INPLASY PROTOCOL

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Review Stage at time of this submission: **Piloting of the study selection process.**

Conflicts of interest:
The authors declare that they have no conflict of interest.

Clinical efficacy and safety of Modified Sijunzi Decoction for the treatment of Ulcerative colitis: A Protocol for a systematic review and meta-analysis

Tian, SW[1]; Zhang, YL[2]; Zhang, J[3]; Wang, B[4]; Liu, JP[5]; Wang, C[6].

Review question / Objective: **Modified Sijunzi Decoction has a good therapeutic effect on ulcerative colitis. It can maintain the tight junctions of intestinal epithelial cells to repair the mechanical barrier of the intestinal mucosa. This program aims to evaluate the effectiveness of Jiawei Sijunzi Decoction in the treatment of ulcerative colitis.**
Condition being studied: **Search databases include: CNKI, China Biomedical Literature Database (CBM), Chinese Science Citation Database (CSCD), Chinese Science and Technology Journal Full-text Database (VIP), Wan Fang Data, Pubmed, Geen Medical etc. We mainly search for suitable articles in Chinese and English, with no restrictions on people, gender and age.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 October 2020 and was last updated on 14 December 2020 (registration number INPLASY2020100102).

INTRODUCTION

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METHODS

Participant or population: Patients must meet the clinical manifestations of ulcerative colitis.

Intervention: The treatment group was treated with Modified Sijunzi Decoction.

Comparator: The control group was treated with other drugs such as Mesalamine.

Study designs to be included: All included studies are described as RCTs.

Eligibility criteria: According to literature review and expert recommendations, the inclusion criteria are as follows: (1) The included patients must meet the clinical manifestations of ulcerative colitis; (2) All experiments are randomized controlled trials (RCTs); (3) The experimental group uses the four gentlemen Decoction for drug treatment, and the control group for other drugs (such as mesalazine); (4) The outcome indicators of each study include at least the following two indicators: clinical effectiveness, recent cure rate, abdominal distension, blood in the stool, and fever, Diarrhea, anal burning, C-reactive protein (CRP), hemoglobin (HGB), liver function and kidney function.

Information sources: CNKI, China Biomedical Literature Database (CBM), Chinese Science Citation Database (CSCD), Chinese Science and Technology Journal Full-text Database (VIP), Wan Fang Data, Pubmed, Geen Medical etc.

Main outcome(s): The clinical total effective rate and the recent cure rate are binary variables, expressed by odds ratio (OR), and described by 95% confidence interval (95% CI). Abdominal distension, pus and blood in the stool, fever, diarrhea, C-reactive protein, hemoglobin, etc. are continuous variables. The weighted mean (WMD) or standardized mean difference (SMD) is used as the effect index, and the 95% confidence interval (CI) is used for description. It is statistically significant when $P<0.05$, and Q statistics and I2 statistics are used to assess heterogeneity.

Quality assessment / Risk of bias analysis: The Cochrane Handbook recommends that the risk of bias be assessed from the following factors: random sequence generation method, allocation concealment, blind result evaluation, incomplete result data, selective reports, and other sources.

Strategy of data synthesis: When describing the outcome indicators, if the data in the study is detailed and clear, it is judged as low risk. If the blinding method is not mentioned in the study, it is judged as high risk. If the experimental data in the study is incomplete or the data is selectively reported, the risk bias cannot be judged.

Subgroup analysis: Analyze the clinical effective rate (clinical symptoms disappeared, mild mucosal inflammation after fiber colonoscopy) and short-term cure rate (clinical symptoms disappeared, fiber colonoscope review mucosa normal, drug withdrawal, 6 observations) No recurrence in a month), whether there is improvement in abdominal distension and diarrhea, etc. to analyze the statistical differences.

Sensibility analysis: Two researchers independently screened the included literature according to the inclusion and exclusion criteria. If there is a divergent literature study, the third party will assist in the judgment. After negotiation, the included literature will be finalized, and the

same data will be processed by different methods to ensure analysis The reliability.

Country(ies) involved: China.

Keywords: Ulcerative colitis; Modified Sijunzi Decoction; Meta-analysis; System review.

Contributions of each author:

Author 1 - ShuWei Tian - design, conception, edit, and writing manuscripts.
Author 2 - YanLing Zhang - Collect literature; performed analysis and interpretation of data.
Author 3 - Juan Zhang - Administrative support; review and editing.
Author 4 - Bin Wang - Provides important ideas for the article, Analysis of the data in this article.
Author 5 - Ji Ping Liu - Strictly revised the article and provided technical support.
Author 6 - Chuan Wang - Final approval of the version to be published, and provided financial support.