

INPLASY PROTOCOL

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**Review Stage at time of this
submission:** Data analysis.

Conflicts of interest:
None.

Comparing the Efficacy and Safety of Three Xinkai Kujiang Decoctions in Treatment of Ulcerative Colitis with Cold-heat Syndrome: Network Meta-analysis

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Review question / Objective: P: People with a diagnosis of ulcerative colitis (UC) I: Experimental group was treated with XKDs or co-applied with SASP treatment C: Control group was treated with SASP treatment O: Clinical effective rate S: Randomized controlled trials (RCTs) and controlled clinical trials (CCTs).

Condition being studied: There are a large number of literature about treating UC by Traditional Chinese medicine. However, there is no literature of compare the difference in efficacy between BXD, GXD and WMP for clinical treatment of UC with cold and heat mixed syndrome.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 July 2020 and was last updated on 14 July 2020 (registration number INPLASY202070055).

INTRODUCTION

Review question / Objective: P: People with a diagnosis of ulcerative colitis (UC) I: Experimental group was treated with XKDs or co-applied with SASP treatment C: Control group was treated with SASP treatment O: Clinical effective rate S:

Randomized controlled trials (RCTs) and controlled clinical trials (CCTs)

Condition being studied: There are a large number of literature about treating UC by Traditional Chinese medicine. However, there is no literature of compare the difference in efficacy between BXD, GXD

and WMP for clinical treatment of UC with cold and heat mixed syndrome.

METHODS

Search strategy: We did our best to include all studies of randomized controlled trials (RCTs) published until date, regarding the association between XKDs (BXD, GXD, WMP) and ulcerative colitis with Cold-heat Syndrome. A literature search was performed in June 13, 2020 using PubMed, Web of Science, CNKI, VIP, and Wanfang databases to identify relevant studies, using various combinations of Medical Subject Headings (MeSH) and non-MeSH terms, without restriction to publication types, regions or languages.

Participant or population: People with a diagnosis of ulcerative colitis (UC).

Intervention: Patients of the experimental group were administered any of the three Xinkai Kujiang Decoctions (XKDs), including BXD, GXD and WMP, or co-applied with Sulfasalazine (SASP).

Comparator: Control group was treated with SASP treatment.

Study designs to be included: Randomized controlled trials (RCTs) and controlled clinical trials (CCTs).

Eligibility criteria: P: People with a diagnosis of ulcerative colitis (UC) I: Experimental group was treated with XKDs or co-applied with SASP treatment C: Control group was treated with SASP treatment O: Clinical effective rate S: Randomized controlled trials (RCTs) and controlled clinical trials (CCTs).

Information sources: PubMed, Web of Science, CNKI, VIP, and Wanfang databases.

Main outcome(s): Clinical effectiveness, adverse drug reactions, Clinical outcome such as TCM symptom integral, levels of inflammatory factors, disease activity score, recurrence rate, etc.

Quality assessment / Risk of bias analysis:

The methodological quality of each study was evaluated according to the quality evaluation criteria described in evaluation tools. Each domain will be quantified (scale of 0-7) by Jadad scale and characterized (high, low or uncertain risk of bias) by Cochrane System Assessment handbook 5.1.0.

Strategy of data synthesis: The present analyses were performed using software of Review Manager (RevMan 5.3) and Stata SE15.1 (Stata Corporation).

Subgroup analysis: The present analyses were performed using software of Review Manager (RevMan 5.3) and Stata SE15.1 (Stata Corporation).

Sensibility analysis: The present analyses were performed using software of Review Manager (RevMan 5.3) and Stata SE15.1 (Stata Corporation).

Country(ies) involved: China.

Keywords: Xinkai Kujiang Decoctions; Banxia Xiexin Decoction; Gancao Xiexin Decoction; Wumei Pill; Ulcerative Colitis; sulfasalazine; network meta-analysis.

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