

INPLASY PROTOCOL

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Conflicts of interest:
None declared.

External treatment of traditional Chinese medicine for constipation after thoracolumbar compression fractures: a protocol for systematic review and meta-analysis

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Review question / Objective: This study is designed to evaluate the efficacy of external treatment of traditional Chinese medicine (TCM) for constipation after thoracolumbar compression fractures.

Condition being studied: Constipation is one of the common complications of thoracolumbar compression fractures, which seriously affects the quality of life and increases pain of patients. External treatment of traditional Chinese medicine has been widely used Clinically for constipation after thoracolumbar compression fractures, and has achieved good results. Therefore, we will conduct a systematic review and meta-analysis to confirm that external treatment of TCM is effective for patients with constipation after thoracolumbar compression fractures.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 May 2021 and was last updated on 01 May 2021 (registration number INPLASY202150005).

INTRODUCTION

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constipation after thoracolumbar compression fractures, and has achieved good results. Therefore, we will conduct a systematic review and meta-analysis to confirm that external treatment of TCM is effective for patients with constipation after thoracolumbar compression fractures.

METHODS

Participant or population: Patients who were diagnosed with constipation after thoracolumbar compression fractures and treated with external treatment of TCM were included, regardless of age, gender, and course of disease.

Intervention: Simple external treatment of TCM (such as external application of Chinese medicine, Chinese drugs at the acupoint, acupuncture, moxibustion, etc) or external treatment of TCM combined with conventional treatment / nursing of Western medicine.

Comparator: For control group, patients only were treated by conventional treatment / nursing of Western medicine.

Study designs to be included: Randomized controlled trials (RCTs) of all external treatments of TCM for constipation after thoracolumbar compression fractures published in domestic and foreign medicine, whether is blind or not, will be included. However, studies on constipation after surgical treatment of thoracolumbar compression fractures or the prevention of constipation after thoracolumbar compression fractures will be excluded.

Eligibility criteria: Inclusion criteria: 1. Randomized controlled trials (RCTs) of all external treatments of TCM for constipation after thoracolumbar compression fractures published in domestic and foreign medicine, whether is blind or not, will be included. However, studies on constipation after surgical treatment of thoracolumbar compression fractures or the prevention of constipation after thoracolumbar compression fractures will be excluded. 2. Patients who were

diagnosed with constipation after thoracolumbar compression fractures and treated with external treatment of TCM were included, regardless of age, gender, and course of disease. 3. Simple external treatment of TCM (such as external application of Chinese medicine, Chinese drugs at the acupoint, acupuncture, moxibustion, etc) or external treatment of TCM combined with conventional treatment / nursing of Western medicine will be included in the treatment group. For control group, patients only were treated by conventional treatment / nursing of Western medicine. 4. The outcomes measures will include the total effective rate, constipation symptom score, adverse events and other outcomes.

Information sources: We will search the following electronic databases: PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literatures Database (CBM), Chinese Scientific Journal Database (VIP), and Wanfang Database.

Main outcome(s): The primary outcome is the total effective rate.

Quality assessment / Risk of bias analysis: The Cochrane risk of bias tool will be used to assess the risk of bias in this study from the following 7 aspects: sequence generation, allocation concealment, blinding of participants and assessors, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. This assessment will be conducted independently by 2 reviewers, and any difference in the assessment process will be resolved through consultation with the third reviewer.

Strategy of data synthesis: Review Manager (RevMan) 5.3 Software will be used for data synthesis. The random-effects model will be used to synthesize the data if the heterogeneity is significant, while the fixed-effects model will be used if

the statistical heterogeneity is not identified.

Subgroup analysis: When there is significant heterogeneity in the study, we will conduct a subgroup analysis to explore possible reasons based on type of intervention, treatment course, and outcome measurements.

Sensitivity analysis: If possible, sensitivity analysis will be performed to verify the robustness of the review conclusions by evaluating the impact of methodological quality, sample size, and missing data.

Country(ies) involved: China.

Keywords: External treatment of traditional Chinese medicine; thoracolumbar compression fractures; constipation; systematic review; meta-analysis.

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