INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of Aidi injection combined with pemetrexed and platinum chemotherapy for stage III/IV non-small cell lung cancer
A protocol for systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to evaluated the effificacy and safety of Aidi injection combined with pemetrexed and platinum chemotherapy for stage III/IV NSCLC.**
Condition being studied: **Aidi injection (ADI) is a commonly used anti-cancer Chinese patent medicine, which can reduce various adverse reactions caused by chemotherapy, and can also enhance immunity,and has long been prescribed as adjunctive treatment to pemetrexed and platinum chemotherapy (PPC) in patients with stage III/IV non-small cell lung cancer(NSCLC). However, the efficacy and safety of this combination therapy remain unclear.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 April 2022 and was last updated on 07 April 2022 (registration number INPLASY202240039).

INTRODUCTION

Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to evaluated the efficacy and safety of Aidi injection combined with pemetrexed and platinum chemotherapy for stage III/IV NSCLC.**

Condition being studied: **Aidi injection (ADI) is a commonly used anti-cancer Chinese patent medicine, which can reduce various adverse reactions caused by**

chemotherapy, and can also enhance immunity, and has long been prescribed as adjunctive treatment to pemetrexed and platinum chemotherapy (PPC) in patients with stage III/IV non-small cell lung cancer(NSCLC). However, the efficacy and safety of this combination therapy remain unclear.

METHODS

Participant or population: Patients with a definite diagnosis of stage III (unresectable) or stage IV NSCLC. There were no restrictions on age, sex, and race.

Intervention: All patients who received Aidi injection combined with pemetrexed and platinum chemotherapy for NSCLC were included in this study.

Comparator: Pemetrexed and platinum chemotherapy.

Study designs to be included: (1) Randomized controlled trials without language restrictions were included in this study.(2) This study investigated the efficacy and safety of Aidi injection combined with pemetrexed and platinum chemotherapy for stage III/IV non-small cell lung cancer.

Eligibility criteria: 2.2.Types of studies. (1) Randomized controlled trials without language restrictions were included in this study.(2) This study investigated the effificacy and safety of Aidi injection combined with pemetrexed and platinum chemotherapy for stage III/IV non-small cell lung cancer 2.3 Types of participants.Patients with a definite diagnosis of stage III (unresectable) or stage IV NSCLC. There were no restrictions on age, sex, and race.2.4 Interventions.All patients who received Aidi injection combined with pemetrexed and platinum chemotherapy for NSCLC were included in this study.2.5 Outcome measurements.(1) Immune function evaluation: CD3+, CD4+, CD8+, and CD4+/CD8+ cell ratios.(2) Quality of life assessment: Karnofsky score (Karnofsky performance ancestatus,KPS) was used as the standard to assess the quality of life in both groups.(3)According to the Guidelines for Clinical Research of New Chinese Medicines, The TCM clinical syndromes in the two groups of patients were evaluated accord.

Information sources: In this systematic review and meta-analysis, we searched the Wanfang, Chinese Biomedical Literature Database, Chinese National Knowledge Infrastructure, PubMed, Embase, Web of Science, Cochrane Library, and Technology Periodical Database databases to identify all eligible studies. All searches were performed in March 2022. The search strategy for PubMed is shown in Table 1. The retrieval strategy for the other electronic databases was performed using PubMed. The retrieval strategy can be slightly changed according to the characteristics of each database.

Main outcome(s): Outcome measurements. (1) Immune function evaluation: CD3+, CD4+, CD8+, and CD4+/CD8+ cell ratios.(2) Quality of life assessment: Karnofsky score (Karnofsky performance ancestatus,KPS) was used as the standard to assess the quality of life in both groups.(3)According to the Guidelines for Clinical Research of New Chinese Medicines, The TCM clinical syndromes in the two groups of patients were evaluated according to the Guidelines for Clinical Research of New Chinese Medicines.

Quality assessment / Risk of bias analysis: Two reviewers, (HD and ZC), independently assessed the quality of the included literature using the Risk of bias Assessment Tool in the Cochrane Risk Assessment Manual. The evaluation results were classified into categories including high risk of bias, low risk of bias, and ambiguity.

Strategy of data synthesis: Data synthesis and statistics were performed using RevMan5.3 software provided by the Cochrane Collaboration, and the results of binary data were analyzed by relative risk, and mean deviation or standard mean deviation were used to analyze the results of continuous data; the confidence

intervals were set for both the binary and continuous data at 95%.The heterogeneity between the included results was assessed by the I2 statistic; if there was no heterogeneity between studies(I2<50%),the fixed-effects model was used for the joint analysis; if heterogeneity existed (I2≥50%), we used the random-effects model for the joint analysis, and both the sensitivity and subgroup analyses were performed to explore the potential causes of the heterogeneity.

Subgroup analysis: Subgroup analysis will be conducted according to clinical stage, duration of TCM treatment, chemotherapy regimen, and survival.

Sensitivity analysis: Sensitivity analysis was performed by excluding individual studies to ensure the stability and reliability of the results.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: Aidi injection, nonsmall cell lung cance, meta-analysis, pemetrexed and platinum, chemotherapy.

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