

INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The efficacy and safety of ulcerative colitis treatment based on the theory of the "lung-gut axis": a meta-analysis

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Review question / Objective: The purpose of this study was to investigate the difference between the curative effect of traditional Chinese medicine or integrated traditional Chinese and Western medicine on ulcerative colitis under the guidance of lung-intestine axis theory and that of Western medicine alone. The selected research method was to search relevant randomized controlled trial in Chinese and English medical databases. The Cochrane bias risk assessment tool was used to analyze the quality of RCT studies, and RevMan 5.3 was used for efficacy evaluation and meta-analysis.

Condition being studied: Ulcerative colitis (UC) is a nonspecific intestinal inflammatory disease that often involves the rectum and colon submucosa. It is characterized by abdominal pain, diarrhea and purulent bloody stool. There is no specific therapy for ulcerative colitis at present. This study investigates the curative effect of traditional Chinese medicine or integrated traditional Chinese and Western medicine therapy on UC under the guidance of lung-intestine axis theory and provides a theoretical basis for the clinical treatment of UC.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 March 2023 and was last updated on 04 March 2023 (registration number INPLASY202330014).

INTRODUCTION

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METHODS

Participant or population: According to the medical history, clinical symptoms, signs and related medical examination, the patient was diagnosed with ulcerative colitis. The patient's age was ≥ 18 years old, and there was no serious basic disease.

Intervention: Traditional Chinese medicine treatment or integrated traditional Chinese and Western medicine treatment based on the concept of the "lung-intestine axis".

Comparator: Western medicine.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: (1) According to the Consensus of Diagnosis and Treatment of Ulcerative Colitis formulated by the Spleen and Stomach Diseases Branch of Chinese Medicine Association in 2010, the diagnosis and curative effect were evaluated. (2) The treatment is based on the theory of "lung-gut axis".

Information sources: CNKI, CBM, VIP, Wanfang Data, Web of Science, PubMed, Cochrane and Embase were searched to retrieve related studies updated on February 2023.

Main outcome(s): Clinical efficacy, adverse reactions and recurrence rate.

Quality assessment / Risk of bias analysis: Cochrane Bias Risk Assessment Tool.

Strategy of data synthesis: RevMan 5.3 software was selected for data analysis, and I² had no significant heterogeneity, so a fixed effect mode was used to combine effect quantities. If I² is more than 50% and P is less than P<0.1, it indicates that there is significant heterogeneity, and it is necessary to determine the causes of heterogeneity through sensitivity analysis, subgroup analysis and other methods and exclude the studies that affect heterogeneity. If the causes of heterogeneity could not be found, the random effect model was used to combine the effects. Stata 15 software was used for sensitivity analysis. Data analysis included the 95% confidence interval (CI) and risk ratio (RR) of binary variables and the mean difference (MD) of continuous variables. If the units of continuous variables are not uniform, they are represented by the standardized mean difference (SMD) and 95% confidence interval.

Subgroup analysis: According to the treatment of traditional Chinese medicine or integrated traditional Chinese and Western medicine, subgroup analysis was carried out.

Sensitivity analysis: Stata software carries out sensitivity analysis and reflects the sensitivity of one article by deleting the change in effect quantity.

Country(ies) involved: China.

Keywords: lung-gut axis, lung, intestine, traditional Chinese medicine, ulcerative colitis.

Dissemination plans: The results of this systematic review will be published in a peer-reviewed journal.

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