

INPLASY PROTOCOL

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None.

Meta-analysis of the therapeutic effect on primary liver cancer treated with Spleen strengthening method combined with western medicine treatment

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Review question / Objective: Can the Spleen-Strengthening Method in TCM combined with Western medicine further improve the clinical efficacy of primary liver cancer compared with simple Western medicine therapy? **Participants:** Patients with primary liver cancer **Interventions:** Spleen-Strengthening Method in TCM combined with Western medicine therapy **Comparisons:** Western medicine therapy **Outcomes:** Length of survival and survival rate; Tumour stabilisation rate; Pre- and Post-treatment KPS; Percentage levels of T-lymphocyte subsets.

Condition being studied: Primary liver cancer is a relatively common malignant disease worldwide, ranking fourth in the causes of cancer death. It is true that western medicine has made some progress in the treatment of primary liver cancer in recent years, while, there are certain limitations in the treatment of PLC in Western medicine, such as the side effects of chemotherapy, which can easily lead to drug resistance, and the majority of patients, once diagnosed, are mostly in the middle and late stages of liver cancer, thus losing the best time for surgical treatment. Therefore, the treatment of primary liver cancer is still facing great challenges.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 January 2021 and was last updated on 14 January 2021 (registration number INPLASY202110043).

INTRODUCTION

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METHODS

Participant or population: Patients with primary liver cancer.

Intervention: Spleen-Strengthening Method in TCM combined with Western medicine therapy.

Comparator: Western medicine therapy.

Study designs to be included: Clinical randomised controlled trials (RCTs) of Chinese medicine decoction of strengthening the spleen combined with Western medical therapy for the treatment of PLC.

Eligibility criteria: Type of study: Clinical randomised controlled trials (RCTs) of Chinese medicine decoction of strengthening the spleen combined with Western medical therapy for the treatment of PLC, languages are limited to English and Chinese. Subjects of research: Patients with primary liver cancer who mainly have symptoms of spleen deficiency and meet the relevant diagnostic criteria, regardless of age, sex and disease duration.

Diagnostic criteria such as the “Chinese Standard for Diagnosis and Treatment of Common Malignant Tumours”, “Diagnostic Criteria for Primary Liver Cancer”, “Diagnostic Criteria for Primary Liver Cancer (2011 edition)”, “Diagnostic Criteria for Primary Liver Cancer (2017 edition)” and so on. Intervention measures: The control group was treated by Western medical therapy, and the experimental group was treated with Chinese medicine decoction of strengthening the spleen on the basis of the control group. Outcome indicators: (i) Length of survival and survival rate: survival is calculated from the start.

Information sources: PubMed and Cochrane Library are the main sources of English literature, while CBM, CNKI, WanFang Data and VIP are the main sources of Chinese literature. Using a combination of subject terms and free words for searching. Contact with Email: liwenjingtcm@163.com. Although this research has been widely searched, there are some unpublished gray documents.

Main outcome(s): (i) Length of survival and survival rate (ii) Tumour stabilisation rate (iii) Pre- and Post-treatment KPS; (iv) Percentage levels of T-lymphocyte subsets.

Quality assessment / Risk of bias analysis: We used the risk of bias assessment tool for RCTs in the Cochrane Handbook for Systematic Evaluators 5.1.0 to evaluate the risk of bias of the included literature. The evaluation includes: (i) whether randomisation is applied, (ii) whether allocation is hidden, (iii) whether blinding is used, (iv) whether the outcome data are complete, (v) whether there is intentional analysis, (vi) whether there is selective reporting of results (vii) other biases. The evaluation is carried out by two researchers alone, and in case of dispute, a third party will negotiate and resolve the issue.

Strategy of data synthesis: Meta-analysis of the outcome indicators was carried out using Review Manager 5.3 software. The dichotomous variable use ratio of values (OR) and 95% confidence intervals (CI) to

indicate the combined results. Continuous variables use mean difference (MD) and 95% CI to represent the combined result, Data were tested for heterogeneity using the χ^2 test, and if $P > 0.05$ and $I^2 < 50\%$, indicating that the included studies were homogeneous, the outcome indicator data could be combined using a fixed effects model. Conversely, this implies that there is heterogeneity between the included studies and that a subgroup analysis of the included studies or a sensitivity analysis can be carried out to determine what causes the heterogeneity in the outcome indicators. If the source of heterogeneity has not been identified after subgroup analysis and sensitivity analysis, a random effects model can be used to combine the results.

Subgroup analysis: Subgroup analysis was carried out according to the treatment measures, such as TCM decoction of strengthening the spleen in combined with transcatheter arterial chemoembolization, radio therapy, chemo therapy, surgical treatment, microwave ablation or Symptomatic supportive treatment.

Sensibility analysis: A sensitivity analysis is carried out on the amount of combined effects, excluding one study at a time and re-Meta-analysing the remaining studies to determine the stability of the results. The results showed no qualitative change in the amount of the combined effect, suggesting that the results of this study are stable.

Country(ies) involved: The systematic review is being carried out in China.

Keywords: Strengthening the spleen, Western medical therapy, Primary liver cancer, Meta-analysis.

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