

# INPLASY PROTOCOL

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None declared.

## Efficacy and safety of Wumei pill combined with acupuncture and moxibustion in the treatment of ulcerative colitis: a protocol for systematic review and meta-analysis

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**Review question / Objective:** Ulcerative colitis (UC) is a chronic inflammatory disease that occurs in the colon, rectal mucosa and submucosa. It has a long course, is difficult to treat, and is prone to recurrent attacks. The etiology of UC has not been clarified in literature research. In clinical practice, it is often treated with aminosalicylic acid and glucocorticoid hormone. Wumei Pill is one of the classic prescriptions of traditional Chinese medicine, and acupuncture and moxibustion is the most common external treatment method of traditional Chinese medicine. Therefore, we designed this research scheme to evaluate the efficacy and safety of Wumei Pill combined with mesalazine in the treatment of UC.

**Study designs to be included:** Inclusion criteria include the randomized controlled trial(RCTs) of Wumei pill combined with acupuncture and moxibustion in the treatment of UC. The test language only includes Chinese or English, and the published status is not limited.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 April 2023 and was last updated on 25 April 2023 (registration number INPLASY202340084).

### INTRODUCTION

**Review question / Objective:** Ulcerative colitis (UC) is a chronic inflammatory disease that occurs in the colon, rectal mucosa and submucosa. It has a long

course, is difficult to treat, and is prone to recurrent attacks. The etiology of UC has not been clarified in literature research. In clinical practice, it is often treated with aminosalicylic acid and glucocorticoid hormone. Wumei Pill is one of the classic

prescriptions of traditional Chinese medicine, and acupuncture and moxibustion is the most common external treatment method of traditional Chinese medicine. Therefore, we designed this research scheme to evaluate the efficacy and safety of Wumei Pill combined with mesalazine in the treatment of UC.

**Condition being studied:** Ulcerative colitis (UC) is a chronic inflammatory disease that occurs in the colon, rectal mucosa and submucosa. Abdominal pain, diarrhea, mucopurulent stool are its main clinical manifestations, and fever and arthralgia are secondary manifestations. Among patients worldwide, arthralgia caused by disease involving joints is the most common manifestation outside the intestine, followed by eyes, skin and mucosa, liver and gall. It has the characteristic of persistent and difficult to treat course of disease, and is prone to recurrent attacks. The cause of UC has not been clearly identified in literature research, but most scholars believe that it is related to factors such as environment, genetics, infection, and immunity. However, there is still a lack of comprehensive research on the efficacy and safety of UC in clinical treatment. Therefore, in this study, the effectiveness and safety of Wumei Pill combined with acupuncture and moxibustion in the treatment of UC will be systematically reviewed and meta analyzed.

## METHODS

**Participant or population:** According to our consensus on the diagnosis and treatment of UC in China (Beijing, 2018), patients are included in the diagnostic criteria for UC, without any restrictions on gender, age, race, degree of illness (mild, moderate, severe), economic status, or educational level.

**Intervention:** The treatment group was mainly treated with Wumei pills combined with acupuncture and moxibustion, while the control group was treated with commonly used clinical drugs (aminosalicylic acid preparations, glucocorticoids, immune preparations), non

drug interventions (such as diet, exercise, etc.), retention enema, and other commonly used clinical drugs.

**Comparator:** Conventional Western Medicine Treatment and Nursing.

**Study designs to be included:** Inclusion criteria include the randomized controlled trial (RCTs) of Wumei pill combined with acupuncture and moxibustion in the treatment of UC. The test language only includes Chinese or English, and the published status is not limited.

**Eligibility criteria:** Patients suffering from Ulcerative colitis.

**Information sources:** Our team will use the following seven electronic databases as the main system search sources: PubMed, Cochrane Library, EMBASE, Web of Science, CNKI, Wanfang Database, and China Biomedical Literature Database (CBM). The search time will be until April 2023, and we will use a combination of subject and free word search methods to search for relevant literature.

**Main outcome(s):** Main outcome measures: total effective rate of wet clinical treatment, symptom scores (abdominal pain, diarrhea, mucopurulent bloody stools).

**Additional outcome(s):** The secondary outcome measures were the status of mucosal changes under colonoscopy, levels of inflammatory cytokines such as IL-6, IL-10, IL-17, TNF- $\alpha$  in serum, and the incidence of adverse events.

**Quality assessment / Risk of bias analysis:** Input the collected data into RevMan5.4 software, and then two members of the team will conduct risk bias assessment and quality assessment according to the Cochrane system evaluation manual system. The main items to be evaluated include random sequence generation, hidden allocation, blinding of researchers and subjects, integrity of the main results of the study, selective reporting and other biases. If there are disagreements during the research process, the third research

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member will evaluate the data and classify it as "high risk", "low risk", and "uncertain" risk bias.

**Strategy of data synthesis:** In RevMan 5.4 software, comprehensive analysis was conducted on the collected data, and weighted or standardized mean differences were used as effectiveness indicators to describe continuous variables such as serum inflammatory factors, abdominal pain, mucopurulent and bloody stools, and diarrhea, with a CI of 95%.

**Subgroup analysis:** Subgroup analysis will be conducted based on different intervention measures, controls, treatment duration, and outcome measurements. Adverse reactions will be tabulated and evaluated using descriptive techniques.

**Sensitivity analysis:** Sensitivity analysis was used to assess whether the combined results were robustness and reliable. It is a study that eliminates the risk of high bias. If the sensitivity analysis does not have a substantial impact on the results of this study, the likelihood of the analyzed results increases significantly. Conversely, the research conclusion should be treated with caution. When there is significant statistical heterogeneity, meta-analysis will be repeated to evaluate the sample size and data for analysis.

**Country(ies) involved:** China.

**Keywords:** ulcerative colitis, meta-analysis, protocol, systematic review.

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