INPLASY

Efficacy and safety of Gegen Qinlian Decoction retention enema for ulcerative colitis: A protocol for systematic review and meta-analysis

INPLASY202620028
doi: 10.37766/inplasy2026.2.0028
Received: 7 February 2026
Published: 7 February 2026

Ding, N.

Corresponding author:
Ning Ding

dn90@qq.com

Author Affiliation:
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University.

ADMINISTRATIVE INFORMATION

Support - Self-funded.

Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202620028

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 February 2026 and was last updated on 7 February 2026.

INTRODUCTION

Review question / Objective To systematically evaluate the clinical efficacy and safety of Gegen Qinlian Decoction retention enema in the treatment of ulcerative colitis.

Rationale Ulcerative colitis (UC) is a chronic non-specific intestinal inflammatory disease with a lingering course and easy recurrence. Conventional Western medicine treatments such as aminosalicylic acid preparations and glucocorticoids are commonly used, but long-term use may cause adverse reactions or drug resistance. Gegen Qinlian Decoction is a classic traditional Chinese medicine formula. Clinical studies have shown that its retention enema administration can directly act on the intestinal lesions, increase local drug concentration, and improve efficacy. However, a high-quality systematic evaluation is currently lacking to verify its comprehensive evidence.

Condition being studied Ulcerative colitis (including active phase and remission phase). In Traditional Chinese Medicine (TCM), this condition falls under the categories of "Dysentery" (Li Ji), "Chronic Dysentery" (Xiu Xi Li), or "Diarrhea" (Xie Xie).Ulcerative colitis.

METHODS

Search strategy We will search the following electronic databases: PubMed, EMBASE, The Cochrane Library, Web of Science, CNKI, WanFang Data, VIP, and CBM. The search terms will include:

Disease terms: "Ulcerative Colitis", "Colitis, Ulcerative", "Idiopathic Proctocolitis", "Chronic Dysentery", "Dysentery", "Diarrhea".

Intervention terms: "Gegen Qinlian Decoction", "Gegen Qinlian Tang", "Gegen Qinlian", "Traditional Chinese Medicine".

Administration terms: "Retention Enema", "Enema", "Rectal administration". The retrieval time limit is from the establishment of the database to December 2025.

Participant or population Patients diagnosed with ulcerative colitis according to recognized diagnostic criteria (combining colonoscopy and pathology). There are no restrictions on:
1. Disease stage: Both active stage and remission stage(including maintenance therapy) are included.
2. TCM Syndromes: All TCM syndrome types (e.g., Large Intestine Damp-Heat, Spleen Deficiency with Dampness, or Cold-Heat Complex) are eligible.
3. Age, gender, or disease course.

Intervention The experimental group received Gegen Qinlian Decoction retention enema (or modified Gegen Qinlian Decoction). It can be used alone or in combination with the basic treatment used in the control group (e.g., oral Mesalazine).

Comparator The control group received conventional Western medicine treatment (e.g., Mesalazine, Sulfasalazine administered orally or via enema) or placebo retention enema.

Study designs to be included Randomized controlled trials (RCTs).

Eligibility criteria Inclusion criteria: (1) RCTs involving Gegen Qinlian Decoction retention enema for UC. (2) Patients diagnosed with UC (including those diagnosed as "Dysentery" or "Diarrhea" in TCM but confirmed as UC by western medical standards). (3) Regardless of whether the patient is in the active phase or remission phase.
Exclusion criteria: (1) Non-RCTs, reviews, animal studies, or case reports. (2) Studies with incomplete data. (3) The intervention included other Traditional Chinese Medicine therapies (such as acupuncture, moxibustion) that might confound the results.

Information sources Electronic databases (PubMed, EMBASE, Cochrane Library, Web of Science, CNKI, WanFang, VIP, CBM) and manual search of reference lists of included studies.

Main outcome(s) Clinical effective rate. Defined as the ratio of patients with significant improvement or disappearance of clinical symptoms (diarrhea, abdominal pain, pus and blood stool) or improvement in colonoscopy results after treatment.

Additional outcome(s) Endoscopic mucosal healing score (e.g., Baron score, Sutherland index).

2. Inflammatory biomarkers: To assess the anti-inflammatory mechanism, we will analyze:
• Tumor Necrosis Factor-alpha (TNF-α)
• Interleukin-6 (IL-6)
• Interleukin-8 (IL-8)
• Interleukin-10 (IL-10)
• C-reactive protein (CRP)
• Erythrocyte Sedimentation Rate (ESR)
3. Disease Activity Index (DAI) score.
4. Recurrence rate: Follow-up data regarding relapse of UC.
5. Adverse events: Incidence of adverse reactions such as nausea, rash, or liver function abnormalities.

Quality assessment / Risk of bias analysis Two reviewers will independently assess the risk of bias using the Cochrane Collaboration's Risk of Bias 2 (RoB 2) tool. Domains include randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result.

Strategy of data synthesis Statistical analysis will be performed using RevMan 5.4 or Stata 16.0 software. For dichotomous variables (e.g., clinical effective rate), Risk Ratio (RR) with 95% Confidence Interval (CI) will be used. For continuous variables (e.g., inflammatory factors), Mean Difference (MD) or Standardized Mean Difference (SMD) with 95% CI will be used. Heterogeneity will be assessed using the I^2 statistic. A random-effects model will be used if $I^2 > 50\%$, otherwise a fixed-effects model will be used.

Subgroup analysis If significant heterogeneity exists, we will conduct subgroup analyses based on:

Course of treatment: (e.g., ≤4 weeks vs. >4 weeks).

Intervention type: Gegen Qinlian Decoction retention enema combined with oral Western medicine vs. oral Western medicine alone; or comparisons involving different dosages.

Disease severity: (e.g., mild-to-moderate UC vs. severe UC).

Control group medication: (e.g., Mesalazine vs. Sulfasalazine).

Sensitivity analysis Sensitivity analysis will be performed by excluding studies with high risk of bias or by using the "leave-one-out" method to verify the stability of the results.

Country(ies) involved China.

Keywords Ulcerative colitis; Gegen Qinlian Decoction; Retention enema; Meta-analysis; Protocol.

Contributions of each author

Author 1 - Ning Ding - Author 1 drafted the manuscript and designed the search strategy.
Email: dn90@qq.com