INPLASY PROTOCOL

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None declared.

Efficacy and safety of traditional Chinese Medicine for cardiac remodeling in patients with chronic heart failure: A protocol for systematic review and meta-analysis

Qu, X[1]; Shi, Y[2]; Jiang, X[3]; Chen, Y[4].

Review question / Objective: **Population: Participants who were definitively diagnosed with chronic heart failure were included. No limitations of location, educational background, and gender were imposed. This study will only consider randomized controlled trials (RCTs) of Chinese herbal medicine for the treatment of patients with chronic heart failure. However, other studies, such as animal studies, reviews, case studies, non-controlled studies, and quasi-RCTs, were excluded. Intervention: Chinese herbal medicine. Comparison: The control intervention based on the treatment guidelines of chronic heart failure, or did not receive any treatment as a blank control. Outcome: Primary outcomes: Clinical therapeutic effect according to the New York Heart Association (NYHA) functional classification. Secondary outcomes: Left ventricular ejection fraction (LVEF), Left ventricular end-diastolic dimension (LVEDD), Left ventricular end-systolic dimension (LVESD), Left atrium internal dimension(LAID), Right ventricular internal dimension(RVID), Right atrium internal dimension(RAID), Cardiac index (CI), Brain natriuretic peptide (BNP)/N-terminal prohormone of BNP (NT-proBNP), 6 minutes walking test (6MWT), adverse reactions and other outcomes recorded in the article. Study design: This meta-analysis is secondary study and the data were extracted from other people's work.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 May 2022 and was last updated on 05 May 2022 (registration number INPLASY202250029).

INTRODUCTION

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Condition being studied: Chronic heart failure, as the end stage of various kinds of cardiovascular disease, is a progressive clinical syndrome in which adequate cardiac output can not be supplied by the heart for the body's metabolic need and accommodating venous return.[1] Epidemiological studies showed that CHF has become more and more common in huge population worldwide, resulting in high rate of mortality and hospitalization, low life quality, and poor prognosis. Therefore, inhibiting the occurrence and development of CHF plays a key role in the treatment of patients with cardiovascular disease.

METHODS

Participant or population: Participants who were definitively diagnosed with chronic heart failure were included. No limitations of location, educational background, and gender were imposed.

Intervention: Chinese herbal medicine.

Comparator: The control intervention based on the treatment guidelines of chronic heart failure, or did not receive any treatment as a blank control.

Study designs to be included: This study will only consider randomized controlled trials (RCTs) of Chinese herbal medicine for the treatment of patients with chronic heart failure. However, other studies, such as animal studies, reviews, case studies, non-controlled studies, and quasi-RCTs, were excluded.

Eligibility criteria: Population: Participants who were definitively diagnosed with chronic heart failure were included. No limitations of location, educational background, and gender were imposed. This study will only consider randomized controlled trials (RCTs) of Chinese herbal medicine for the treatment of patients with chronic heart failure. However, other studies, such as animal studies, reviews, case studies, non-controlled studies, and quasi-RCTs, were excluded.Intervention: Chinese herbal medicine. Comparison: The control intervention based on the treatment guidelines of chronic heart failure, or did not receive any treatment as a blank control.Outcome: Primary outcomes: Clinical therapeutic effect according to the New York Heart Association (NYHA) functional classification. Secondary outcomes: Left ventricular ejection fraction (LVEF), Left ventricular end-diastolic dimension (LVEDD), Left ventricular end-systolic dimension (LVESD), Left atrium internal dimension(LAID), Right ventricular internal dimension(RVID), Right atrium internal dimension(RAID), Cardiac index (CI), Brain natriuretic peptide (BNP)/N-terminal prohormone of BNP (NT-proBNP), 6 minutes walking test (6MWT), adverse reactions and other outcomes recorded in the article.Study design: This meta-analysis is secondary study and the

data were extracted from other people's work.

Information sources: This study will use the Cochrane Library, Web of Science, PubMed, Embase, Allied and Complementary Medicine Database (AMED), China Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database (VIP), Wanfang Database, and Ongoing Clinical Trials Database. There is no definite time limit for the retrieval literature, and the languages are limited to Chinese and English. We will consider articles published between database initiation and August 2021. The search terms were Chinese herbal medicine, Chinese medicine, traditional Chinese medicine, proprietary Chinese medicine, and cardiac remodeling.

Main outcome(s): Clinical therapeutic effect according to the New York Heart Association (NYHA) functional classification.

Additional outcome(s): Left ventricular ejection fraction (LVEF), Left ventricular end-diastolic dimension (LVEDD), Left ventricular end-systolic dimension (LVESD), Left atrium internal dimension(LAID), Right ventricular internal dimension(RVID), Right atrium internal dimension(RAID), Cardiac index (CI), Brain natriuretic peptide (BNP)/ N-terminal prohormone of BNP (NT-proBNP), 6 minutes walking test (6MWT), adverse reactions and other outcomes recorded in the article.

Quality assessment / Risk of bias analysis: Two investigators will separately assess the risk of bias of the selected RCTs using the Cochrane risk of bias assessment tool. The evaluation of each study mainly included the following seven aspects: random sequence generation, allocation hiding, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, incomplete outcome data, selective outcome reporting, and other biases. Finally, the bias of the study will be rated on three levels: “low”, “high”, and “ambiguous”. These even domains will be separately appraised by two reviews, and discrepancies will be addressed by consulting a third reviewer.

Strategy of data synthesis: #1 Cardiac Remodeling (all field)
#2 Ventricular Remodeling (all field)
#3 Atrial Remodeling (all field)
#4 #1 OR #2–3
#5 Chinese medicine (all field)
#6 Traditional Chinese medicine (all field)
#7 Chinese herb medicine (all field)
#8 Proprietary Chinese medicine (all field)
#9 Chinese Herbs (all field)
#10 Chinese herbal (all field)
#11 #5 OR #6–10
#12 randomized controlled trial (all field)
#13 randomly (all field)
#14 controlled clinical trial (all field)
#15 randomized (all field)
#16 random allocation (all field)
#17 placebo (all field)
#18 single-blind method (all field)
#19 double-blind method (all field)
#20 trials (all field)
#21 Comparators
#22 Allocation
#23 #12 OR #13–22
#24 #4 And #11 And #23.

Subgroup analysis: We will investigate the source of heterogeneity using subgroup analysis based on different interventions, controls, and outcomes.

Sensitivity analysis: We will carry out a sensitivity analysis to investigate the robustness and stability of outcome results by removing low methodological quality studies. The main analysis points included the impact of method quality, sample size, and missing data on the study. In this way, we will be able to assess the impact of individual studies on the overall results and determine whether the results are strong.

Country(ies) involved: China.

Keywords: cardiac remodeling; traditional Chinese Medicine.

Dissemination plans: This protocal is expected to be published in medical journals.

Contributions of each author:

Author 1 - Wantong Qu - Author 1 drafted the manuscript.
Email: 554579142@qq.com
Author 2 - Yanyu Shi - The author provided statistical expertise.
Author 3 - Xiaotian Jiang - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Ying Chen - The author read, provided feedback and approved the final manuscript.