INPLASY PROTOCOL

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Li, X¹; Liu, B²; Wu, Y³; Liu, Z⁴; Li, L⁵; Zhu, J⁶; Li, X⁷; Zhou, Y⁸.

Review question / Objective: This study aims to systematically evaluate the efficacy of combination of traditional chinese medicine and adoptive cellular immunotherapy for lung cancer.

Condition being studied: Lung cancer is still the leading cause of the cancer death worldwide. The high mobidity and mortality of lung cancer seriously threat people's lives and health.Adoptive cellular immunotherapy has become a new treatment method besides surgery, radiotherapy, chemotherapy and targeted therapy. Many immune cells can improve the clinical symptoms of lung cancer and increase the vacancy rate of the disease. At the same time, many studies have found that traditional chinese medicine(TCM) can fight with cancer in many ways, such as suppressing cell growth, reducing angiogenesis, enhancing cell apoptosis, etc. Evidence shows that traditional chinese medicine combined with adoptive cellular immunotherapy has a remarkable effect in the treatment of lung cancer, improves the clinical symptoms better.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2021 and was last updated on 26 April 2021 (registration number INPLASY202140134).

INTRODUCTION

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METHODS

Participant or population: The patients(over 18 years old) diagnosed with lung cancer by pathology or cytlogy regardless of their sex or ethnicity.

Intervention: Traditional chinese medicine combined with adoptive cellular immunotherapy were the main intervention.

Comparator: Use adoptive cellular immunotherapy alone.

Study designs to be included: Data from RCTs was sought electronically.The RCTs about traditional chinese medicine combined with adoptive cellular immunotherapy for lung cancer would be included.

Eligibility criteria: We would just include RCTs irrespective of the language.The animal mechanism studies, case reports, self-pre-and postcontrol, or non-RCTs were excluded. The patients(over 18 years old) diagnosed with lung cancer by pathology or cytlogy would be included in this study. In the experimental group, traditional chinese medicine combined with adoptive cellular immunotherapy, while the controls were only treated by adoptive cellular immunotherapy. Survival time, morbidity, clinical symptoms, quality of life and immunity would be measured as the outcomes.

Information sources: The Pubmed, Embase, Cocharane Library, VIP information

Database, Wanfang Database, Chinese National Knowledge Information, Chinese Biological and Medical database, and Chongqing VIP Chinese Science would be independently retrieved by two reviewers. And the above mentioned databases were researched from inception to April 2021.

Main outcome(s): Primary outcomes consisted of the survival time and morbidity.

Quality assessment / Risk of bias analysis: The quality of each selected studies would be evaluated using the Grading of Recommendations Assessment, Development, and Evaluation approach by 3 investigators. Two authors would independently assess the methodological quality of included trials. The methodological quality of the included randomized controlled trials would be assessed according to the guidance of the **Cochrane Handbook for Systematic Review** of Interventions, Version5.1.0. 7 criterias were included: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessments (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias), and other sources of bias. Consensus would be reached by discussion with a third author in case of discrepancies.

Strategy of data synthesis: We would use RevMan 5.3 software (The Cochrane Collaboration, Oxford, England) to calculate for data synthesis. If there was no obvious statistical heterogeneity among the trials included, we would apply fixed effects model to perform in the analysis. However, the random-effects model would be used, when apparent clinical heterogeneity among the trials included. Meanwhile, subgroup or sensitivity analysis would be conducted. a=0.05 would be deemed statistically significant.

Subgroup analysis: Subgroup analysis would be conducted according to sex,

locations, histologic diagnosis, timing of TCM therapies and adoptive cellular immunotherapy.

Sensitivity analysis: Sensitivity analysis would be conducted to explore the quality of studies of the document following sample size, the outcome of missing data, and methodological quality.

Country(ies) involved: China.

Keywords: traditional chinese medicine, adoptive cellular immunotherapy, protocol, lung cancer, systematic review.

Contributions of each author:

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