INPLASY PROTOCOL

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Conflicts of interest:
None declared.

External treatment of traditional Chinese medicine for radiation enteritis: A protocol for systematic review and meta-analysis

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Review question / Objective: **The present study performed a systematic review and meta-analysis to compare TCM external treatment and conventional treatment for RE to evaluate the effectiveness and safety of external treatment of traditional Chinese medicine in the treatment of RE.**

Eligibility criteria: **①Randomized controlled trials; ②The subjects were patients with radiation enteritis, and there were specific diagnostic criteria; ③The experimental group was treated with External treatment of traditional Chinese medicine (TCM) (including enema of traditional Chinese medicine, acupuncture and moxibustion, ear point pressing beans, etc.) or combined with conventional treatment, while the control group was only treated with conventional treatment; ④At least one of the following outcome indicators should be included: efficacy rate, TCM symptom score, KPS, inflammatory cytokine level, etc.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2021 and was last updated on 24 April 2021 (registration number INPLASY202140120).

INTRODUCTION

Review question / Objective: **The present study performed a systematic review and meta-analysis to compare TCM external treatment and conventional treatment for RE to evaluate the effectiveness and safety of external treatment of traditional Chinese medicine in the treatment of RE.**

Condition being studied: **Radiation enteritis (RE) often refers to a common complication of abdominal and pelvic malignant tumors after radiotherapy. In clinical work, the course of acute radiation enteritis is**

generally limited to no longer than 3 months, and those more than 3 months or up to several years are called chronic radiation enteritis. A team has reported that about 70% of cancer patients need to receive radiotherapy. In this part of patients receiving abdominal and pelvic radiotherapy, about 50% - 70% suffer from acute radiation enteritis, and 5% - 11% will develop into chronic radiation enteritis. The main symptoms of RE were abdominal pain, diarrhea, bloody mucus, incontinence, nausea and vomiting. In clinic, anti-inflammatory, hemostatic, analgesic and antidiarrheal methods are often used in the treatment of RE. Although the use of above conventional treatment has achieved good results, but many patients' symptoms are only temporarily relieved, and is easy to relapse. Therefore, this disease is difficult to cure. As a result, many scholars have attempted to identify more treatment methods, and the external treatment of traditional Chinese medicine (TCM) was identified as a more safe and effective approach. A large number of clinical studies on the treatment of RE with external treatment of TCM have been reported, but there is no relevant systematic review. So this study aims to comprehensively and systematically evaluate the efficacy and safety of external treatment of TCM in the treatment of RE.

METHODS

Participant or population: Radiation enteritis.

Intervention: Patients with external treatment of TCM.

Comparator: Patients with conventional treatment.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: ①Randomized controlled trials; ②The subjects were patients with radiation enteritis, and there were specific diagnostic criteria; ③The experimental group was treated with External treatment of traditional Chinese medicine (TCM) (including enema of traditional Chinese medicine, acupuncture and moxibustion, ear point pressing beans, etc.) or combined with conventional treatment, while the control group was only treated with conventional treatment; ④At least one of the following outcome indicators should be included: efficacy rate, TCM symptom score, KPS, inflammatory cytokine level, etc.

Information sources: Cochrane Library, PubMed, Embase, China National Knowledge Infrastructure (CNKI), Wan-Fang database, VIP Chinese Science and Technique Journals Database, and the Chinese Biomedical Literature Database (CBM).

Main outcome(s): The main results will include efficacy rate. The secondary outcomes will be the adverse events, KPS score, inflammatory cytokine level, and TCM symptom score. The TCM symptom score includes abdominal pain score, diarrhea score, mucus purulent stool score, etc.

Quality assessment / Risk of bias analysis: If more than 10 studies were included, the funnel plot was used to determine the publication bias. Egger's test and Begg's test were performed to quantitatively assess the publication bias using the Stata V.16.0 software. The results were estimated based on the Cochrane Handbook for Systematic Reviews of Interventions.

Strategy of data synthesis: The meta-analysis will be performed by RevMan V.5.3 statistical software and STATA 16.0.

Subgroup analysis: When there is significant heterogeneity in the trials and have enough randomized controlled trials, then we will analyze the subgroups according to age, sex, course of intervention, and type of intervention in the experimental and control groups.

Sensitivity analysis: The sensitivity analysis was conducted to evaluate the robustness

and reliability of the pooled results. If adequate data was available for analysis, a sensitivity analysis for the primary outcomes was conducted to test the strength of the review conclusions, which included the quality of the methods and studies, and the impact of the sample size and missing data.

Country(ies) involved: China.

Keywords: radiation enteritis, external treatment, traditional Chinese medicine, meta-analysis.

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