INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Clinical efficacy and safety of Chinese herb injections combination with platinum-based chemotherapy for advanced non-small cell lung cancer: A protocol for systematic review and meta-Analysis

Cao, KD[1]; Hu, SH[2]; Li, Z[3]; Qiao, CX[4]; Wang, Z[5]; Wang, S[6]; Wang, JK[7]; Hou, W[8].

Review question / Objective: **To determine whether Chinese herb injections(CHIS) combined with platinum-based chemotherapy shows superior efficiency and safety, compared with platinum-based chemotherapy alone, for the treatment of non-small cell lung cancer.**

Information sources: **Eight public domain electronic databases will be systematically searched with a time frame of build to July 2023. The databases are as follows: PubMed, Cochrane Library, Embase, Chinese National Knowledge Infrastructure, WanFang database, China Biology Medicine Database and Chongqing VIP Chinese Scientific Journals Full-text Database. Searches will be performed using the following keywords: herbal injections and (lung cancer or lung malignancy or NSCLC) and platinum-based chemotherapy. We will modify the search strategy to accommodate all databases. The language of articles is limited to Chinese and English.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 January 2022 and was last updated on 03 October 2023 (registration number INPLASY202210104).

INTRODUCTION

Review question / Objective: **To determine whether Chinese herb injections(CHIS) combined with platinum-based chemotherapy shows superior efficiency and safety, compared with platinum-based chemotherapy alone, for the treatment of non-small cell lung cancer.**

Condition being studied: **As one of the major diseases threatening human health, lung cancer has received widespread attention all around the world, because of**

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its high incidence, recurrence and mortality rates. Studies have shown that non-small cell lung cancer (NSCLC) accounts for more than 80% of lung cancer, and the 5-year survival rate is less than 15%. Because the pathological mechanism of NSCLC is complex and not yet well understood, there is no fundamental therapy for the disease. The current platinum-based two-drug combination chemotherapy regimen as first-line therapy has resulted in significantly higher objective response rate and significantly longer median Overall survival in patients with NSCLC, especially for those who cannot receive targeted therapy. However, the side effects of chemotherapy often increase patients' pain and affect their quality of life. As the research achievement of the modernization of traditional Chinese medicine, CHIS is a preparation extracted from natural Chinese herbal medicine. As a complementary and alternative medicine, CHIS has shown good curative effects on NSCLC. However, there is still a lack of consensus on the efficacy of CHIS in the treatment of NSCLC. The aim of this study was to conduct a meta-analysis to systematically evaluate the efficacy and safety of CHIS combined with platinum-based chemotherapy in the treatment of NSCLC.

METHODS

Participant or population: Patients with stage III-IV NSCLC were diagnosed by pathological or cytological examination. Gender, race, age, economic and educational status were not restricted. Patients did not receive any concomitant radiotherapy, non-platinum-based chemotherapy, or herbal therapy in this study.

Intervention: In the experimental group, platinum-based chemotherapy combined with at least one herbal injection were involved. There were no restrictions on the type, dose, duration of chemotherapy drugs or herbal injections. Patients was treated with platinum-based chemotherapy only in the control group.

Comparator: We will compare the efficacy and safety of CHIS combined with platinum-based chemotherapy regimens to platinum-based chemotherapy regimens alone.

Study designs to be included: We will plan to include only randomized controlled trials (RCT s) comparing the efficacy and safety of CHIS in combination with platinum-based chemotherapy and platinum-based chemotherapy alone for the treatment of advanced NSCLC. Studies will be excluded if data are not available by contacting the authors.

Eligibility criteria: Only RCTs will be included in this study to compare the efficacy and safety of Chinese herbal injections in combination with platinum-based chemotherapy and platinum-based chemotherapy alone for the treatment of advanced NSCLC. The patients must be confirmed by cytology or pathology as non-small cell lung cancer. In the experimental group, platinum-based chemotherapy combined with at least one herbal injection were involved.

Information sources: Eight public domain electronic databases will be systematically searched with a time frame of build to July 2023. The databases are as follows: PubMed, Cochrane Library, Embase, Chinese National Knowledge Infrastructure, WanFang database, China Biology Medicine Database and Chongqing VIP Chinese Scientific Journals Full-text Database. Searches will be performed using the following keywords: herbal injections and (lung cancer or lung malignancy or NSCLC) and platinum-based chemotherapy. We will modify the search strategy to accommodate all databases. The language of articles is limited to Chinese and English.

Main outcome(s): The primary outcome include the effect of antitumor therapy. These include objective response rate (ORR).

Additional outcome(s): Additional outcomes will include safety and quality of

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life outcomes. These include indicators of bone marrow suppression, gastrointestinal symptoms, indicators of abnormal liver and kidney function, and Quality of Life Assessment.

Quality assessment / Risk of bias analysis: The risk of bias for each included study will be assessed by using the Cochrane Risk of Bias (RoB) tool for randomised controlled trials. Seven domains will be assessed in terms of selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. The methodological quality of the included RCT s will be assessed independently by 2 researchers, and if there will be disagreement between the two researchers, we will resolve the inconsistency through discussion or with the help of senior researchers.

Strategy of data synthesis: This study will use Review Manager Version 5.4 software for meta-analysis. Binary variables are expressed by risk ratio (RR) or odds ratio (or) with 95% confidence intervals (CI) as the effect measure. continuous variables are expressed by weighted mean difference (MD) or standardized mean difference (SMD) with 95% confidence intervals (CI) as the effect measure. If $P > 0.1$ and $I2 < 50\%$, it indicates that there is little heterogeneity among the included studies, and the fixed effect model is used for meta-analysis. If $P < 0.1$ and $I2 > 50\%$, it indicates that there is great heterogeneity among the included studies, and the random effect model is used for meta-analysis.

Subgroup analysis: If heterogeneity is high, we will perform a subgroup analysis. such as race, sex, age, different forms of intervention, treatment time, and drug dosages.

Sensitivity analysis: If necessary, the corresponding literature will be excluded according to the publication time, literature quality and sample size of the included literature for sensitivity analysis.

Language: Chinese or English.

Country(ies) involved: China.

Keywords: Chinese herb injection, platinum-based Chemotherapy, non-small cell lung cancer, Protocol, Systematic review, meta-analysis.

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