INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of Guizhi Plus Jiahoupu Xingzi Decoction in the treatment of Bronchial Asthma：A protocol for systematic review and meta-analysis

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Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Guizhi Jiahoupu Xingzi Decoction in patients with bronchial asthma.**
Condition being studied: **Bronchial asthma (BA) is characterized by chronic airway inflammation involving a variety of cells (such as eosinophils, mast cells, T lymphocytes, neutrophils, airway epithelial cells, etc.) and cellular components. A heterogeneous disease, this chronic inflammation is associated with airway hyper-responsiveness, often with widespread and variable reversible expiratory airflow limitation. According to the latest epidemiological study, more than 339 million people worldwide have BA . r. The World Health Organization (WHO) estimates that the number of asthma patients will increase to 400 million by 2025 worldwide. From researches,the prevalence of asthma is 1% to 18% worldwide. As of now, the incidence of asthma is about 4.2% in China. The number of related drugs for the clinical treatment of BA is gradually increasing, but the long-term application of glucocorticoids, β2 receptor agonists, anticholinergic drugs, leukotriene receptor antagonists and theophylline drugs can relieve asthma in the acute phase. Remarkable effects have been achieved in patients with seizures, but long-term application will lead to a decline in the therapeutic effect. The morbidity and mortality of asthma have not decreased, but have shown an upward trend, suggesting that Western medicine has obvious curative effects on the control of clinical symptoms of the disease, but cannot be cured.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 April 2022 and was last updated on 28 April 2022 (registration number INPLASY202240165).

INTRODUCTION

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METHODS

Search strategy: We will search the following databases: China National Knowledge Infrastructure, VIP Database, Wanfang Database, Chinese Biomedical Literature Database, Excerpt Medical Database (EMBASE), Web of Science, the Cochrane Library, PubMed, three clinical registry platforms, including the WHO International Clinical Trials Registry Platform, NIH Clinical trials.gov and Chinese Clinical Trial Registry, and other sources. The retrieval time is from the establishment time to March 2022. The retrieval method adopts the combination of free words and medical subject words. Including "Asthma", "Guizhi Jiahoupu Xingzi Decoction", "Asthma", "Asthma", "Guizhi Houpu Apricot Decoction", "Guizhi Jiahoupu Apricot Decoction", "Guizhi Houpu Xingzi Decoction" ", "Guizhi Magnolia Almond Soup". Search terms including English search terms will be accurately translated to other databases. The PubMed retrieval strategy is shown in Table 1.

Participant or population: The diagnosis of bronchial asthma must be based on GINA (Global Initiative for Management of Asthma).All patients are in line with the clinical diagnosis of bronchial asthma, regardless of age, gender, ethnicity, region and disease time, and will include all types of bronchial asthma diagnosed using any recognized criteria.

Intervention: The traditional Chinese medicine is Guizhi Jiahoupu Xingzi Decoction. All Chinese patent medicines have been approved by the State Drug Administration. There are no restrictions on the mode of administration.

Comparator: Under normal circumstances, the control group received conventional western medicines including aminophylline, fluticasone propionate, ketotifen, promethazine, prednisone, seretide, butaline tablets, montelukast sodium, budesonide, salbutamol one or more of these drugs.

Study designs to be included: RCTs will be inlcuded.

Eligibility criteria: We will search the following databases for randomized controlled trials of Guizhi Jiahoupu Xingzi Decoction in the treatment of bronchial asthma, including China National Knowledge Infrastructure, VIP Database, Wanfang Database, Chinese Biomedical Literature Database, Excerpt Medical Database (EMBASE), Web of Science, the Cochrane Library, PubMed, three clinical registry platforms, including the WHO International Clinical Trials Registry

Platform, NIH Clinical trials.gov and Chinese Clinical Trial Registry, and other sources.

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Main outcome(s): The primary documented outcome was the total response rate in bronchial patients.

Additional outcome(s): 1. Evaluate cough according to TCM symptom score standard: Nighttime: 0 = no symptoms, no positive sleep, 1 = 1 sleep interruption due to cough, 2 = 2 interruptions, 3 = more than 2 interruptions; daytime: 0 = no symptoms; 1 = occasional cough ; 2 = intermittent monophonic cough; 3 = intermittent paroxysmal cough. 2. Asthma recurrence rate: number of asthma recurrences/total number of participants 3. Time to disappearance of wheezing in the lungs, time to disappearance of cough, time to disappearance of asthma sounds, duration of chest tightness and shortness of breath.

Quality assessment / Risk of bias analysis: First, the Cochrane Collaboration Bias Risk Tool was used to assess the methodological quality of RCTS. The evaluation contents include: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. The methodological quality of the included studies was evaluated using the Jadad scale. The scoring content is mainly evaluated from four aspects: randomization, allocation concealment, blinding, withdrawal and withdrawal. RCTs were graded on a scale of 0-5, with ≤3 as low-quality studies and 4-7 as high-quality studies. Funnel plots were drawn by RevMan5.4 software to detect publication bias. Disagreements will be resolved through discussion and consultation by the third reviewer.

Strategy of data synthesis: For meta-analysis, Stata V.16.0 and Revman 5.4 software were used for data synthesis. Determine fixed-effects or random-effects models based on heterogeneity. If P>0.1 and I2<50%, it is considered that there is no heterogeneity or no statistical difference in heterogeneity among the data in the included literature, and a fixed effect model is used; If P50%, it was considered that there was heterogeneity among the data, a random effect model was used, and subgroup analysis was performed. P≤0.05 indicates that the results are statistically significant.

Subgroup analysis: We will assess the statistical heterogeneity using a χ2 test.If P >0.1, I2<50%, it is considered that there is no heterogeneity or no statistical difference between the data in the included literature, and the fixed effect combined effect size is adopted; If P<0.1, I2>50%, it is considered that there is heterogeneity between the data.To verify the accuracy of the results, we will perform a sensitivity analysis. The random effect is combined with the effect size, and further sensitivity analysis and subgroup analysis are performed to explore the source of heterogeneity.

Sensitivity analysis: We will assess the statistical heterogeneity using a χ2 test.If P >0.1, I2<50%, it is considered that there is no heterogeneity or no statistical difference between the data in the included literature, and the fixed effect combined effect size is adopted; If P<0.1, I2>50%, it is considered that there is heterogeneity between the data.To verify the accuracy of the results, we will perform a sensitivity analysis. The random effect is combined with the effect size, and further sensitivity analysis and subgroup analysis are

performed to explore the source of heterogeneity.

Country(ies) involved: China.

Keywords: Guizhi Jiahoupu Xingzi Decoction; bronchial asthma; randomized controlled trials; systematic review;meta-analysis.

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