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**No conflict of interest.**

# Efficacy and safety of Heat-sensitive moxibustion in the Treatment of ulcerative colitis：a protocol for a systematic review and meta-analysis

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**Review question / Objective:** **How about the efficacy and safety of heat-sensitive moxibustion in the treatment of ulcerative colitis.**
**Condition being studied:** **Ulcerative Colitis (UC) is a chronic nonspecific intestinal inflammatory disease with unclear etiology occurring in the colonic mucosa. Its clinical manifestations are characterized by recurrent abdominal pain, diarrhea, mucous pus and blood stool. The severity of the disease varies, and its characterized by a high recurrence rate. UC occurs most frequently in young adults. Epidemiological studies have shown that the incidence of inflammatory bowel disease is increasing year by year worldwide, and the prevalence of inflammatory bowel disease in China is about 116/100,000. At present, western medicine usually uses glucocorticoids, amino salicylic acid preparations, immunosuppressive agents, biological preparations, surgery and other treatments for UC, but the clinical treatment effect is not good, with obvious side effects. Because of its long course of disease, easy to relapse, protracted and difficult to recover, seriously affect the quality of life, increase the economic burden of patients and society, and even the risk of developing cancer, it has become one of the hot issues of general concern in the medical field. Heat-sensitive moxibustion is a kind of traditional Chinese medicine external therapy, which has the characteristics of simple, safe, effective and non-toxic side effects.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 November 2020 and was last updated on 29 November 2020 (registration number INPLASY2020110134).

## INTRODUCTION

**Review question / Objective:** **How about the efficacy and safety of heat-sensitive moxibustion in the treatment of ulcerative colitis.**

**Rationale:** A systematic review and meta-analysis of clinical randomized controlled studies on heat-sensitive moxibustion for ulcerative colitis following the rules of evidence-based medicine.

**Condition being studied:** Ulcerative Colitis (UC) is a chronic nonspecific intestinal inflammatory disease with unclear etiology occurring in the colonic mucosa. Its clinical manifestations are characterized by recurrent abdominal pain, diarrhea, mucous pus and blood stool. The severity of the disease varies, and its characterized by a high recurrence rate. UC occurs most frequently in young adults. Epidemiological studies have shown that the incidence of inflammatory bowel disease is increasing year by year worldwide, and the prevalence of inflammatory bowel disease in China is about 116/100,000. At present, western medicine usually uses glucocorticoids, amino salicylic acid preparations, immunosuppressive agents, biological preparations, surgery and other treatments for UC, but the clinical treatment effect is not good, with obvious side effects. Because of its long course of disease, easy to relapse, protracted and difficult to recover, seriously affect the quality of life, increase the economic burden of patients and society, and even the risk of developing cancer, it has become one of the hot issues of general concern in the medical field. Heat-sensitive moxibustion is a kind of traditional Chinese medicine external therapy, which has the characteristics of simple, safe, effective and non-toxic side effects.

## METHODS

**Search strategy:** We will search Eight electronic databases, including PubMed, Embase, Web of Science, Cochrane Library, the China National Knowledge Infrastructure, Chinese Science and Technology Periodical Database, Wanfang Database, and Chinese Biomedical Literature Database. We will search above electronic databases from the beginning to December 2020, without any language restriction.

**Participant or population:** There are clear and recognized diagnostic criteria and efficacy criteria, and all patients are diagnosed as UC, regardless of gender, age and origin of the case.

**Intervention:** Heat-sensitive moxibustion therapy, or mixed therapies based on heat-sensitive moxibustion will also be include.

**Comparator:** The control group will receive one of the following treatment methods: conventional pharmacological therapy, no treatment, and placebo.

**Study designs to be included:** Clinical randomized controlled trials (RCTs) containing heat-sensitive moxibustion for UC were included, with no limitation of language and publication status.

**Eligibility criteria:** Reported in chinese and English, and meet the "PICOS", will be considered for inclusion in this overview.

**Information sources:** Eight electronic databases will be searched, including PubMed, Embase, Web of Science, Cochrane Library, the China National Knowledge Infrastructure(CNKI), Chinese Science and Technology Periodical Database(VIP), Wanfang Database(WF), and Chinese Biomedical Literature Database(CBM). We will search above electronic databases from the beginning to December 2020, without any language restriction.

**Main outcome(s):** Clinical efficacy, including total effective rate or cure rate, clinical symptom integral (abdominal pain, diarrhea, purulent stool), and recurrence rate will be accepted as the primary outcomes.

**Additional outcome(s):** The changes of cytokine Hs-CRP、IL-6、TNF-α levels in serum, and improvement of colorectal mucosa will be used as secondary outcomes.

**Data management:** The two researchers independently read the title and abstract of

the literature we obtained, read the full text of the trials that might meet the inclusion criteria to determine whether the inclusion criteria were truly met, and discussed the conflicting literatures or let the third researcher decide whether to include them. Two researchers independently extracted data from the included studies, including study design, intervention measures and methods, measurement indicators, results, methodological contents such as hidden grouping and blind method, etc., and a third evaluator checked the consistency of the data. If the required information is incomplete, we will contact the original author for the required data.

**Quality assessment / Risk of bias analysis:** Two evaluators independently select the literature according to the inclusion and exclusion criteria and cross-check. In case of disagreement, a third evaluator will assist in the decision. The extracted data included the first author, year of publication, number of patients, age, gender, intervention measures, outcome indicators, etc. The Jadad scale to evaluate quality into literature, including: random sequence (right 2 points, 1 points not clear, inappropriate 0), distribution, hidden (right 2 points, 1 points not clear, inappropriate 0), blinded (right 2 points, 1 points not clear, inappropriate 0), lost to follow-up and exit (describe 1 points, not describe 0); 0-3 is classified as low quality and 4-7 as high quality.

**Strategy of data synthesis:** Meta analysis will be performed using Rev Man5.3.0 software. The odds ratio (OR) and its 95% Confidence Interval (CI) will be used as the counting data, while the weighted mean difference (WMD) and its 95% CI will be used as the measurement data.

**Subgroup analysis:** The heterogeneity test will be carried out first among all studies, I2 test will be used. When P > 0.1 and I2 < 50%, the fixed effect model will be used; otherwise, the random effect model will be used. When the clinical heterogeneity between the two studies is large, only descriptive analysis will be performed.

**Sensibility analysis:** The purpose of sensitivity analysis is to determine the sources and confounding factors of heterogeneity. If the trial data is sufficient, low or high quality studies will be excluded one by one for sensitivity analysis.

**Language:** No limitation of language.

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

**Keywords:** Heat-sensitive moxibustion; ulcerative colitis; systematic review and meta Analysis.

**Contributions of each author:**

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