International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

INPLASY202430060

doi: 10.37766/inplasy2024.3.0060

Received: 15 March 2024

Published: 15 March 2024

Corresponding author:

Jie Wang

wangjie0103@126.com

Author Affiliation:

Guang'anmen Hospital of China Academy of Chinese Medical Sciences. The Effectiveness and Safety of Wenxin granule combined with western medicine on Treating Chronic Pulmonary Heart Disease with Arrhythmia : A Meta-Analysis

Zhang, L¹; Liu, LC²; Wang, J³.

ADMINISTRATIVE INFORMATION

Support - State Administration of Traditional Chinese Medicine and National Traditional Chinese Medicine Inheritance Studio Construction Project (Official Letter of the State Office of Traditional Chinese Medicine (2022) No. 245); (No. HLCMHPP2023083) High Level Chinese Medical Hospital Promotion Project; State Administration of Traditional Chinese Medicine National Traditional Chinese Medicine Experts Inheritance Studio Construction Project (National Letter of Traditional Chinese Medicine Practitioners (2022) No. 75).

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202430060

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 March 2024 and was last updated on 15 March 2024.

INTRODUCTION

Review question / Objective To systematically evaluate the clinical efficacy and safety of Wenxin granule combined with western medicine in the treatment of chronic pulmonary heart disease with arrhythmia.

Condition being studied Chronic pulmonary heart disease (CPHD) is frequently attributed to chronic obstructive pulmonary disease (COPD). The primary clinical manifestations encompass cough, wheezing, dyspnea, palpitation, and edema. Moreover, this condition gives rise to diverse complications such as respiratory failure, heart failure, pulmonary encephalopathy, shock, and other life-threatening disorders. Notably, arrhythmia represents one of the prevailing complications.

METHODS

Search strategy

PubMed

#1"Pulmonary Heart Disease"[Mesh]

#2(((((Heart Disease, Pulmonary[Title/Abstract]) OR (Heart Diseases, Pulmonary[Title/Abstract])) OR (Disease, Pulmonary Heart[Title/Abstract])) OR (Cor Pulmonale[Title/Abstract])) OR (Diseases, Pulmonary Heart[Title/Abstract])) OR (Pulmonary Heart Diseases[Title/Abstract]) #3 #1 AND #2 #4"Arrhythmias, Cardiac"[Mesh]

INPLASY

#5((((((Cardiac Arrhythmia[Title/Abstract]) OR (Arrhythmia[Title/Abstract])) OR (Arrythmia[Title/ Abstract])) OR (Cardiac Arrhythmias[Title/ Abstract])) OR (Arrhythmia, Cardiac[Title/Abstract])) OR (Cardiac Dysrhythmia[Title/Abstract])) OR (Dysrhythmia, Cardiac[Title/Abstract]) OR (Dysrhythmia, Cardiac[Title/Abstract]) OR (by the state of the state

Participant or population Chronic pulmonary heart disease with arrhythmia.

Intervention Wenxin granule combined with western medicine.

Comparator Western medicine.

Study designs to be included RCT.

Eligibility criteria Inclusion Criteria: (1) Subjects: Patients diagnosed with chronic pulmonary heart disease and arrhythmia caused by various factors; 2 Intervention measures: The experimental group received combined treatment of Wenxin granule and western medicine, while the control group received western medicine alone (with the same type as the experimental group). ③ Outcome indicators: The primary indicator was the overall effective rate, and secondary indicators included precontraction frequency, total effective rate based on 24-hour Holter monitoring, adverse reactions, etc. ④ Clinical efficacy evaluation criteria: Marked efficacy was defined as complete or substantial disappearance of clinical symptoms without recurrence, effectiveness was defined as significant improvement in clinical symptoms, and ineffectiveness was defined as no improvement or worsening of symptoms. Literature standards may be referenced for outcome indicators and assessment criteria. (5) Study design: This study is a randomized controlled trial conducted.Exclusion Criteria:Non-randomized controlled trials and articles that did not meet the inclusion criteria were deleted, as well as duplicate clinical data.

Information sources The databases including China National Knowledge CNKI, Wanfang Data, VIP, SinoMed, PubMed, Web of Science and Cochrane Library and Embase were searched.

Main outcome(s) The clinical total effective rate.

Quality assessment / Risk of bias analysis The quality of the included randomized controlled trials was evaluated according to the "ROB2.0 risk of bias assessment" tool recommended by Cochrane Reviewer's Hand book5.1.0.

Strategy of data synthesis Statistical analysis was performed using Stata 12 software. The continuous data use the mean difference (MD) or standardized mean difference (SMD) as the effect indicator, and the dichotomous data use the risk ratio (RR) as the effect indicator. Each effect size is given its point estimate and 95% confidence interval (CI). The Chi² test was used for heterogeneity assessment. When the heterogeneity is significant (P < 0.10, $I^2 \le 50\%$), it can be considered that the included literature has homogeneity, and the fixed-effects model can be used for meta-analysis. Otherwise, it can be considered that the included literature is heterogeneous, and then we will further analyze the source of heterogeneity through sensitivity analysis and subgroup analysis. After excluding obvious clinical heterogeneity, a random effects model can be used for meta-analysis. Since the number of studies included in this meta-analysis is \geq 10, a funnel chart can be used to test publication bias.

Subgroup analysis Comparing Wenxin keli combined with propafenone and propafenone alone

comparing Wenxin keli combined with digoxin and digoxin alone

comparing Wenxin keli combined with metoprolol and metoprolol alone

comparing Wenxin keli combined with captopril and captopril alone

ECG Efficiency.

Sensitivity analysis The results of the metaanalysis were compared with those before the exclusion.

Country(ies) involved China.

Keywords Wenxin granule; chronic pulmonary heart disease; arrhythmia; Meta-analysis.

Contributions of each author

Author 1 - Lei Zhang. Email: 3244273174@qq.com Author 2 - Lan-Chun Liu. Author 3 - Jie Wang.