

INPLASY PROTOCOL

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Conflicts of interest:
None.

Efficacy and safety evaluation of acupoint embedding for patients with ulcerative colitis: a protocol of systematic review and meta-analysis

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Review question / Objective: This review aims to systematically evaluate the efficacy and safety of acupoint embedding for ulcerative colitis patients reported in randomized clinical trials (RCTs).

Condition being studied: Ulcerative colitis is generally considered to be a gastrointestinal disease that promotes intestinal inflammation in the body by genetic, environmental and immune factors. The clinical symptoms are mainly abdominal pain, diarrhea, bloody stool, etc. Occasionally may be accompanied by complications such as major gastrointestinal bleeding, intestinal obstruction, and canceration. Not only the clinical recurrence rate is high, the delay is difficult to heal, and its incidence has increased year by year, becoming one of the clinically refractory diseases.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2020 and was last updated on 06 July 2020 (registration number INPLASY202040166).

INTRODUCTION

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gastrointestinal bleeding, intestinal obstruction, and canceration. Not only the clinical recurrence rate is high, the delay is difficult to heal, and its incidence has increased year by year, becoming one of the clinically refractory diseases.

METHODS

Participant or population: Inclusion: Patients diagnosis with ulcerative colitis, without restrictions on the TCM classification of UC, such as age, sex, disease duration, and race. But some special patients will not be included even if they meet the clinical criteria for UC, such as pregnant or nursing women, people with severe heart, liver or lung disease. Exclusion: Crohn's disease, and other patients with enteritis.

Intervention: The treatment group will use acupoint embedding.

Comparator: Western medicine, enema, moxibustion, placebo, Chinese herbal medicine or other treatments regularly of the comparator.

Study designs to be included: Only randomized controlled trial will be included.

Eligibility criteria: Participants clinically diagnosed with UC, without restrictions on the TCM classification of UC, such as age, sex, disease duration, and race. But some special patients will not be included even if they meet the clinical criteria for UC, such as pregnant or nursing women, people with severe heart, liver or lung disease.

Information sources: These English databases will be searched: PubMed, Embase, Web of Science, and include some Chinese databases: CNKI, WanFang, Chinese Scientific Journals Database (VIP), and China biomedical literature data base (CBM). The literature search will be constructed around search terms for Ulcerative colitis therapy, and search terms for randomized controlled trial and adapted for each database as necessary.

Main outcome(s): The primary outcome is clinical effectiveness.

Quality assessment / Risk of bias analysis: This study will use the risk assessment tool recommended by Cochran Handbook 5.3 to evaluate the quality of the literature included in the study, which mainly includes the following aspects: selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias.

Strategy of data synthesis: The combined analysis of various research results is mainly carried out using Revman 5.3 software. The results of this study mainly involve binary variables and continuous variables. Among the binary variables, the relative risk (RR) is used as the effect scale index, and the continuous variable is the mean difference (MD) as the effect scale index, and the software is used to obtain point estimates and 95% confidence intervals (CI). I² is used to measure the heterogeneity. If I² > 10) will be used to assess publication bias.

Subgroup analysis: None.

Sensibility analysis: Sensitivity analysis will be used to find the cause of heterogeneity.

Language: English.

Country(ies) involved: China.

Keywords: Ulcerative colitis; acupoint embedding; meta; study protocol.

Contributions of each author:

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Author 5 - Xu Chen.

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