INPLASY PROTOCOL

To cite: Qiao et al. Effectiveness and Safety of Shenqi Fuzheng injection Combined with Platinum-based chemotherapy for advanced non-small cell lung cancer: A Systematic Review and Meta-analysis. Inplasy protocol 202270026. doi: 10.37766/inplasy2022.7.0026

Received: 06 July 2022

Published: 06 July 2022

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Support: **Chinese Medicine Evidence-Based Capacity Building Project 60101.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Effectiveness and Safety of Shenqi Fuzheng injection Combined with Platinum-based chemotherapy for advanced non-small cell lung cancer: A Systematic Review and Meta-analysis

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Review question / Objective: **The aim of this study will to be assess the clinical efficacy and safety of Shenqi Fuzheng injection(SFI) combined with platinum-based chemotherapy for advanced non-small cell lung cancer.**
Information sources: **Eight public domain electronic databases will be systematically searched with a time frame of build to May 1st, 2022. The databases are as follows: PubMed, Cochrane Library, Embase, Web of Science, 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: Shenqi Fuzheng injection 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 06 July 2022 and was last updated on 06 July 2022 (registration number INPLASY202270026).

INTRODUCTION

Review question / Objective: **The aim of this study will to be assess the clinical efficacy and safety of Shenqi Fuzheng injection(SFI) combined with platinum-based chemotherapy for advanced 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 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. Studies have confirmed that SFI, as a product of the modernization process of traditional Chinese medicine, can improve clinical efficacy and have good safety in combination with conventional chemotherapy. However, many studies on SFI combination with platinum-based chemotherapy are of limited reference value.

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 SFI. There were no restrictions on the dose and 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 SFI combined with platinum-based chemotherapy regimens to platinum-based chemotherapy regimensalone.

Study designs to be included: We will plan to include only randomized controlled trials (RCTs) comparing the efficacy and safety of SFI 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 SFI 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 SFI.

Information sources: Eight public domain electronic databases will be systematically searched with a time frame of build to May 1st, 2022. The databases are as follows: PubMed, Cochrane Library, Embase, Web of Science, 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: Shenqi Fuzheng injection 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), disease control rate (DCR).

Additional outcome(s): Additional outcomes will include safety and quality of life outcomes. These include indicators of bone marrow suppression, gastrointestinal symptoms, and Karnofsky scores.

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 RCTs 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: Review Manager 5.3 was used to conduct statistical analyses. Risk ratios (RRs) were used to evaluate effectiveness and safety for dichotomous outcomes with 95% confidence intervals (CI). P values<0.05 were considered to indicate statistical significance. The heterogeneity was judged based on the I2 value and P value. If the studies had non-significant heterogeneity within the studies or subgroups (I20.1), we used a fixed effects model. If there was great heterogeneity within the studies or subgroups (I2>50%, P<0.1), we used the random effects model. Where data could not be synthesized quantitatively or where few studies were included, we performed a qualitative analysis of the available data. Funnel plots will be used to assess publication bias for each outcome indicator with more than 10 included trials.

Subgroup analysis: If heterogeneity is high, we will perform a subgroup analysis.

Sensitivity analysis: To ensure the robustness of the results, sensitivity analyses were performed based on the quality of the studies, sample size, and year of publication.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: Shenqi Fuzheng injection, platinum-based Chemotherapy, non-small cell lung cancer, Protocol, Network meta-analysis.

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