INPLASY PROTOCOL

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None declared.

The efficacy and safety of traditional Chinese medicine formulas in the treatment of chronic obstructive pulmonary disease complicated with pulmonary hypertension: a systematic review and meta-analysis study

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Review question / Objective: **This systematic review and meta-analysis was intended to evaluate the efficacy and safety of traditional Chinese medicine(TCM) formulas in the treatment of chronic obstructive pulmonary disease(COPD) complicated with pulmonaryhypertension (PH).**
Condition being studied: **Chronic obstructive pulmonary disease(COPD) complicated with pulmonary hypertension(PH) is classified as the third group PH.According to epidemiology, the most common cause of PH associated with lung diseases and/or hypoxia is COPD, but the prevalence rate of COPD with PH range from 20% to 91% variously. In China, many TCM formulas are regularly used in COPD patients , thus TCM formulas therapy is worth considering.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 October 2022 and was last updated on 12 October 2022 (registration number INPLASY2022100061).

INTRODUCTION

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Condition being studied: Chronic obstructive pulmonary disease(COPD) complicated with pulmonary hypertension(PH) is classified as the third group PH.According to epidemiology, the most common cause of PH associated with lung diseases and/or hypoxia is COPD, but the prevalence rate of COPD with PH range from 20% to 91% variously. In China, many TCM formulas are regularly used in COPD patients , thus TCM formulas therapy is worth considering.

METHODS

Participant or population: patients (≥18 years) must be diagnosed COPD with PH, with no limitations on gender, race, education or economic status.

Intervention: The treatment group was treated with TCM formulas or Chinese patent drug on the basis of routine western medicine, and the time was not limited.

Comparator: The control group was treated with a routine western medicine.

Study designs to be included: RCTs.

Eligibility criteria: 1) Study design: RCT, with or without withdrawal and loss of follow-up. 2)Participants: patients (≥18 years) must be diagnosed COPD with PH, with no limitations on gender, race, education or economic status. 3)Interventions: the control group was treated with a routine western medicine, and the treatment group was treated with TCM formulas or Chinese patent drug on the basis of routine western medicine, and the time was not limited. 4) The primary outcomes were as follows: pulmonary artery systolic pressure (PASP) , mean arterial pressure (mPAP), forced expiratory volume in one second (FEV1%), and one second rate (FEV1/FVC(%)), The secondary outcomes included 6-minute walking distance (6MWD),clinical efficacy rate and TCM syndrome score.

Information sources: We searched PubMed, Web of Science, Cochrane Library database Chinese National Knowledge Infrastructure (CNKI), WanFang Database, Chinese Scientific and Technological Periodical Database (VIP) from January 2015 to October 2022.

Main outcome(s): Pulmonary artery systolic pressure (PASP) , mean arterial pressure (mPAP), forced expiratory volume in one second (FEV1%), and one second rate(FEV1/FVC(%))

Additional outcome(s): 6-minute walking distance (6MWD),clinical efficacy rate and TCM syndrome score.

Quality assessment / Risk of bias analysis: The funnel plots were made to assess the publication bias.

Strategy of data synthesis: Meta-analysis was performed using Reviewer Manager Software 5.4 by the Cochrane Collaboration. [19] Dichotomous data are presented as relative risk ratio (RR) with 95% confidence interval (CI). Continuous data are presented as mean difference (MD) with 95 % CI when the measurement method of outcome is the same, or otherwise the standard mean deviation (SMD) will be used.

Subgroup analysis: The above three indexes were divided into subgroups from the aspects of literature quality, publication time, course of treatment, course of disease, TCM syndrome type, TCM dosage form, measurement method and integral standard, but there was still heterogeneity in the subgroup, the source of heterogeneity has not been found yet.

Sensitivity analysis: Any RCT is excluded, there is still heterogeneity.

Language restriction: English.

Country(ies) involved: China.

Keywords: Traditional Chinese medicine formulas; Chronic obstructive pulmonary disease; Pulmonary hypertension; Meta-analysis; Systematic review.

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