INPLASY PROTOCOL

Efficacy and safety of Shenfuqiangxin Pills in complementary treatment of chronic heart failure: A protocol for systematic review and meta-analysis

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Review Stage at time of this submission: Piloting of the study selection process.

Conflicts of interest: None.

Review question / Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Shenfuqiangxin Pills (SFQX) in complementary treatment of chronic heart failure (CHF), so as to provide sufficient evidence-based medical evidence for further guidance of clinical medication.

Condition being studied: As the last link in the chain of cardiovascular events, chronic heart failure (CHF) has high morbidity, high mortality, and poor prognosis. It is one of the main causes of death and disability worldwide. Shenfuqiangxin Pills (SFQX) is widely used as a Chinese herbal medicine (CHM) prescription for CHF, but there is still a lack of strict evidence-based medical evidence.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 5 January 2021 and was last updated on 5 January 2021 (registration number INPLASY202110019).

INTRODUCTION

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widely used as a Chinese herbal medicine (CHM) prescription for CHF, but there is still a lack of strict evidence-based medical evidence.

METHODS

Participant or population: Patients with CHF, whether diagnosed by clinician, or by any recognized criteria diagnosis of CHF, will be included. There are no restrictions on nationality, age, gender, or race. Patients who have received acute heart failure, or patients with severe liver and kidney, or blood diseases, or malignant tumors, or other uncontrolled systemic diseases are excluded.

Intervention: The treatment group was given SFQX on the basis of routine western medicine of CHF. Routine western medicine mainly includes diuretics, ACEI, ARB, β-receptor blockers, ivabradine, digitalis and inotropic drugs, vasodilators, anticoagulants, etc.

Comparator: The control group was only given routine western medicine, or the same dose of placebo was given on the basis of routine western medicine. Routine western medicine mainly includes diuretics, ACEI, ARB, β-receptor blockers, ivabradine, digitalis and inotropic drugs, vasodilators, anticoagulants, etc.

Study designs to be included: Randomized controlled trials (RCTs) will be included in this study irrespective of language or publication category.

Eligibility criteria: We will formulate the inclusion and exclusion criteria for this study based on the PICOS principles. Participants. Patients with CHF, whether diagnosed by a clinician, or by any recognized criteria diagnosis of CHF, will be included. There are no restrictions on nationality, age, gender, or race. Patients who have received acute heart failure, or patients with severe liver and kidney, or blood diseases, or malignant tumors, or other uncontrolled systemic diseases are excluded. Interventions and Comparators. The treatment group was given SFQX on

the basis of routine western medicine of CHF. The control group was only given routine western medicine, or the same dose of placebo was given on the basis of routine western medicine. Routine western medicine mainly includes diuretics, ACEI, ARB, β-receptor blockers, ivabradine, digitalis and inotropic drugs, vasodilators, anticoagulants, etc. Outcomes. The primary outcomes include TCM syndrome scores, New York Heart Association classification (NYHA classification); the secondary outcomes include LVEF, N terminal pro B type natriuretic peptide (NT-proBNP), quality of life (QOL), etc; the safety indicators include gastrointestinal reactions, such as nausea and vomiting, liver function indicators, allergic and other adverse reactions. Type of studies. Randomized controlled trials (RCTs) will be included in this study irrespective of language or publication category. Animal trials, review article and studies with incorrect RCT designs will be excluded.

Information sources: We will conduct literature search from the following electronic databases: PubMed, EMBASE, the Cochrane Library, Web of Science, CNKI, Wan-fang Data, Chinses Biomedical Literature Database, Chinese Scientific Journal Database. There are no restrictions on publication date and language. In addition, the references listed in each included article are also manually searched. Retrieve the databases by combining subject words with random words. If any of the information in the included literature is incomplete, we will contact the corresponding author via email to obtain the required data.

Main outcome(s): The primary outcomes include TCM syndrome scores, New York Heart Association classification (NYHA classification); the secondary outcomes include LVEF, N terminal pro B type natriuretic peptide (NT-proBNP), quality of life (QOL), etc; the safety indicators include gastrointestinal reactions, such as nausea and vomiting, liver function indicators, allergic and other adverse reactions.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the quality of the included literature according to the Cochrane Collaboration's tool for randomized controlled trials. If there is a disagreement between two reviewers, the third reviewer resolves the issue. According to Cochrane Handbook V.5.2.0, Characteristics of each item will be evaluated in three categories: low, unclear and high. The results of the quality assessment will be completed using software Review Manager 5.3.

Strategy of data synthesis: We will execute Rev Man 5.3 and STATA 14.2 software for traditional meta-analysis. For dichotomous data, we will calculate a summary estimate with 95% confidence interval (CI) odds ratio (OR) value; for continuous data, we will calculate a summary estimate of standardized mean difference (SMD) with 95% CI, and P50%, it indicates that there is heterogeneity among the included literature, and assess the effect size by the random effect; on the contrary, a fixed effect model is used.

Subgroup analysis: Taking into account the issue of heterogeneity, we will conduct a subgroup analysis based on the specific circumstances of the included literature. If there is a problem of heterogeneity, we will conduct subgroup analysis of age, gender, and interventions. In addition, in order to understand whether the LVEF will affect the efficacy of SFQX, it will be used for CHF patients with LVEF<40% and CHF with unknown LVEF the TCM syndrome scores and NYHA classification are analyzed by subgroups.

Sensibility analysis: This systematic review will use the method of eliminating each study one by one for sensitivity analysis. If the effective indicators (e.g., TCM syndrome scores and NYHA classification) of SFQX in complementary treatment of CHF have not changed significantly, it indicates that the study is robustness. On the contrary, it is not robustness.

Country(ies) involved: China.

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Author 1 - Lili Ren.
Author 2 - Guohua Dai.
Author 3 - Wulin Gao.
Author 4 - Hui Guan.