INPLASY PROTOCOL

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Conflicts of interest: None declared.

INTRODUCTION

Review question / Objective: The purpose of this systematic review and meta-analysis is to assess the effectiveness and safety of YNBY across RCTs investigating hemoptysis treatments and to provide a summary of evidence and guidance for the

Yunnan Baiyao Adjuvant Treatment for Patients with Hemoptysis: A Systematic Review and Meta-Analysis

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Review question / Objective: The purpose of this systematic review and meta-analysis is to assess the effectiveness and safety of YNBY across RCTs investigating hemoptysis treatments and to provide a summary of evidence and guidance for the clinical use and continued research of YNBY. Condition being studied: Yunnan Baiyao (YNBY) is a traditional Chinese medicine widely used to treat bleeding in patients. However, its effect on patients with hemoptysis is still uncertain. Our study evaluated the combined efficacy of YNBY plus conventional pharmaceutical treatment (YNBY + CPT) versus the efficacy of CPT alone in patients with hemoptysis.

Information sources: The Cochrane Library, Web of Science, EMBASE, PubMed, CNKI (China National Knowledge Infrastructure), Chongqing VIP Chinese Science and Technology Periodical Database, and Wanfang database were searched from inception to June 30, 2021 for RCTs investigating the clinical efficacy of YNBY.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 July 2021 and was last updated on 03 July 2021 (registration number INPLASY202170007).

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METHODS

Participant or population: Patients diagnosed with hemoptysis; patients in both test and control groups were given cough relief, expectorant, bed rest, antiinfection, phentolamine or pituitrin, and other conventional treatments.

Intervention: The YNBY group was treated with YNBY + CPT.

Comparator: The control group was treated with only the CPT.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Only RCTs (except Quasi-RCTs and cluster RCTs) will be included. Animal mechanism studies and nonrandomised clinical trials will be excluded. Article that substantially overlaps with another published article in print or electronic media will be excluded. Duplicate publications produced by a single experiment and published as separate papers with different criteria for measuring results, priority will be given to original publications and other publications will be excluded. The language and time of publication will not be restricted.

Information sources: The Cochrane Library, Web of Science, EMBASE, PubMed, CNKI (China National Knowledge Infrastructure), Chongqing VIP Chinese Science and Technology Periodical Database, and Wanfang database were searched from inception to June 30, 2021 for RCTs investigating the clinical efficacy of YNBY.

Main outcome(s): Effective rate for the treatment on hemoptysis.

Quality assessment / Risk of bias analysis: The two independent reviewers evaluated random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessments, incomplete outcome data, selective reporting, and other biases in each RCT. Each item was classified as low risk, high risk, or unclear risk . Any disagreements were resolved by a discussion among all reviewers.

Strategy of data synthesis: Statistical analyses were performed using RevMan 5.3 and Stata 14.0. Risk ratios (RR) and 95% confidence intervals were used for dichotomous data. Mean difference (MD) and 95% CIs were used for continuous data. The heterogeneity among the studies was assessed using the 2 test and I2 statistics. If P > .10 and I2 < 50%. the study would be considered to have no statistical heterogeneity and a fixed-effect model would be used in the analysis. If P <.10 and $l_2 > 50\%$, a study would be considered to be statistically heterogeneous and a random-effects model would be used in the analysis. The results of the meta-analysis were presented as forest maps. If there were 10 or more studies in any group or subgroup, the Egger's test was performed and funnel plots were generated to assess publication bias.

Subgroup analysis: Subgroup analysis was used to determine any source of heterogeneity. Due to different efficacy evaluation criteria in the RCTs, we will conduct subgroup analyses based on predefined variables.

Sensitivity analysis: Sensitivity analysis (SA) will be conducted by excluding RCTs one by one and comparing analysis results with those before the RCTs' exclusions.

Country(ies) involved: China.

Keywords: Yunnan Baiyao; hemoptysis; Systematic review.

Contributions of each author:

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