INPLASY PROTOCOL

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The authors have no conflicts of interest to disclose.

Efficacy and safety of Chinese Herbal Medicine for Myelosuppression after platinum-based chemotherapy: A protocol for systematic review and meta-analysis

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Review question / Objective: **Efficacy and safety of Chinese Herbal Medicine for Myelosuppression after platinum-based chemotherapy.**
Information sources: **The English databases include PubMed, Embase, Web of Science, Cochrane Library, and Chinese databases include China National Knowledge Infrastructure (CNKI), Wanfang Data, Chongqing VIP Information Resource Integration Service Platform (VIP), China Biomedical Literature (CBM) will be searched from the establishment of the database to December, 2020. We will also retrieve ongoing or unpublished trials from the International Clinical Trial Registration Platform and Chinese Clinical Trial Registry Platform. These search terms will be accurately translated into other databases.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 November 2020 and was last updated on 26 November 2020 (registration number INPLASY2020110116).

INTRODUCTION

Review question / Objective: **Efficacy and safety of Chinese Herbal Medicine for Myelosuppression after platinum-based chemotherapy.**

Condition being studied: **The National Cancer Institute defines it as a disease in which bone marrow activity is reduced, leading to decreased red blood cells, white blood cells, and platelets. Platinum-based drugs are highly effective chemotherapeutic drugs for the treatment**

of various types of malignant tumors.But various degrees of myelosuppression is a direct result caused by platinum-based chemotherapy. Chemotherapy-induced myelosuppression often leads to an increased risk of life-threatening infections , shortness of breath, fatigue and potentially excessive bleeding. Platinum and non-platinum drugs were widely used in cancer chemotherapy. They not only directly act on bone marrow cells and hematopoietic progenitor cells, but also indirectly affect the hematopoietic system through their interaction with the bone marrow microenvironment and hematopoietic regulatory factors, which ultimately leads to bone marrow suppression. Currently, medical treatment for CIM were expensive, with high adverse reaction rates and unsatisfactory curative effects. Therefore, there is an urgent need for a new treatment for chemotherapy-induced myelosuppression. Traditional Chinese medicine, a long history, treat CIM with relatively low costs and fewer side effects. Evidence from randomized clinical trials has shown that TCM is an effective way in treating CIM.

METHODS

Participant or population: Patients who are pathologically diagnosed as malignant tumors.

Intervention: The treatment group was treated with Chinese herbal medicine (decoctions, granules, tablets and injections) and symptomatic routine platinum-based chemotherapy.

Comparator: The control group is treated with symptomatic routine platinum-based chemotherapy.

Study designs to be included: (1)Type of studies. This review will include randomized controlled trials (RCTs), Whether using blinding. (2) Type of participants. Patients who are pathologically diagnosed as malignant tumors. (3) Types of interventions. The treatment group was treated with Chinese herbal medicine(decoctions, granules, tablets and injections) and symptomatic routine platinum-based chemotherapy (4) Type of comparators. The control group is treated with symptom.

Eligibility criteria: (1)Republished literature (2)Non-RCT literature (3)Research data is incomplete or full text is not available (4)Literature of the experimental group using non-Chinese medicine interventions (acupuncture, rehabilitation, etc.).

Information sources: The English databases include PubMed, Embase , Web of Science, Cochrane Library, and Chinese databases include China National Knowledge Infrastructure (CNKI), Wanfang Data, Chongqing VIP Information Resource Integration Service Platform (VIP), China Biomedical Literature (CBM) will be searched from the establishment of the database to December, 2020. We will also retrieve ongoing or unpublished trials from the International Clinical Trial Registration Platform and Chinese Clinical Trial Registry Platform. These search terms will be accurately translated into other databases.

Main outcome(s): The incidence of leukopenia; the incidence of platelet decline and the incidence of hemoglobin decline.

Quality assessment / Risk of bias analysis: Methodological quality for each included trial will be assessed using the tools of Cochrane Handbook for Systematic Reviews of Interventions. The bias risk assessment category will include the following 7 areas: randomized sequence generation; allocation concealment; blinding of participants; blinding of outcome assessors; incomplete outcome data; selective outcome reporting; other bias. Two independent risk assessments of bias were conducted on the literature, and any differences would be discussed and resolved with the third researcher.Each assessment is labeled "high risk", "low risk" or "unclear risk".

Strategy of data synthesis: (1)Quantitative data synthesis. We will use Revman 5.3 software to conduct meta analysis. If it is

continuous data, it will be calculated based on the mean difference (MD) of the 95% confidence interval(CI), and the dichotomous data will be calculated based on the risk ratio (RR) of the 95% CI. (2) Assessment of heterogeneity. Chi-square test and I2 test were used to test the heterogeneity of the included literature. When P>0.1and I2<50%, it indicates that there is no statistical heterogeneity between the studies; conversely, when P50%, it is considered that there is statistics heterogeneity between the studies.

Subgroup analysis: Group analysis will be conducted to explore the differences between types of Chinese herbal medicines and CIM if possible.

Sensibility analysis: In order to evaluate the robustness of data analysis, sensitivity analysis will be performed.

Country(ies) involved: Chinese and English.

Keywords: chemotherapy, protocol, myelosuppression, Chinese herbal medicine, systematic review.

Contributions of each author:

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