

# INPLASY

## Efficacy and safety of tanshinone IIA in combination with mesalazine in the treatment of ulcerative colitis: a Systematic review and meta-analysis

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Chen, X<sup>1</sup>; Zhou, QJ<sup>2</sup>; Wang, BL<sup>3</sup>; Feng, DD<sup>4</sup>; Jiang, RL<sup>5</sup>; Wang, X<sup>6</sup>.

### Corresponding author:

Xi Wang

wangxixi@zcmu.edu.cn

### Author Affiliation:

The First Affiliated Hospital of Zhejiang Chinese Medical University.

### ADMINISTRATIVE INFORMATION

**Support** - Not applicable.

**Review Stage at time of this submission** - Completed but not published.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202420103

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 February 2024 and was last updated on 24 February 2024.

### INTRODUCTION

**Review question / Objective** This study aims to assess the overall response rate associated with the use of tanshinone IIA in conjunction with mesalazine for UC treatment. Additionally, the investigation encompasses the examination of alterations in inflammatory markers and immune responses, alongside an exploration of the incidence of adverse events. The ultimate goal is to offer valuable insights guiding the clinical management of UC.

**Condition being studied** 1)patients with ulcerative colitis.

### METHODS

**Search strategy** (((("Colitis, Ulcerative"[Mesh]) OR (Idiopathic Proctocolitis[Title/Abstract])) OR

(Ulcerative Colitis[Title/Abstract])) OR (Colitis Gravis[Title/Abstract])) OR (Inflammatory Bowel Disease, Ulcerative Colitis Type[Title/Abstract])) AND (tanshinone IIA[Title/Abstract]).

**Participant or population** Patients with ulcerative colitis.

**Intervention** Tanshinone IIA plusmesalazine.

**Comparator** The control group was treated with mesalazine alone.

**Study designs to be included** RCT.

**Eligibility criteria** Inclusion criteria:1)Subjects: patients with ulcerative colitis2) Interventions: tanshinone IIA plus mesalazine3) Control: The control group was treated with mesalazine alone4) Outcome indicators: total effective rate, TNF- $\alpha$ , C-

reactive protein (CRP), interleukin (IL)-6, expression of major histocompatibility complex (MHC)-II and the incidence of adverse events.5) Study design: Randomized controlled trial (RCT) Exclusion criteria: Duplicate publications; studies for which full text was not available or for which data extraction was not possible; studies using animal studies; reviews and systematic reviews.

**Information sources** Pubmed, Embase, Cochrane Library, CNKI, Wanfang, CQVIP, CBM.

**Main outcome(s)** Total effective rate, TNF- $\alpha$ , C-reactive protein (CRP), interleukin (IL)-6, expression of major histocompatibility complex (MHC)-II and the incidence of adverse events.

**Data management** The literature search, screening, and information extraction were all independently completed by two researchers. When there were doubts or disagreements, the decision was made after discussion or consultation with a third person. The data extraction included the author, year, study design, sample size, sex, age of patients, duration of disease, measurements and the indicators for evaluating outcome, including total effective rate, TNF- $\alpha$ , CRP, IL-6, expression of MHC-II and the incidence of adverse events.

**Quality assessment / Risk of bias analysis** Two researchers independently carry out the literature quality evaluation, using the Review manager 5.3 software (Cochrane Collaboration) risk assessment tool [13], according to the Cochrane risk assessment scale, according to the random sequence generation, allocation hiding, blinding, whether the research results are blindly evaluated, and the result data are complete evaluate the included literatures based on gender, choice of report research results, other biases, etc., and decide through discussion or consultation with a third party when opinions are inconsistent. This meta-analysis is performed based on the related items of the Preferred Reporting Items for Systematic Reviews and Meta-analysis statement (PRISMA statement) [14].

**Strategy of data synthesis** All data were processed with the statistical software STATA (15.1, StataCorp LP, College Station, TX, USA) [15]. Ratio rate (RR) (95%CI) was used to combined the binary variable, and Weighted mean difference (WMD) (95%CI) was used to combined the continuous variable. I<sup>2</sup> is used to evaluate heterogeneity. If the heterogeneity test is  $P \geq 0.1$  and  $I^2 \leq 50\%$ , it indicates that there is homogeneity between studies, and the fixed effects model is

used for combined analysis; if  $P > 0.1$ , it indicates that the study If there is heterogeneity, use sensitivity analysis to find the source of heterogeneity. If the heterogeneity is still large, use the random effects model or give up the combination of results and use descriptive analysis. Funnel plot and Egger's test was used to analyze publication bias.

**Subgroup analysis** None.

**Sensitivity analysis** We carried out sensitivity analysis by eliminating each included study one by one, and performing a summary analysis of the remaining studies.

**Country(ies) involved** China.

**Keywords** Tanshinone IIA; Mesalazine; Ulcerative colitis; Efficacy and safety; Systematic review and meta-analysis.

#### Contributions of each author

Author 1 - Xiao Chen - Author 1 drafted the manuscript.

Author 2 - Qiujun Zhou - The author provided statistical expertise.

Author 3 - Bolin Wang - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 4 - Dandan Feng - The author read, provided feedback and approved the final manuscript.

Author 5 - Ronglin Jiang - The author conceived the final approval of the version to be submitted and provided the funding.

Author 6 - Xi Wang - The author conceived the final approval of the version to be submitted and provided the funding.