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

Lu, J1; Zhou, J2; Wang, L3; Zhong, C4; Chen, X5; Jia, B6.

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 24 April 2020 (registration number INPLASY202040166).
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METHODS

Participant or population: Inclusion: Patients diagnosis with ulcerative colitis, regardless of various dialectics, patient age, gender, source, etc. Exclusion: Crohn's disease, and other patients with enteritis.

Intervention: The treatment group will use acupoint embedding or acupoint embedding plus western medicine for UC.

Comparator: The control group was western medicine treatment, placebo or blank control.

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

Eligibility criteria: Only randomized controlled trials are included. Patients with Crohn's disease and other inflammatory bowel diseases, as well as those with other serious diseases, such as coronary heart disease and hypertension, will be excluded. We will exclude no control group or other traditional Chinese medicine treatment methods, such as massage, acupuncture, enema, etc; animal experiments or reviews will also be excluded.

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 database (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). I^2 is used to measure the heterogeneity. If I^2 > 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.