

INPLASY PROTOCOL

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Conflicts of interest:
None.

The effects of traditional Chinese medicine combined with chemotherapy on immune function and quality of life in patients with non-small cell lung cancer: a protocol for systematic review and meta-analysis

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Review question / Objective: Because of the occult incidence of lung cancer, most patients have been diagnosed as advanced stage and lost the opportunity of operation. Chemotherapy is one of the main treatment methods besides surgical treatment, but most of the chemotherapeutic drugs are cytotoxic periodic drugs with weak selectivity, which can kill tumor cells and damage normal cells to varying degrees at the same time, resulting in a serious decline in patients' immune function and quality of life. Therefore, it is essential to find drugs that can alleviate the suppression of immune function by chemotherapy. In recent years, traditional Chinese medicine (TCM) emphasizes the combination of strengthening body and anti-cancer in cancer treatment, which has unique advantages in enhancing body immunity, reducing toxic and side effects of chemotherapy, and improving patients' quality of life. This article will review the effects of TCM combined with chemotherapy on immune function and quality of life of non-small cell lung cancer (NSCLC) patients, and review the published toxic and side effects.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 July 2020 and was last updated on 16 July 2020 (registration number INPLASY202070071).

INTRODUCTION

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Condition being studied: Lung cancer is one of the most common malignant tumors in humans, and its incidence and mortality rank among the top in the world, with a five-year survival rate of only 19%, which seriously affects human health. Non-small cell lung cancer accounts for about 80%-85% of all lung cancers, and most patients have been diagnosed as advanced and missed the best operation time. Therefore, chemotherapy is one of the main treatment methods for advanced NSCLC. Chemotherapeutic drugs are easy to cause serious toxic and side effects, inhibit the immune function of the body, and greatly affect the quality of life of patients. TCM has many advantages in treating tumors, such as improving clinical symptoms, regulating immune function and improving quality of life. In recent years, it has been reported that TCM combined with chemotherapy has a synergistic and attenuating effect in the treatment of NSCLC, which can significantly improve immune function and improve the quality of life of patients.

METHODS

Participant or population: 1) Pathologically diagnosed as non-small cell lung cancer,

age ≥ 18 years old, no restriction on gender and race; 2) No major diseases such as heart, liver, lung, kidney, blood system, etc.

Intervention: Traditional Chinese medicine combined with chemotherapy.

Comparator: Chemotherapy alone.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: Inclusion criteria: 1) the literatures included in this study are all randomized controlled trials, and there is no language restriction; 2) we can extract valid data or find full text; 3) The article deals with the effect of Chinese medicine combined with chemotherapy on immune function and quality of life of non-small cell lung cancer. Exclusion criteria: 1) Non-randomized controlled trials; 2) Duplicate articles or data; 3) The full text cannot be obtained through various channels; 4) Animal research or subjects; 5) Literature without evaluation indexes of immune function and quality of life.

Information sources: The databases we will search include: PubMed, EMBASE, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), China Biomedicine (CBM), Wan fang Data and Technology Periodical Database (VIP). The search date is from inception to June, 2020. There are no restrictions on the document language.

Main outcome(s): 1. Evaluation of immune function: a) ratio of CD3+, CD4+, CD8+, CD4+/CD8+, NK cells; b) levels of IgA, IgG and IgM; 2. Quality of life assessment: Karnofsky score (Karnofsky performance status, KPS) will be used as the criterion to evaluate the changes of patients' quality of life.

Additional outcome(s): Evaluation of toxic and side effects: according to the WHO anti-tumor drug toxic reaction criteria, it is divided into 0 to 4 grades to evaluate various toxic and side effects during treatment.

Data management: We will use EndnoteX9 and pre-designed Excel tables to manage literature and data. Two reviewers independently searched the database and screened for titles and abstracts, and then read the full text to identify studies that met the criteria. The research team designed the data extraction table in advance, including: first author, publication year, nationality, research period, patient age, gender, sample size, TNM stage, Chinese medicine intervention, chemotherapy regimen, treatment time, outcome indicators, etc. Any disagreement on study selection and data extraction will be discussed and resolved by two reviewers, and if necessary, by a third reviewer.

Quality assessment / Risk of bias analysis: We will use the Cochrane collaboration tool to evaluate each study. Two examiners evaluated independently. If there are any differences, we will resolve them through discussion or consultation with the third inspector.

Strategy of data synthesis: We will use Revman 5.3 to merge the data and analyze it. If there is no obvious heterogeneity, the fixed effect model will be used for analysis; if the heterogeneity is large, the random effect model will be used. The source of heterogeneity will be explored through sensitivity analysis and subgroup analysis.

Subgroup analysis: We will conduct a subgroup analysis of age, gender, treatment cycle, and TNM stage.

Sensibility analysis: To ensure the reliability and stability of the results, we will conduct a sensitivity analysis to assess the impact of studies with a high risk of bias.

Language: No language restrictions.

Country(ies) involved: China.

Keywords: Traditional Chinese Medicine, chemotherapy, non-small cell lung cancer, immune function, quality of life.

Dissemination plans: We will publish the results when the research is completed.

Contributions of each author:

Author 1 - Li-na Zhao - retrieve literature and write manuscripts.

Author 2 - Hua Xiao - provide guidance.

Author 3 - Wen-wen Wang - retrieve and screen literature, check and enter data.

Author 4 - Qian Li - screen literature, check and enter data.

Author 5 - Ren-long Liang - quality evaluation and bias risk assessment of the study.

Author 6 - Qian-ru Yu - quality evaluation and bias risk assessment of the study.

Author 7 - De-qing Tian - read manuscripts and provide feedback.