INPLASY PROTOCOL

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The authors have no conflicts of interest to disclose.

Effects of salvianolic acid B on liver fibrosis animal models: a systematic review and meta-analysis protocol

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Review question / Objective: **P: liver fibrosis animal models; I: treatment with salvianolic acid B; C: treatment with saline or without treatment; O:liver fibrosis scores, indicators of liver fibrosis,indicators of liver function; S: Randomized controlled studies.**
Condition being studied: **Liver fibrosis is widespread in the development of various chronic liver diseases, such as viral hepatitis, alcoholic liver disease, non-alcoholic fatty liver disease, etc; without effectively control, liver fibrosis can develop into cirrhosis and increase the risk of liver cancer. Salvianolic acid B is the most abundant and bioactive member of the salvianolic acids in Traditional Chinese herb of Danshen. Many experiment studies have showed that salvianolic acid B produced a good effect in reverse liver fibrosis, but there is limited evidence regarding its effectiveness. So, we will conduct this preclinical systematic review to evaluate the effectiveness of salvianolic acid B for experimental liver fibrosis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 April 2020 and was last updated on 13 April 2020 (registration number INPLASY202040073).

INTRODUCTION

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METHODS

Participant or population: Liver fibrosis animal models.

Intervention: Salvianolic acid B

Comparator: XXXXXooth extraction without any additional intervention (natural healing)XXX.

Study designs to be included: Randomized controlled studies.

Eligibility criteria: (1) Animal models were induced by carbon tetrachloride (CCl4) or diethylnitrosamine (DEN) or dimethylnitrosamine (DMN) and thioacetamide (TAA); (2) The treatment group was received salvianolic acid B as only treat in any dose. Interventions for control group were normal saline or no treatment; (3) The primary outcome measures were the liver fibrosis scores, indicators of liver fibrosis, such as hyaluronidase, laminin, and indicators of liver function (alanine aminotransferase, aspartate aminotransferase, total bilirubin. the second outcome measures were mechanisms of salvianolic acid B for liver fibrosis.

Information sources: (1)Electronic databases: Date were searched from the following seven databases: PubMed, EMBASE, Web of science, China National Knowledge Infrastructure (CNKI), China Biology Medicine (CBM), Wan fang Database for Chinese Technical Periodicals and VIP Database. All the databases were searched from inception to December 2019. (2)Searching other resources: Gray literature compiles materials and researches that are not covered in the databases mentioned, as well as the sites of animal research organizations , Google Scholar and Baidu Scholar. Additionally, a manual search will check the reference list or citations found in secondary studies to verify and identify possible eligible studies. Whenever necessary, the authors of the main studies will be contacted for further information.

Main outcome(s): (1)Primary outcome measures were the liver fibrosis scores, indicators of liver fibrosis, such as hyaluronidase, laminin, and indicators of liver function (alanine aminotransferase, aspartate aminotransferase, total bilirubin. (2)Second outcome measures were mechanisms of Sal B for liver fibrosis.

Quality assessment / Risk of bias analysis: Quality assessment: The study quality assessment was independently valued with the Collaborative Approach to Meta-Analysis and Review of Animal Data from Experimental Studies (CAMARADES). 10-item quality checklist criteria: peer reviewed publication, control of temperature, random allocation to treatment or control, blinded induction of model, blinded assessment of outcome, use of anesthetic without significant intrinsic neuroprotective activity, animal model (aged, diabetic, or hypertensive),sample size calculation, compliance with animal welfare regulations, statement of potential conflict of interests. Risk of bias analysis: SYRCLE's risk of bias tool for animal studies.

Strategy of data synthesis: Manager 5.2 version software (The Cochrane Collaboration, Software Update, Oxford, United Kingdom). The estimate of the combined effect sizes was calculated by the standardized mean difference (SMD). The heterogeneity assumption was checked by I2 statistics, when I2 was less than 50%, fixed effects model was used for meta-analysis, otherwise, random effects

model was carried out. 95% confidence intervals (CIs) of all results were calculated, the significance was determined by Z-test, with a P value<0.05 as significant level.

Subgroup analysis: Subgroup analysis will be conducted to explain the potential causes of heterogeneity when necessitated. The subgroup analysis will be implemented according to animal species, the method of animal model induced, the duration of treatment and the quality of studies.

Sensibility analysis: Sensibility analysis will be assessed the effect of each study on the random effects model when necessitated. The sensibility analysis of the overall comprehensive effect of all outcome indicators was carried out by exclusion method, each study will be excluded, and the remaining studies were re-analyzed to determine the stability of the results. If the results show that there is no qualitative change in the comprehensive effect, the results are stable.

Country(ies) involved: None.

Keywords: Salvianolic acid B;Liver fibrosis;Animal experimentation;Study protocol; Systematic review.