INPLASY PROTOCOL

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None declared.

Sijunzi Decoction and Shashen Maidong Decoction addition and subtraction Combined with Chemotherapy for Advanced Non-Small Cell Lung Cancer Influence of patients' quality of life, immune function, and efficacy of TCM syndromes A protocol for systematic review and meta-analysis

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Review question / Objective: **The aim of this meta-analysis randomized controlled trials to evaluate the effects of SJD and SMD addition and subtraction combined with chemotherapy on immune function, quality of life and TCM syndrome efficacy in NSCLC patients, so as to provide evidence-based basis for clinical practice.**
Condition being studied: **Systemic therapy has become particularly important for patients with advanced NSCLC, including: molecular targeted therapy, chemotherapy, traditional Chinese medicine and immunotherapy.Targeted therapy is only suitable for patients with sensitive gene mutations, and immunotherapy only benefits patients with high PDL-1 expression, and drug tolerance is inevitable. The majority of patients are not eligible for these two precision treatments, therefore, chemotherapy remains the main treatment option for advanced NSCLC.At present, the combination of traditional Chinese and western medicine has a remarkable curative effect in the treatment of NSCLC.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 March 2022 and was last updated on 22 March 2022 (registration number INPLASY202230115).

INTRODUCTION

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METHODS

Search strategy: In this systematic review and metaanalysis, we searched the database of Wanfang, Chinese Biomedical Literature Database, Chinese National Knowledge Infrastructure, PubMed, Embase, and Web of Science, Cochrane Library and Technology Periodical Database to identify all eligible studies. All searches were performed in March 2022. The search strategy for PubMed is exhibited in Table 1. The retrieval strategy of other electronic databases was performed on the basis of PubMed. According to the characteristics of each database, the retrieval strategy could be changed slightly.

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

Intervention: All patients who received SJD and SMD addition and subtraction combined with chemotherapy for NSCLC were included.

Comparator: The intervention method of the control group was conventional treatment, such as Platinum-based chemotherapy, docetaxel, pemetrexed, etc.

Study designs to be included: (1) The literature included in this study were randomized controlled trials without language restrictions; (2) This study involves the effect of SJD and SMD addition and subtraction combined with chemotherapy on the quality of life, immune function, and the efficacy of TCM syndrome in NSCLC patients.

Eligibility criteria: 1.Types of studies. (1) The literature included in this study were randomized controlled trials without language restrictions;(2) This study involves the effect of SJD and SMD addition and subtraction combined with chemotherapy on the quality of life, immune function, and the efficacy of TCM syndrome in NSCLC patients.2.Types of participants.Patients with definite diagnosis of stage III (unresectable) and IV NSCLC. There are no restrictions on age, gender and race. 3.Interventions.All patients who received SJD and SMD addition and subtraction combined with chemotherapy for NSCLC were included. 4.Outcome measurements.(1) Immune function evaluation: CD3+, CD4+, CD8+, CD4+/CD8+ cell ratio.(2) Quality of life assessment: The Karnofsky score (karnofsky performancestatus,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 of the two groups of patients were evaluated.

Information sources: Wanfang, Chinese Biomedical Literature Database, Chinese National Knowledge Infrastructure, PubMed, Embase, and Web of Science, Cochrane Library and Technology Periodical Database.

Main outcome(s): (1) Immune function evaluation: CD3+, CD4+, CD8+, CD4+/CD8+ cell ratio. (2) Quality of life assessment: The Karnofsky score (karnofsky performance status, 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 of the two groups of patients were evaluated.

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

Strategy of data synthesis: Data synthesis and statistics were performed using the RevMan5.3 software provided by the Cochrane Collaboration.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 included results was assessed by the I2 statistic,If there is no heterogeneity between studies(I2<50%),the fixed-effects model was then used for the joint analysis;If the heterogeneity exists (I2≥50%), and we will use the random-effects model for the joint analysis.Meanwhile, both the sensitivity and subgroup analyses will be performed to explore the potential causes of the heterogeneity.

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

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

Country(ies) involved: China.

Keywords: nonsmall cell lung cance, SJD and SMD, chemotherapy, immune function.

Contributions of each author:
Author 1 - Huan Ding - The author drafted the manuscript.
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Author 2 - Li Shi - The author provided funding acquisition and administrated project.
Author 3 - Yue Zhang - The author read, provided feedback and approved the final manuscript.
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