INPLASY PROTOCOL

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None declared.

Efficacy and safety of Jianpi-Qingchang decoction in the treatment of ulcerative colitis: A protocol for systematic review and meta-analysis

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Review question / Objective: **Efficacy and safety of Jianpi-Qingchang decoction in the treatment of ulcerative colitis.**
Condition being studied: **Ulcerative colitis (UC) is a chronic non-specific intestinal inflammatory disease with unknown etiology. In recent years, the global incidence has been increasing. Mesalazine is an common drug to treat UC with the satisficial efficacy and safety. Jianpi-Qingchang decoction (SJZD) is a traditional Chinese medicine that has been used for treatment of other diseases in previous studies as it has no side effects and it has a pharmacological effect in gastrointestinal function, immune system, ulcers, and tissue repair. It is essential to compare the efficacy and safety between the two drugs.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2022 and was last updated on 15 April 2022 (registration number INPLASY202240085).

INTRODUCTION

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METHODS

Participant or population: People with ulcerative colitis.

Intervention: Jianpi-Qingchang decoction.

Comparator: Mesalazine.

Study designs to be included: RCT.

Eligibility criteria: The inclusion criteria are as the follows: 1. selected patients must meet the clinical manifestations of UC. 2. All trials are randomized controlled trials. 3. The experimental group was treated with JPQCD or modified JPQCD, while the control group was treated with mesalazine.The exclusion criteria are as follows:1. the patient has other concomitant symptoms. 2. The experiment was not described as a randomized controlled trial. 3. The outcome indicators of the study did not include clinical effectiveness, adverse event rate.

Information sources: Searches will be performed in the following 7 databases: PubMed/EMBASE/Cochrane Library/Web of Science/CNKI/VIP/WanFang Data. The search period will be from establishment to March 2022. All publications in English and Chinese will be included.

Main outcome(s): Clinical efficacy, adverse event rate.

Quality assessment / Risk of bias analysis: The risk of bias of the included studies was assessed independently by two researchers (Chang and Cai) using the Cochrane Collaboration System Evaluation Manual (version 5.1.0) criteria. The risk of bias scale included the following five entries: Random sequence generation (selection bias), Blinding of participants and personnel (performance bias), Blinding of outcome assessment (detection bias), Incomplete outcome data (attrition bias) and Selective reporting (reporting bias). Based on the information extracted from each eligible trial, each potential source of bias will be classified as high risk, unclear or low risk, and any disagreement will be determined by the third author (Dong).

Strategy of data synthesis: Review Manager 5.3 and STATA 14.2 software were used for the meta statistical analysis of the included studies. It was statistically significant when P0.1,I2<50% using a fixed effects model, while P50% indicated significant heterogeneity and a random effects model was used. When heterogeneity between groups was too large, descriptive analyses were conducted.

Subgroup analysis: Heterogeneity is 1 of the main factors affecting the stability of meta-analysis; when the heterogeneity is large, we can use subgroup analysis to explore the source of the heterogeneity. We will perform a subgroup analysis from the following points to determine the source of heterogeneity: difference in dosage, combination with Guanchang Decoction, people of different degrees of UC, gender difference, inclusion of differences in studies quality.

Sensitivity analysis: Sensitivity analysis was carried out using an exclusion-by-exclusion method.

Language: Only Chinese and English literature is included.

Country(ies) involved: China.

Keywords: meta-analysis, Jianpi-Qingchang decoction, mesalazine, protocol, systematic review, ulcerative colitis.

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Author 4 - Zhen Sun.