

# INPLASY PROTOCOL

To cite: Zhong et al. Gancao Xiexin decoction combined with mesalazine in the treatment of Ulcerative Colitis: a protocol for a systematic review and meta-analysis. Inplasy protocol 202080008. doi: 10.37766/inplasy2020.8.0008

Received: 04 August 2020

Published: 04 August 2020

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**Support:** 16ZA0125

**Review Stage at time of this submission:** The review has not yet started.

**Conflicts of interest:**  
None.

## Gancao Xiexin decoction combined with mesalazine in the treatment of Ulcerative Colitis: a protocol for a systematic review and meta-analysis

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**Review question / Objective:** Investigate the efficacy and safety of Gancao Xiexin decoction combined with mesalazine in the treatment of Ulcerative Colitis.

**Condition being studied:** Ulcerative colitis(UC), the main kind of inflammatory bowel disease, is a chronic autoimmune disease. The main symptoms of ulcerative colitis include abdominal pain, diarrhea, mucous stool, and bloody stool, listed by the World Health Organization as one of the world's refractory diseases. Western medicine treatment included aminosalicylic acid, glucocorticoid, and immunosuppressant, but there are many adverse reactions. Recent studies have shown that traditional Chinese medicine can significantly improve ulcerative colitis. Gancao Xiexin decoction(GCXXD), as a supplementary alternative treatment of ulcerative colitis, showed a definite effect. This meta-analysis aimed to evaluate the efficacy and safety of Gancao Xiexin decoction combined with mesalazine in the treatment of ulcerative colitis.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 August 2020 and was last updated on 04 August 2020 (registration number INPLASY202080008).

### INTRODUCTION

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world's refractory diseases. Western medicine treatment included aminosalicyclic acid, glucocorticoid, and immunosuppressant, but there are many adverse reactions. Recent studies have shown that traditional Chinese medicine can significantly improve ulcerative colitis. Gancao Xiexin decoction(GCXXD), as a supplementary alternative treatment of ulcerative colitis, showed a definite effect. This meta-analysis aimed to evaluate the efficacy and safety of Gancao Xiexin decoction combined with mesalazine in the treatment of ulcerative colitis.

## METHODS

**Participant or population:** We will include patients who were clinically diagnosed with ulcerative colitis regardless of sex, age, ethnicity, economic status, or education.

**Intervention:** The intervention measures of the experimental group were any GCXXD combined with mesalazine. The dose and administered frequency are not limited.

**Comparator:** Only mesalazine in the control group.

**Study designs to be included:** Randomized controlled trials (RCTs) will be included without limitations on publication type or language.

**Eligibility criteria:** Only randomized controlled trials(RCTs) are included, and participants are clinically diagnosed with Ulcerative Colitis. The experiment group used GCXXD combined with mesalazine, while the control group applied for mesalazine monotherapy.

**Information sources:** PubMed, Web of Science, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI) database, Wanfang Data Knowledge Service Platform, and the VIP database.

**Main outcome(s):** This review's primary outcome will focus on the remission of clinical symptoms and the level of inflammatory cytokines such as IL-6, IL-10, TNF- $\alpha$ .

## Quality assessment / Risk of bias analysis:

The qualities in the included studies were assessed by two investigators using the Cochrane risk of bias (ROB) tool which consists of the following items of bias related to the quality of RCTs: random sequence generation, allocation concealment, blinding of participants, blinding of personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other potential biases.

**Strategy of data synthesis:** Data synthesis will be finished using RevMan 5.3 software when meta-analyses were allowed for the included studies. We will estimate the heterogeneity of enrolled literature by I<sup>2</sup> tests. If the data had high heterogeneity ( $P < 0.1$  or  $I^2 > 50\%$ ), we chose a random-effects model for analysis, or a fixed-effects model was selected. Odds ratio (OR) will be used to assess the efficacy of GCXXD combined with mesalazine compare to mesalazine monotherapy. Mean difference (MD) will be calculated for continuous outcomes, and 95% confidence interval (CI) was given.

**Subgroup analysis:** If there is high heterogeneity, we will carry out a subgroup analysis.

**Sensibility analysis:** Sensitivity analysis is mainly used to evaluate the stability of the meta-analysis.

**Language:** English.

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

**Keywords:** ulcerative colitis, GanCao XieXin Decoction, mesalazine, protocol, systematic review and meta-analysis.

## Contributions of each author:

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