INPLASY PROTOCOL

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None declared.

Effectiveness and Safety of Aidi 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 Aidi injection combined with platinum-based chemotherapy for advanced non-small cell lung cancer by using meta-analysis.**
Information sources: **Eight public domain electronic databases will be systematically searched with a time frame of build to January 1, 2023. 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: 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 09 July 2022 and was last updated on 26 March 2023 (registration number INPLASY202270046).

INTRODUCTION

Review question / Objective: **The aim of this study will to be assess the clinical efficacy and safety of Aidi injection combined with platinum-based chemotherapy for advanced non-small cell lung cancer by using meta-analysis.**

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. Clinical studies have confirmed that Aidi injection, as a product of the modernization process of traditional Chinese medicine, can improve clinical efficacy and have good safety in combination with conventional chemotherapy in NSCLC patients. However, not only there is little higher-level evidence about the application of Aidi injection in NSCLC, but also the methodological quality of the existing high-level evidence is low, thus limiting the clinical evidence-based application.

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 Aidi 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 Aidi injection 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 (RCTs) comparing the efficacy and safety of Aidi injection 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 Aidi 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 Aidi injection were involved.

Information sources: Eight public domain electronic databases will be systematically searched with a time frame of build to January 1, 2023. 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: 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), 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 50%, P<0.1), we used the random effects model. If the data quantitative synthesis was not possible, we analyzed the available data qualitatively.

Subgroup analysis: We will perform a subgroup analysis if the collected data is sufficient, the following variables will be taken into account: the treating principle of Aidi injection based on TCM theories, the duration of Aidi injection treatments, patients characteristics, etc.

Sensitivity analysis: To determine the robustness of results, sensitivity analyses were conducted based on the quality of trials, participants' number, treatment duration of Aidi and publication year. Trial sequential analysis (TSA) was used to calculate the required information size (RIS) in the meta-analysis.

Language: Chinese and English.

Country(ies) involved: China.

Other relevant information: We will use a funnelplot to assess publication bias if there are more than 10 articles for the meta-analysis.

Keywords: Aidi injection; platinum-based Chemotherapy; non-small cell lung cancer; Protocol; Meta-analysis.

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