INPLASY PROTOCOL

To cite: Li et al. Efficacy and safety of yiqi yangyin therapy for premature ventricular contractions: A systematic review and meta-analysis. Inplasy protocol 202110007. doi:

10.37766/inplasy2021.1.0007

Received: 2 January 2021

Published: 3 January 2021

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Support: None.

Review Stage at time of this submission: The review has not yet started.

Conflicts of interest: None.

Efficacy and safety of yiqi yangyin therapy for premature ventricular contractions: A systematic review and meta-analysis

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Review question / Objective: The aim of this meta-analysis of randomized controlled trial to evaluate the efficacy and safety of yigi yangyin therapy for premature ventricular contractions. Condition being studied: With the acceleration of the pace of life in modern society, the prevalence of cardiovascular disease is rising, and the incidence of premature ventricular contractions (PVCs) is also increasing.PVCs belongs to the category of palpitation in traditional Chinese medicine system, and its main pathogenesis is inseparable from Qi and yin deficiency (gi yin liangxv) . Based on the research of Qi and vin deficiency combined with different traditional Chinese medicine, it has been proved to be effective for the treatment of PVCs. However, due to the particularity of TCM compatibility, there is no comprehensive systematic evaluation. Therefore, we will analyze and summarize the treatment of PVCs with Yiqi Yangyin method.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 3 January 2021 and was last updated on 3 January 2021 (registration number INPLASY202110007).

INTRODUCTION

Review question / Objective: The aim of this meta-analysis of randomized controlled trial to evaluate the efficacy and safety of yiqi yangyin therapy for premature ventricular contractions.

Condition being studied: With the acceleration of the pace of life in modern society, the prevalence of cardiovascular

disease is rising, and the incidence of premature ventricular contractions (PVCs) is also increasing. PVCs belongs to the category of palpitation in traditional Chinese medicine system, and its main pathogenesis is inseparable from Qi and yin deficiency (qi yin liangxv) . Based on the research of Qi and yin deficiency combined with different traditional Chinese medicine, it has been proved to be effective for the treatment of PVCs. However, due to the particularity of TCM compatibility, there is no comprehensive systematic evaluation. Therefore, we will analyze and summarize the treatment of PVCs with Yiqi Yangyin method.

METHODS

Participant or population: Meet the diagnostic criteria of premature ventricular contractions. Participants in the review will have no restrictions on age, sex or ethnic background.

Intervention: The intervention was either yiqi yangyin therapy or yiqi yangyin therapy combined with conventional western medicine. We will not set limitations on dosages and course of treatment.

Comparator: Conventional western medicine.

Study designs to be included: RCTs whether use blind or not that reporting the application of yiqi yangyin therapy for PVCs will be included.

Eligibility criteria: This study will include RCTs that explored the efficacy and safety yiqi yangyin therapy for PVCs.

Information sources: PubMed, Cochrane Library, EMBASE, Web of Science, China National Knowledge Infrastructure(CNKI), VIP Database, Chinese Biomedical Database (CBM), Wangfang Database, and ClinicalTrials.gov.

Main outcome(s): 1.Changes in the number of PVCs. 2.total efficacy rate.

Additional outcome(s): 1.clinical symptoms. 2.adverse events.

Quality assessment / Risk of bias analysis:

The 2 authors will independently assess the risk of bias of the included studies based on the bias risk assessment tool recommended in the Cochrane "Risk of bias"assessment tool. including 7 items: random sequence generation, allocation concealment, blinding method, incomplete outcome data, selective reporting, and other biases. The quality of each trial will be divided into 3 levels: low bias risk, high bias risk, and unclear bias risk. The 2 authors will exchange assessment results and check whether the assessment results are consistent.If there is a disagreement, the third author will participate in the discussion and determine the final result.

Strategy of data synthesis: Stata13 software will be used to analyze the results of the studies. Dichotomous data will be reported as risk ratio(RR)with corresponding 95% confidence interval(CI), whereas continuous data will be reported as the mean difference (MD) or standardized the mean difference (SMD)with corresponding 95% confidence interval(CI). The I2 test will be used to assess statistical heterogeneity. Results of the meta-analysis will be visualised by forest plots. Sensitivity and subgroup analyses will be performed to explore the potential origins of significant heterogeneity.

Subgroup analysis: If there is enough necessary and valuable data, subgroup analyses will be carried out for patients. The purpose of subgroup analyses is to explore potential sources of heterogeneity.

Sensibility analysis: The sensitivity analysis will be conducted to test the robustness of the study. We will eliminate low qualities studies 1 by 1 to evaluate the reliability of the results of the meta-analysis.

Language: Literatures must be published in English or China.

Country(ies) involved: China.

Keywords: premature ventricular contractions (PVCs); yiqi yangyin; meta-analysis; protocol; systematic review.

Contributions of each author:

Author 1 - Yezi Li - The author drafted the manuscript and provided statistical expertise.

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Author 2 - Haibin Zhao - The author provided scientific research ideas and quidance.

Author 3 - Tianyuan Jiang - The author contributed to the development of the selection criteria and the risk of bias assessment strategy.

Author 4 - Zihao Ren - The author contributed to the development of the selection criteria.

Author 5 - Hongyan Jiang - The author read the feedback provided and approved the final manuscript.