

INPLASY PROTOCOL

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None declared.

Clinical efficacy and safety of Huoxue Huayu method in the treatment of idiopathic pulmonary fibrosis A protocol for systemic 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 clinical efficacy and safety of Huoxue Huayu method in the treatment of idiopathic pulmonary fibrosis

Condition being studied: Idiopathic pulmonary fibrosis is a chronic progressive pulmonary disease caused by a variety of pathogenic factors. Dry cough and progressive dyspnea are the main clinical manifestations, and can cause serious impact on the quality of life and mental health of patients, and has become one of the major global public health problems in the world. The underlying pathophysiology is not fully understood, the cause of the disease is not yet clear, and there is a lack of effective treatment methods. Traditional Chinese medicine treatment adopts syndrome differentiation and treatment according to individual conditions. In recent years, with the deepening of traditional Chinese medicine treatment measures for pulmonary fibrosis, and more and more clinical studies on the use of Huoxue Huayu method in the treatment of pulmonary fibrosis, it is still unclear whether it can improve the lung function of patients and slow down the disease progression clearly. We plan to collect RCTs (randomized controlled trials) studies on the treatment of pulmonary fibrosis with Huoxue Huayu method, conduct a systematic evaluation, and deeply explore the efficacy and safety of Huoxue Huayu method in the treatment of pulmonary fibrosis.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 April 2022 and was last updated on 10 April 2022 (registration number INPLASY202240056).

INTRODUCTION

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a variety of pathogenic factors. Dry cough and progressive dyspnea are the main clinical manifestations, and can cause serious impact on the quality of life and mental health of patients, and has become one of the major global public health problems in the world. The underlying pathophysiology is not fully understood, the cause of the disease is not yet clear, and there is a lack of effective treatment methods. Traditional Chinese medicine treatment adopts syndrome differentiation and treatment according to individual conditions. In recent years, with the deepening of traditional Chinese medicine treatment measures for pulmonary fibrosis, and more and more clinical studies on the use of Huoxue Huayu method in the treatment of pulmonary fibrosis, it is still unclear whether it can improve the lung function of patients and slow down the disease progression clearly. We plan to collect RCTs (randomized controlled trials) studies on the treatment of pulmonary fibrosis with Huoxue Huayu method, conduct a systematic evaluation, and deeply explore the efficacy and safety of Huoxue Huayu method in the treatment of pulmonary fibrosis.

METHODS

Participant or population: We will limit our overview to the studies of patients with idiopathic pulmonary fibrosis in stable stage (fulfilling any recognized diagnostic criteria of idiopathic pulmonary fibrosis), the patient's nationality, race, gender, age and onset time are not limited.

Intervention: The treatment group will receive Chinese medicine Huoxue Huayu method alone or combined with conventional treatment.

Comparator: The control group will receive conventional treatment or placebo with conventional treatment.

Study designs to be included: We only select Randomized, controlled trials (RCTs) focusing on the effect of Huoxue Huayu method in the treatment of idiopathic pulmonary fibrosis regardless of the

language. Duplicate and no sufficient information studies will be excluded.

Eligibility criteria: 1) We only select randomized controlled trials (RCTs) of Huoxue Huayu method in the treatment of idiopathic pulmonary fibrosis. (2) The study objects are idiopathic pulmonary fibrosis patients with clear and standardized diagnostic criteria, regardless of patient's nationality, race, gender, age and onset time.(3) The treatment group will receive Chinese medicine Huoxue Huayu method alone or combined with conventional treatment, and the control group will receive conventional treatment or placebo with conventional treatment. (4) According to the efficacy evaluation index, including clinical effective rate or St. George's Respiratory Questionnaire (SGRQ) (5)Animal experiments and other studies, non randomized controlled trials, studies without clear efficacy evaluation criteria, reviews, poorly designed studies, cross sectional studies, repeated or plagiarized articles will be excluded.

Information sources: We will search the randomized controlled trial of Huoxue Huayu method in the treatment of idiopathic pulmonary fibrosis in PubMed, Medline, EMBASE, Cochrane Library, China National Knowledge Infrastructure (CNKI), VIP and Wanfang database from their respective inception dates to February 2022. We will search the ClinicalTrials.gov and Chinese Clinical Trial Registry (ChiCTR) to find potentially relevant literature. A manual search will also be conducted at the library of Heilongjiang University of Traditional Chinese Medicine. There will be no language restrictions in the search of trials.

Main outcome(s): Total effective rate and St. George's Respiratory Questionnaire (SGRQ).

Additional outcome(s): Pulmonary function index, blood oxygen saturation .6-minute walking test and adversereactions.

Quality assessment / Risk of bias analysis: Study quality will be assessed by two

reviewers via the Cochrane collaboration's tool, which contains following items: random sequence generation (selection bias), allocation concealment (selection bias), binding of participants and personnel (selection bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and others bias. Each item is classified as "Low risk", "High risk" or "Unclear risk". Any disagreements are solved by discussion of all reviewers.

Strategy of data synthesis: All articles will be read by two review authors independently who will extract data from the articles according to predefined criteria. For each study, the following data will be extracted: the first author(s), year of publication, country, sample size, age and gender of participants, interventions details in control and treatment groups, main outcomes, additional outcomes and adverse events. Disagreement between two authors will be resolved by discussion or consultation with a third reviewer. The corresponding authors of the included articles would be contacted if the requisite data were unavailable.

Subgroup analysis: The subgroup analysis was based on Huoxue Huayu method Chinese medicine formula, course of treatment, and disease severity.

Sensitivity analysis: We will use sensitivity analyses by excluding literature with different quality and methodology to determine whether the literature affects heterogeneity. If the heterogeneity changes after sensitivity analyses, indicating that the results is lack of reliable, we will analyze the reasons. On the contrary, if there is no significant change in heterogeneity, the results are reliable.

Country(ies) involved: China.

Keywords: idiopathic pulmonary fibrosis, traditional Chinese medicine, Huoxue Huayu method, sustematic review, meta-analysis.

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