INPLASY PROTOCOL

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None.

Effectiveness and Safety of Adjunctive Traditional Chinese Medicine Therapy for Constipation after Cancer Chemotherapy: A Protocol Systematic Review and Meta-analysis

Dai, Q[1].

Review question / Objective: **As an alternative for constipation after cancer chemotherapy, Chinese medicine has gradually attracted the attention of clinicians based on the theory of syndrome differentiation and treatment. However, due to the lack of evidence-based medical evidence, the author designed the program to evaluate the effectiveness and safety of Chinese medicine.**
Condition being studied: **Constipation is a common and underestimated complication in patients with advanced cancer. Constipation is a subjective and objective feeling, and it is difficult to accept a general definition, although it is widely regarded as a clinical symptom, that is, the frequency of bowl movement decreases and the consistency increases. The constipation rate of patients with advanced cancer is 50% 87%. Constipation is the third most common symptom. The overall prevalence of patients receiving cytotoxic chemotherapy is 16%, of which 5% is severe and 11% is moderate. The basic mechanism of constipation after cancer chemotherapy is roughly defined in the smallest clinical studies available. It is distinguished from secondary constipation, medical treatment, chemotherapy, cancer-induced symptoms (such as anti-nausea and vomiting, and opioid therapy for pain), mainly in the study of disorders. In recent years, clinical research on the prevention and treatment of chemotherapy-related constipation by traditional Chinese medicine (TCM) has increased day by day, and its curative effect is remarkable. In China and some Southeast Asian countries, Chinese medicine has long been used to treat constipation. However, whether TCM treatment of constipation after cancer chemotherapy is also safe and effective is still controversial.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 July 2020 and was last updated on 09 July 2020 (registration number INPLASY202070027).

INTRODUCTION

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to the lack of evidence-based medical evidence, the author designed the program to evaluate the effectiveness and safety of Chinese medicine.

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METHODS

Participant or population: According to the National Comprehensive Cancer Network (NCCN) Clinical Guidelines for Liver Cancer, cancer patients confirmed by pathology, cytology or imaging, and patients undergo chemotherapy treatment and cause constipation. The diagnosis of constipation complies with Roman standards.

Intervention: Traditional Chinese medicine is used alone or in combination with other treatment methods. The types of Chinese medicines and methods of combination will be ignored.

Comparator: Other treatments (including any other non-Chinese medicine treatment) or combined with fake Chinese medicine.

Study designs to be included: Only randomized controlled trials (RCT) meet our requirements.

Eligibility criteria: According to the National Comprehensive Cancer Network (NCCN) Clinical Guidelines for Liver Cancer, cancer patients confirmed by pathology, cytology or imaging, and patients undergo chemotherapy treatment and cause constipation. The diagnosis of constipation complies with Roman standards. Observation group: Traditional Chinese medicine is used alone or in combination with other treatment methods. The types of Chinese medicines and methods of combination will be ignored. Control group: Other treatments (including any other non-Chinese medicine treatment) or combined with fake Chinese medicine. Main outcomes: abdominal distension; Fecal traits; Defecation time;Defecation effort. Additional outcomes: quality of Life, improvement of clinical symptoms, such as fatigue, and loss of appetite, adverse events (AEs). Only randomized controlled trials (RCT) meet our requirements.

Information sources: Use computer search and manual search for all published articles. The searched databases include PubMed, EMBASE database, Cochrane central controlled trial registration database, Chinese biomedical database, Chinese national knowledge infrastructure, Chinese scientific journal database, and Wanfang database. All randomized controlled trials (RCT) of traditional Chinese medicine used to treat constipation after chemotherapy will be searched until December 2021. The specific search strategy will be formulated with a specific database. Among them, the author lists the search strategy of the PubMed database (Table 1), and will be supplemented by manually searching for relevant literature.

Main outcome(s): The scoring standard of constipation efficacy refers to "Roman Standard", abdominal distension: 0 points for no abdominal distension, 1 point for mild abdominal distension, 2 points for more obvious abdominal distension, 3 points for obvious abdominal distension and affecting daily life. Fecal traits: According to the "Bristol stool profile", type 1 is a separate hard block; type 2 is a clump; type 3 is a dry and cracked sausage; type 4 is a soft sausage; type 5 is a soft clump; 6 Type 7 is muddy; Type 7 is watery stool; Types 4 to 7 count 0 points; Type 3 counts 1 point; Type 2 counts 2 points; Type 1 counts 3 points. Defecation time: 3Omin counts 3 points. Defecation effort: 0 points for smooth defecation, 1 point for difficulty in defecation, 2 points for difficulty in defecation, 2 points for difficulty in defecation, 3 points for defecation, enema or enema.

Quality assessment / Risk of bias analysis: The two researchers will independently conduct a bias risk assessment of studies that meet the inclusion criteria based on the Cochrane bias risk tool. It mainly includes 7 aspects: (1) generation of random sequence, (2) concealment of allocation, (3) blindness of participants and personnel, (4) blindness of result data, (5) incompleteness of result data, (6) Selective reports and (7) other biases. If there are differences during the evaluation process, they will be resolved through discussion.

Strategy of data synthesis: If no fewer than two studies meet the inclusion criteria, we will conduct a paired meta-analysis. OR will be used to assess the magnitude of the impact of dichotomous variables, while the magnitude of the impact of continuous variables will be assessed using the mean difference. Since the included studies may lead to heterogeneity in methods, clinical and statistical analysis, we will use a random effects model to synthesize the data (32). Heterogeneity is inevitable due to the methods and clinical diversity that always exist in meta-analysis. We will evaluate the heterogeneity of the study by calculating I2. The interpretation of I2 will be based on the threshold level proposed in the Cochrane collaboration. If there is significant heterogeneity affecting the results, we will conduct subgroup analysis and meta-regression analysis to study the potential influencing factors, such as the participant's age, sample size, disease duration, treatment process, and study quality. Sensitivity analysis will be used to check the stability of the results. If the number of studies is greater than 10, we will also assess the publication bias of the included studies.

Subgroup analysis: In order to explore whether TCM syndromes cause heterogeneity, we will conduct a subgroup analysis of TCM syndrome types.

Sensibility analysis: Sensitivity analysis will be used to check the stability of major decisions made during the review process. Several decision nodes will be considered in the system review process, such as small sample size, lack of method and lack of data. The results of the sensitivity analysis will be presented in the form of a summary table. As the sensitivity analysis results show, the risk of bias in the review process will be discussed.

Language: None restriction.

Country(ies) involved: China.

Keywords: Constipation after cancer chemotherapy, meta-analysis, protocol, systematic review, traditional Chinese medicine.

Contributions of each author:
Author 1 - Qianxiang Dai.