INPLASY PROTOCOL

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None declared.

Clinical efficacy and safety of Traditional Chinese Medicine adjuvant Therapies for hepatitis B virus related Hepatocellular Carcinoma: A protocol for Network Meta-Analysis and Systematic Review

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Review question / Objective: **The purpose of this study is to evaluate the status of traditional Chinese medicine (TCM) adjuvant treatments for HBV related HCC, and compare it to western medicine treatments with the aim of illustrating the efficacy and safety of TCM adjuvant treatments for HBV related HCC.**

Condition being studied: **Hepatocellular carcinoma (HCC) is a major threat to global health, resulting in a weighed medical burden. Chronic hepatitis B virus (HBV) infection is one of a major risk factors of HCC. Clinical and experimental researches point out that traditional Chinese medicine (TCM) is able to improve the clinical manifestations of HCC patients. However, the comparative efficacy and safety of different TCM adjuvant treatments for HBV related HCC remain unclear. We will evaluate the efficacy and safety of TCM adjuvant treatments for HBV related HCC.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 September 2022 and was last updated on 25 September 2022 (registration number INPLASY202290113).

INTRODUCTION

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point out that traditional Chinese medicine (TCM) is able to improve the clinical manifestations of HCC patients. However, the comparative efficacy and safety of different TCM adjuvant treatments for HBV related HCC remain unclear. We will evaluate the efficacy and safety of TCM adjuvant treatments for HBV related HCC.

METHODS

Participant or population: Patients are diagnosed with chronic hepatitis B and hepatocellular carcinoma.

Intervention: The intervention group acceptd TCM adjuvant therapies (TCM combined with western medicine).

Comparator: Blank group; western medicine treatment (such as ablation, surgery, systematic treatment, etc.)

Study designs to be included: Randomized controlled trials (RCTs) in English and Chinese.

Eligibility criteria: Participants diagnosed with CHB and HCC based on The Asian Pacific Association for the Study of the Liver (APASL) will be included. Moreover, there are no restrictions on age, gender or nationality in this study.

Information sources: Articles will be searched PubMed, Web of Science, the Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI), China Biological Medicine Database, Chinese Scientific Journals Database (VIP), Wan Fang Data.

Main outcome(s): The changes of tumor image, number and TCM syndrome score will be regarded as primary outcomes in this research.

Additional outcome(s): There will be several secondary outcomes as following: HBV-DNA, HBeAg, ALT, AST, major complications and Adverse events (eg, death, liver transplantation, side effect).

Quality assessment / Risk of bias analysis: The bias risk assessment in all included RCTs will be completed by three researchers with the help of the Cochrane Collaboration`s tool. They will pay attention to the following aspects: random sequence generation, task concealment, blinding for patients, researchers, and outcome evaluators, completeness of outcome data, selective reporting, and other bias. The results of each domain in bias risk assessment will be composed of three levels: “high bias risk”, “low bias risk” and “unclear bias risk”.

Strategy of data synthesis: First, for the conventional meta-analysis, we will use STATA (version 15.0) to complete direct comparisons. Mean difference or standard mean difference with 95% confidence interval (CI) will be applied for continuous variables, as well as odds ratio with 95% CI for dichotomous variables. Second, for network meta-analysis, we will use WinBUGS version 1.4.3 (MRC Biostatistics Unit, Cambridge, UK) and STATA to complete the network meta-analysis through the Markov chain Monte Carlo algorithm. Third,the surface under the cumulative ranking curve (SUCRA) will be calculated to forecast the ranking probability of different treatments.

Subgroup analysis: According to the participant characteristics (e.g, sample size and age), disease severity and other relevant parameters, subgroup analysis will be performed when heterogeneity or inconsistency among included studies is detected.

Sensitivity analysis: After each removal of 1 study, sensitivity analysis will be performed to ensure the stability of the result.

Language restriction: English and Chinese.

Country(ies) involved: China.

Keywords: hepatocellular carcinoma, hepatitis B virus, network meta-analysis, protocol, traditional Chinese medicine.

Contributions of each author:

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Author 2 - Piao Long.
Author 3 - Yuying Yang.
Author 4 - Dan Ouyang.
Author 5 - Jianzhong Cao.