INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and Pharmacological Mechanism of Poria cocos-based Formulas Combined with Chemotherapy for Ovarian Cancer: A Integrated Systems Pharmacology Study

Wang, Q[1]; Peng, X[2]; Jia, C[3].

Review question / Objective: **The efficacy of Poria cocos-based formulas combined with chemotherapy in the treatment of ovarian cancer is controversial. This study analyzed the efficacy and safety of drugs in the randomized controlled trials, combined with systems pharmacology to analyze the potential mechanism, to provide evidence and guidance for the clinical application and continuous research of poria Cocos.**
Condition being studied: **The efficacy of poria cocos-based formulas combined with paclitaxel and carboplatin in treating ovarian cancer patients undergoing is uncertain. Our study evaluated the efficacy of poria cocos-based formulas in combination with paclitaxel and carboplatin versus chemotherapy alone in patients with ovarian cancer.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 August 2021 and was last updated on 14 August 2021 (registration number INPLASY202180060).

INTRODUCTION

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METHODS

Participant or population: Patients diagnosed with ovarian cancer.

Intervention: The Chinese medicine group was treated with poria cocos-based formulas combined with paclitaxel and carboplatin.

Comparator: The control group was treated with paclitaxel and carboplatin.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Only RCT s (except Quasi-RCT s and cluster RCT s) will be included. Animal mechanism studies and non-randomised clinical trials will be excluded. Article that substantially overlaps with another published article in print or electronic media will be excluded. Duplicate publications produced by a single experiment and published as separate papers with different criteria for measuring results, priority will be given to original publications and other publications will be excluded. The language and time of publication will not be restricted.

Information sources: The PubMed, EMBASE, Web of Science, Cochrane Library, Chinese Science and Technology Journals (CQVIP), China Academic Journals (CNKI), and Chinese Biomedical Literature database were searched systematically for all articles published before July 2021 to compare poria cocos-based formulas combined with chemotherapy, or with chemotherapy alone in the treatment of ovarian cancer.

Main outcome(s): Tumor response rate, traditional chinese medicine syndrome score, Karnofsky performance status.

Additional outcome(s): Whether poria cocos-based formulas can indeed decrease the side-effects of systemic chemotherapy, quality of life (QOL), blood system, the expression of tumor maker(CA125).

Quality assessment / Risk of bias analysis: The two independent reviewers evaluated random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessments, incomplete outcome data, selective reporting, and other biases in each RCT . Each item was classified as low risk, high risk, or unclear risk. Any disagreements were resolved by a discussion among all reviewers,

Strategy of data synthesis: Statistical analyses were performed using RevMan 5.4 and Stata 16.0. Risk ratios (RR) and 95% confidence intervals were used for dichotomous data. Mean difference (MD), Standard Mean Difference(SMD) and 95% CIs were used for continuous data. The heterogeneity among the studies was assessed using the Q test and I2 statistics. If $P > 0.10$ and $I2 < 50\%$, the study would be considered to have no statistical heterogeneity and a fixed-effect model would be used in the analysis. If $P < 0.10$ or $I2 > 50\%$, a study would be considered to be statistically heterogeneous and a random-effects model would be used in the analysis. The results of the meta-analysis were presented as forest maps. If there were more studies in any group or subgroup, the Egger's test was performed and funnel plots were generated to assess publication bias.

Subgroup analysis: Subgroup analysis was used to determine any source of heterogeneity. Due to different efficacy evaluation criteria in the RCT s, we will conduct subgroup analyses based on predefined variables.

Sensitivity analysis: Sensitivity analysis (SA) will be conducted by excluding RCT s one by one and comparing analysis results with those before the RCT s' exclusions.

Country(ies) involved: China.

Keywords: Poria cocos-based formulas, ovarian cancer, integrated systems pharmacology.

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