INPLASY PROTOCOL

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None declared.

Herbal umbilical therapy for ascites in patients with cirrhosis: A protocol for systematic review and meta-analysis

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Review question / Objective: **How does umbilical therapy with herbal medicine impact on prognosis of ascites with cirrhosis compared to routine treatment?**
Condition being studied: **Cirrhosis is the end stage of a large number of chronic liver diseases in which the normal liver structure has been widely destroyed and altered with diffuse hepatic fibrosis and regenerative nodule formation. Ascites, accumulation of at least 200 mL fluid within peritoneal cavity, is the most common complication of liver cirrhosis. Ascites seriously impaires the quality of life of patients, causing many symoptoms such as abdomind discomford, shortness of breath, poor appetite. The treatment methods are limited. Therefore, an effective approach to relieve the suffering of patients with cirrhotic ascites is required.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 August 2021 and was last updated on 19 August 2021 (registration number INPLASY202180041).

INTRODUCTION

Review question / Objective: **How does umbilical therapy with herbal medicine impact on prognosis of ascites with cirrhosis compared to routine treatment?**

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METHODS

Participant or population: Adult patients(18 years old and above) with establised cirrhosis with ascites.

Intervention: The intervention group was treated with umbilical therapy of herbal medicine alone or combined with regular therapies.

Comparator: The control group was given no treatment, placeo or regular treatment without umbilical therapy of herbal medicine.

Study designs to be included: RCTs.

Eligibility criteria: Studies are included if they met the PICOS(Population, Intervention, Comparator, Outcomes, and Study design) criteria.

Information sources: Electronic databases including PubMed, the Cochrane Library, Web of Science, EMBASE, China National Knowledge Infrastructure, Chinese Scientific and Technical Journals Database(VIP), Wan-fang Database, Chinese Biomedical Literature Database will be searched from the inception to August 2021. In addition, we will search other sources from PROSPERO, clinical Trials.gov, Chinese Clinical Trial Registry, the US National Institutes of Health register, the World Health Organization International Clinical Trials Registry Platform.

Main outcome(s): The primary outcomes include total effective rate, health-related quality of life using 36-Item short Form Health Survery(SF-36).

Quality assessment / Risk of bias analysis: Based on the Cochrane risk of bias assessment tool, two reviews(YM and XQ) in depently evaluate the risk of bias in eligible studies. The items include random sequence generation, allocation concealment, blinding methods, imcomplete data, selective outcome reporting and other bias. Each subject will be categoried into three levels “low bias,” “unclear,” “high bias”. When the disagreement arise between the two reviews, they should discuss and hold counsel with the third review(KS).

Strategy of data synthesis: Two reviewers(HL and JS) will indepently extract data by using the pre-detemined data extraction table. The data extraction includes general data, participants, interventions, outcome. The collected data will be managed using Microsoft Excel 2016.

Subgroup analysis: If enough studies include, subgroup analysis will be performed according to the patients information, intervention measures.

Sensitivity analysis: The objective of sensitive analysis is to evaluate the stability and robustness of primary results. Sensitive analysis can be carried ouu in several ways like reducing literature by one to see if the final conclusion has changed, changing a statistical method and deleting low quality study.

Country(ies) involved: China.

Keywords: umbilical therapy of herbal medicine, ascites, cirrhosis, meta-analysis, protocol.

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