INPLASY PROTOCOL

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Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
There are no conflicts of interest to disclose.

Clinical efficacy and safety of Ganshuang granules as an adjuvant treatment for chronic hepatitis B liver fibrosis: A protocol for systematic review and meta analysis

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Review question / Objective: **To explore clinical efficacy and safety of Ganshuang Granules as an adjuvant treatment for chronic hepatitis b liver fibrosis: a systematic review and meta-analysis.**
Condition being studied: **Chronic hepatitis B liver fibrosis in adults, and improvements in liver fibrosis and in liver function. Traditional Chinese medicine (TCM)-Ganshuang Granules is used as an adjuvant drug for the treatment of chronic hepatitis B liver fibrosis and is used frequently. However, We still do not know it Efficacy and Safety. Therefore, we decided to use meta analysis to solve this problem. It is particularly important to compare the effectiveness and safety of multiple interventions at one time, and therefore, this study will use a meta-analysis approach to compare multiple interventions and to rank the various interventions in terms of improvements in each efficacy index.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 September 2020 and was last updated on 06 September 2020 (registration number INPLASY202090027).

INTRODUCTION

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METHODS

Participant or population: Patients, of any age and gender, with chronic hepatitis B liver fibrosis, diagnosed according to established diagnostic criteria.

Intervention: The control group used entecavir, and the experimental group used Ganshuang granules combined with entecavir.

Comparator: Control group: entecavir.

Study designs to be included: Any randomized controlled trials (RCTs) involving efficacy and safety of GSG for treating chronic hepatitis B liver fibrosis will be included.

Eligibility criteria: 1. The searching languages include Chinese and English; 2. Patients were included in accordance with a clear diagnostic criteria, and confirmed by the regular hospital for chronic hepatitis B liver fibrosis; 3. Age and gender of patients in this Study were not limited; 4. All included studies were randomized controlled trials and quasi-randomized controlled trials; 5. The control group used entecavir, and the experimental group used Ganshuang granules combined with entecavir.

Information sources: By searching Web of Science, PubMed, China Knowledge Network (CNKI), China Biomedical Database (CBM), Wan Fang,VIP database, Embase, and Cochrane Library. The following criteria are included in this study: 1. The searching languages include Chinese and English; 2. Patients were included in accordance with a clear diagnostic criteria, and confirmed by the regular hospital for chronic hepatitis B liver fibrosis; 3. Age and gender of patients in this Study were not limited; 4. All included studies were randomized controlled trials and quasi-randomized controlled trials; 5. The control group used entecavir, and the experimental group used Ganshuang granules combined with entecavir. The search time is from the date of establishment of database to July 2020.

Main outcome(s): The primary outcomes of this study were HA, LN, PCIII and IV-C.

Additional outcome(s): The secondary outcomes of this study were AST, ALT and HBV-DNA negative conversion rate.

Quality assessment / Risk of bias analysis: Methodological quality of included trials will be assessed by Cochrane risk of bias tool. Every study will be assessed the risk of bias. We will divide each study into 3 grades: low risk, high risk and unclear risk. An information sheet will list the results of quality evaluation.

Strategy of data synthesis: Data analysis will be conducted by RevMan 5.3 software. Weighted mean difference (WMD) will be used for continuous outcomes. Risk ratio (RR) will be adopted for dichotomous results. Heterogeneity across studies will be checked by using I^2 test. $I^2 < 50\%$ or $P > .10$ suggests heterogeneity across studies, and a fixed-effects model will be conducted for pool analysis. If $I^2 > 50\%$ or $P < .10$, the pooled effect sizes will be calculated by a random-effects mode. The confidence interval (CI) will be set at 95%. The publication bias will be visually assessed by funnel plots.

Subgroup analysis: If required, a subgroup analysis will be performed based on the different study characteristics, study quality and outcome measurements.

Sensibility analysis: Stability of merger results will be checked by sensitivity

analysis. If any low-quality trials exist, we will remove it.

Country(ies) involved: China.

Keywords: Ganshuang granules, adjuvant treatment, chronic hepatitis B liver fibrosis, protocol.

Contributions of each author:
Author 1 - Shaoqian Zeng - Author 1 drafted the manuscript.
Author 2 - Yefang Liu - The author provided statistical expertise.
Author 3 - Cen Jiang - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Baixue Li - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 5 - Li Wen - This author contribute to the data synthesis and sensitivity analysis.
Author 6 - Quansheng Feng - This author revised and review the final version.