INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The Efficacy and Safety of Berberine for Irritable Bowel Syndrome: A Protocol for Systematic Review and Meta-Analysis of Randomized Controlled Trials

Kan, ZQ[1]; Yan, WL[2]; Gao, HY[3]; Fang, YQ[4], Wang, N[5]; Song, YM[6].

Review question / Objective: **The purpose of this systematic review and meta-analysis of randomized controlled trials was to evaluate the efficacy and safety of berberine for irritable bowel syndrome.**
Condition being studied: **Irritable bowel syndrome (IBS) is one of the most common functional bowel disorders. According to the Rome IV diagnostic criteria, data from a global study of 33 countries conducted by the Rome Foundation indicated that the overall prevalence of IBS was 3.8%. Berberine is an isoquinoline alkaloid isolated from Chinese herbs such as Coptidis Rhizome. A growing number of clinical controlled studies have found that berberine is effective in the treatment of irritable bowel syndrome. However, there is still uncertainty about its safety and efficacy. Therefore, we plan to evaluate the efficacy and safety of berberine for the treatment of irritable bowel syndrome.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 May 2022 and was last updated on 09 May 2022 (registration number INPLASY202250051).

INTRODUCTION

Review question / Objective: **The purpose of this systematic review and meta-analysis of randomized controlled trials was to evaluate the efficacy and safety of berberine for irritable bowel syndrome.**

Condition being studied: **Irritable bowel syndrome (IBS) is one of the most common functional bowel disorders. According to the Rome IV diagnostic criteria, data from a global study of 33 countries conducted by the Rome Foundation indicated that the overall prevalence of IBS was 3.8%. Berberine is an isoquinoline alkaloid**

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isolated from Chinese herbs such as Coptidis Rhizome. A growing number of clinical controlled studies have found that berberine is effective in the treatment of irritable bowel syndrome. However, there is still uncertainty about its safety and efficacy. Therefore, we plan to evaluate the efficacy and safety of berberine for the treatment of irritable bowel syndrome.

METHODS

Participant or population: All patients diagnosed with IBS, regardless the age, gender, source of cases, and IBS type. Diagnosis of IBS based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome III criteria, Rome IV criteria or the Manning criteria).

Intervention: The intervention measures in the treatment group will be berberine used alone or berberine combination therapy.

Comparator: The control group will be treated with conventional basic treatment or combined regimen to remove berberine. Basic treatment includes traditional Chinese medicine and western medicine treatment except berberine.The control group was treated with conventional basic treatment or combined regimen to remove berberine. Basic treatment includes traditional Chinese medicine and western medicine treatment except berberine.

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

Eligibility criteria: All studies were randomized controlled trials (RCTS), regardless of language, with or without assignment concealment and blinding. Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded.

Information sources: PubMed, the Cochrane Library (CENTRAL), Embase, Web of Science, China National Knowledge Infrastructure (CNKI), Chongqing VIP Information (VIP), and WanFang Data, China Biomedical Literature Database (CBM), ClinicalTrials.gov and Chinese Clinical Trial Registry (ChiCTR).

Main outcome(s): The primary outcome assessed will be the total effective rate.

Additional outcome(s): Secondary outcome measures include the efficiency of single symptom and symptom score.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the quality of the selected studies according to the Cochrane Collaboration's tool for randomized control trials. Items will be evaluated in three categories: low risk of bias, unclear risk of bias and high risk of bias. The following seven characteristics will be assessed: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other biases. Results from these questions will be graphed and assessed using Review Manager 5.4.

Strategy of data synthesis: The meta-analysis will be performed by the Review Manager 5.4 software. The dichotomous variables will be assessed by risk ratios (RR) with 95% confidence intervals (95% CIs) and continuous variables will be analyzed with their mean difference (MD) or standard mean difference (SMD) with 95% CIs. According to the results of the heterogeneity test, random effect model or fixed effect model will be selected for data analysis. Between-study heterogeneity will be assessed using x^2 test and I^2 statistic. If $I^2<50\%$ then the fixed-effect model will be applied for data synthesis. Otherwise, the random-effect model will be conducted if the heterogeneity is significant ($I^2\geq50\%$). Outcomes will be calculated using P values and $P<0.05$ is considered statistically significant.

Subgroup analysis: If the necessary data are available, subgroup analyses will be performed to investigate differences in gender, age, berberine dosage, etc.

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Sensitivity analysis: Sensitivity analysis will be performed to assess the stability of the decision. It includes influences such as study quality, study design and sample size. In addition, we will present the results of sensitivity analysis in the summary table.

Country(ies) involved: China.

Keywords: Berberine, Irritable Bowel Syndrome, Systematic Review, Meta-Analysis.

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