data. As for grey literature, we will retrieve on the following websites: GreyNet International, SIGLE (The System for Information on Grey Literature in Europe), Open Gery, Gery Literature Report. The secondary literature

search will be performed on the included references to reduce the omission factor.

Main outcome(s): The primary outcomes are total effective rate (total effective rate = significant efficiency + effective rate), liver function (ALT, AST, ALB, TBIL) and liver and spleen colour to exceed.

Quality assessment / Risk of bias analysis:

As for the risk of bias in the literature, two researchers will independently use the tool for assessing risk of bias recommended by Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 (Cochrane Handbook 5.1.0 Part 2: 8.5-8.7) to assess the quality of the included literature and risk of bias. Evaluation content includes: selection bias (random sequence generation, and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective outcome reporting), and other bias (other sources of bias). Evaluators judge the risk level by carefully reading the full text, which is divided into low risk, high risk and unknown risk. If the research reported in the literature is not detailed enough, the judgement is usually "unknown risk" of bias. For example, the study uses random number table for grouping, so the random sequence generation will be expressed as "low risk." If there are any differences, we would consult the third reviewer for solution.

Strategy of data synthesis: The meta-analysis in this review will use RevMan 5.3 and Stata 13.0 software. For the outcome index of the two categorical variables, relative risk (Relative Risk, RR) will be adopted, and for the outcome index of continuous variables, the mean difference (MD) or standardized mean difference (SMD) will be adopted with a confidence interval (CI) of 95%. Heterogeneity tests will be used for the included studies which will be tested by chi-square test. If $P > 0.10$ and $I^2 < 50\%$, there is no significant statistical heterogeneity or no statistical difference in heterogeneity, a fixed effect model will be

adopted. If $P < 0.05$, there is significant heterogeneity between studies, a random effect model will be adopted. Further analysis of the source of heterogeneity, if necessary, perform subgroup analysis. There are clinical and methodological differences in the experimental studies. Therefore, random effects models will be selected in this study. Finally, a funnel chart will be drawn to evaluate the publication bias of the literature.

Subgroup analysis: We will conduct subgroup analysis and meta-regression analysis to study the potential influencing factors, such as the participant's age, sample size, disease duration, treatment process, and study quality.

Sensitivity analysis: Sensitivity analysis will be used to check the stability of the results.

Country(ies) involved: China.

Keywords: hepatocirrhosis with splenomegaly, protocol, systematic review, Traditional Chinese medicine.

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