INPLASY PROTOCOL

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Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
The authors have no conflicts of interest to disclose.

Chinese herbal medicine for small cell lung cancer patients: a protocol for a systematic review and meta-analysis

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Review question / Objective: **We conducted this systematic review to evaluate the efficacy and safety of Chinese Herbal Medicine adjuvant to chemotherapy for patients with Small cell lung cancer.**
Condition being studied: **Small Cell Lung Cancer (SCLC) is an aggressive disease. Chemotherapy is the standard treatment for SCLC, but the resistance and the adverse effects of Chemotherapy still remains a major problem. Although Chinese herbal medicine (TCM) is wildly applied for patients with SCLC in China, the evidence of TCM in the treatment for SCLC is limited.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 November 2020 and was last updated on 14 November 2020 (registration number INPLASY2020110055).

INTRODUCTION

Review question / Objective: **We conducted this systematic review to evaluate the efficacy and safety of Chinese Herbal Medicine adjuvant to chemotherapy for patients with Small cell lung cancer.**

Condition being studied: **Small Cell Lung Cancer (SCLC) is an aggressive disease.**

Chemotherapy is the standard treatment for SCLC, but the resistance and the adverse effects of Chemotherapy still remains a major problem. Although Chinese herbal medicine (TCM) is wildly applied for patients with SCLC in China, the evidence of TCM in the treatment for SCLC is limited.

METHODS

Participant or population: Adult patients diagnosed with small cell lung cancer regardless of age, gender, and chemotherapy regimen. The diagnosis must have been confirmed by pathological or cytology diagnosis.

Intervention: Participants in the TCM group should be treated by TCM and conventional chemotherapy. The formulations of TCM included decoction, tablet, pill, powder, granule, capsule, oral liquid and injection.

Comparator: Participants in the control group should be treated by conventional chemotherapy alone or conventional chemotherapy plus placebo.

Study designs to be included: Randomized controlled trials (RCTs) regarding efficacy and safety of TCM in the treatment of SCLC will be included without restriction language.

Eligibility criteria: (1)Types of studies: Randomized controlled trials (RCTs) regarding efficacy and safety of TCM in the treatment of SCLC will be included without restriction language. (2)Types of participants: Adult patients diagnosed with small cell lung cancer regardless of age, gender, and chemotherapy regimen. The diagnosis must have been confirmed by pathological or cytology diagnosis. (3) Types of interventions: According to the Pharmacopoeia of the People's Republic of China edited by the China Food and Drug Administration in 2015, TCM was defined as herbal agents and materials that originated from botanical herbal products, mineral and animal sources. The formulations of TCM included decoction, tablet, pill, powder, granule, capsule, oral liquid and injection. Usually, a TCM formula is composed of two or more herbs to achieve synergistic effect for certain conditions, which is prescribed based on the traditional Chinese medicine pattern diagnosis and treatment thresholds by experienced physicians. Participants in the TCM group should be treated by TCM and conventional chemotherapy. Participants in the control group should be treated by conventional chemotherapy alone or conventional chemotherapy plus placebo. No restrictions regarding number of herbs, formulations of TCM, or treatment duration was pre-established. The specified exclusion criteria included: (a) case reports, case series, reviews, editorials, commentaries, and animal studies; (b) non-SCLC patients; (c) other TCM complementary and alternative therapies, including acupuncture, moxibustion, cupping, massage, qigong, Tai Chi, and music therapy, were contained in either TCM or control group; (d) duplication reporting the same results.

Information sources: The Cochrane Library, MEDLINE, Embase, Chinese BioMedical Database (CBM), China National Knowledge Infrastructure (CNKI), Chinese VIP Information (VIP), Wangfang Database will be searched regardless of publication date or language.

Main outcome(s): The main outcome measure is therapeutic effect according to standard for therapeutic effect evaluation of solid tumor by Response Evaluation Criteria in Solid Tumors (RECIST).

Additional outcome(s): Second outcome measures are survival time, quality of life evaluated with Karnofsky score, and adverse events.

Quality assessment / Risk of bias analysis: Two authors will independently assess the methodological quality of included trials. The methodological quality of the included RCTs will be assessed according to the guidance of the Cochrane Handbook for Systematic Review of Interventions, Version 5.1.012, which includes the following seven criteria: 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 will be reached by discussion with a third author in case of discrepancies. If necessary, we will contact the authors for missing data, methods of blinding and randomization.

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

Subgroup analysis: Subgroup analysis will be conducted according to sex, smoking status, locations, histologic diagnosis, TNM stage, duration of TCM therapies, timing of TCM therapies, chemotherapy regimens.

Sensibility analysis: Sensitivity analysis will 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, Solid Tumor, KPS, Adverse Events, Survival Time.

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