INPLASY PROTOCOL

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Conflicts of interest:
None.

Effectiveness and Safety of Traditional Chinese medicines for Pulmonary Heart Disease: A protocol for systematic review and meta-analysis

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Review question / Objective: **Previous reviews indicate that the effect of Traditional Chinese medicines (TCM) on Pulmonary heart disease (PHD) remains uncertainty. Therefore, we designed this study to systematically evaluate the effectiveness and safety of TCM in the treatment of PHD.**
Information sources: **We will search nine database from the inception dates to October 01. 2021: WanFang, China Science and Technology Journal Database (VIP), China National Knowledge Infrastructure (CNKI), PubMed, Embase, the Cochrane Library, and China Biomedical Literature (CBM) databases.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 December 2020 and was last updated on 04 December 2020 (registration number INPLASY2020120024).

INTRODUCTION

Review question / Objective: **Previous reviews indicate that the effect of Traditional Chinese medicines (TCM) on Pulmonary heart disease (PHD) remains uncertainty. Therefore, we designed this study to systematically evaluate the effectiveness and safety of TCM in the treatment of PHD.**

Condition being studied: **Pulmonary heart disease (PHD) is a type of heart disease that causes abnormal lung function and tissue structure lesions caused by lung tissue, bronchus, pulmonary vascular disease, and respiratory regulation**

disorders, thereby causing heart damage1,2. Slow, can be divided into acute and chronic cor pulmonale. Chronic pulmonary heart disease is mainly caused by chronic diseases such as lung tissue, bronchi, and thorax that cause increased pulmonary circulatory resistance and pulmonary hypertension, which leads to enlargement of the right heart or accompanied by cardiac insufficiency. Acute pulmonary heart disease is mainly due to embolism in the main trunk or main branches of the pulmonary artery, and even the pulmonary artery. The pressure suddenly increases, causing acute dilation of the right heart and acute heart failure3,4. Traditional Chinese medicine is the heritage and essence of China for 5000 years and has improved the health of the Chinese people. Studies have found that traditional Chinese medicine has a certain effect on the stable phase of PHD5-12, but the results of different studies are inconsistent. And the drugs used in different institutes are different. Therefore, we designed this systematic review and meta-analysis to evaluate whether traditional Chinese medicine is safe and effective for the.

METHODS

Participant or population: The trial included patients of any age, regardless of gender and stage of cor pulmonale. All participants must be diagnosed from the domestic literature based on the 1977/1980 Chinese pulmonary heart disease diagnostic criteria (Wei, 1992) and the English literature based on the WHO pulmonary heart disease diagnostic criteria (WHO, 1961).

Intervention: We will include all trials using traditional Chinese medicine (experimental group) and non-Chinese medicine (control group) to treat pulmonary heart disease, without limiting the types and applicable methods of traditional Chinese medicine. Trials initiated by pharmaceutical companies or clinicians are also included.

Comparator: Control groups with placebo or other active treatments are also included. Active treatment includes drugs such as antibiotics, analgesics, and corticosteroids.

Study designs to be included: We will include randomized controlled trial (RCT). Multi-weapon tests that meet the above criteria will be included. For crossover experiments, data will only be extracted from the first stage to avoid potential carry-over effects. Another study design will be excluded.

Eligibility criteria: Criteria for inclusion These standards are pre-designated according to the PICOS standard, which involves patients or populations, interventions, comparisons, results, and study design. Types of participants The trial included patients of any age, regardless of gender and stage of cor pulmonale. All participants must be diagnosed from the domestic literature based on the 1977/1980 Chinese pulmonary heart disease diagnostic criteria (Wei, 1992) and the English literature based on the WHO pulmonary heart disease diagnostic criteria (WHO, 1961). Types of interventions We will include all trials using traditional Chinese medicine (experimental group) and non-Chinese medicine (control group) to treat pulmonary heart disease, without limiting the types and applicable methods of traditional Chinese medicine. Trials initiated by pharmaceutical companies or clinicians are also included. Types of comparator(s)/ control Control groups with placebo or other active treatments are also included. Active treatment includes drugs such as antibiotics, analgesics, and corticosteroids. Types of outcome indicators Primary outcomes (1) Effective rate: refers to the ratio of responders to the total patients, based on the efficacy standards of the Chinese National Conference on Cor Pulmonale in 1977/1980 (2) Death Secondary outcomes Quality of life score, Partial Pressure of Oxygen (PaO2) and Carbon Dioxide (PaCO2), Adverse Events. Types of studies We will include randomized controlled trial (RCT). Multi-weapon tests that meet the above criteria will be included. For crossover experiments, data will only be extracted from the first stage to avoid potential carry-

over effects. Another study design will be excluded.

Information sources: We will search nine database from the inception dates to October 01. 2021: WanFang, China Science and Technology Journal Database (VIP), China National Knowledge Infrastructure (CNKI), PubMed, Embase, the Cochrane Library, and China Biomedical Literature (CBM) databases.

Main outcome(s): (1) Effective rate: refers to the ratio of responders to the total patients, based on the efficacy standards of the Chinese National Conference on Cor Pulmonale in 1977/1980 (2) Death.

Additional outcome(s): Quality of life score, Partial Pressure of Oxygen (PaO2) and Carbon Dioxide (PaCO2), Adverse Events.

Quality assessment / Risk of bias analysis: The risk of bias for included studies will be evaluated using the Cochrane Collaboration's tool for assessing risk of bias14. For each domain, we will categories the risk of bias as low, unclear or high risk of bias. The domains for risk of bias are as follows: 1. Selection bias (randomization sequence generation and allocation concealment); 2. Performance bias (blinding of participants and personnel); 3. Detection bias (blinding of outcome assessment); 4. Attrition bias (incomplete outcome data). 5. Reporting bias (selective reporting); 6. Other bias (including baseline imbalance, claimed to have been fraudulent, differential diagnostic activity and contamination).

Strategy of data synthesis: Before integrating the data, we will unify the unit of each result of different experiments according to the international unit system. All data will be synthesized using RevMan5.2 or STATA software. The 95% confidence interval (CIs) of the risk ratio (RR) / odds ratio (OR) will give the results of the dichotomous data analysis, while the continuous results will use the 95% confidence interval of the mean difference (MD) / standardized mean difference (SMD) Investigate. When I2 <75% comes from the heterogeneity test, the data will be synthesized and analyzed. When the heterogeneity test shows slight or no statistical heterogeneity in these trials (I2 value is not less than 40%), we will use a fixed-effects model for the combined data. When significant heterogeneity is detected (I2 40%, <75%), a random effects model will be used for data synthesis. If there is considerable heterogeneity in the trial, no meta-analysis is performed. In this case, we will try to determine the source of heterogeneity from both clinical and methodological aspects, and provide a qualitative summary. When more than 10 trials are included, a funnel chart will be generated to observe the reported deviation.

Subgroup analysis: If enough trials are included, we will use STATA software to explore the following possible sources of heterogeneity by performing subgroup analysis or meta-regression on changes in trial participant characteristics, TCM treatment, sample size, methodology, missing data, etc.

Sensibility analysis: Sensitivity analysis will be used to check the stability of major decisions made during the review process. Several decision nodes will be considered in the system review process, such as small sample size, lack of method and lack of data. The results of the sensitivity analysis will be presented in the form of a summary table. As the sensitivity analysis results show, the risk of bias in the review process will be discussed.

Language: English.

Country(ies) involved: China.

Keywords: Pulmonary heart disease; Systematic review; Meta-analysis; Traditional Chinese Medicines; GRADE

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