INPLASY

The efficacy and safety of Panax quinquefolius saponin for Heart Failure: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

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

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 April 2024 and was last updated on 10 April 2024.

INTRODUCTION

Review question / Objective This systematic review aims to evaluate the efficacy and safety of Panax quinquefolius saponin for heart failure patients.

Condition being studied The high morbidity and mortality of heart failure will bring a great burden to the global society. Previous clinical studies have shown that Panax quinquefolius saponin (PQS) can effectively treat heart failure, and have been made into PQS preparations, which are frequently used as adjunctive therapy for patients with Heart Failure in China. It is necessary to evaluate the efficacy of PQS for Heart Failure.

METHODS

Participant or population Patients with heart failure.

Intervention Panax quinquefolius saponin preparations alone or combined with Panax quinquefolius saponin preparations on the basis of conventional treatment.

Comparator Treatments in control groups included routine treatment or placebo.

Study designs to be included Randomized controlled trials.

Eligibility criteria Only randomized controlled trials (RCTs) were included in this systematic review. The inclusion criteria for the studies were as follows; ①Type of participants: patients with a definitive diagnosis of heart failure.②Type of interventions: Panax quinquefolius saponin preparations alone or combined with Panax quinquefolius saponin preparations on the basis of conventional treatment. ③Type of control group interventions: treatments in control groups

included routine treatment or placebo. ④Type of outcomes:Primary outcomes included cardiovascular events: cardiac death, rehospitalization due to heart failure and hospitalisation duration; heart function left ventricular ejection fraction (LVEF), left ventricular end-diastolic volume (LVEDV), left ventricular end-systolic volume (LVESV), left ventricular end-diastolic dimension (LVEDD), interventricular septum thickness (IVST), and left ventricular posterior wall thickness (LVPWT); NYHA functional classification; serum N-terminal pro-B-type natriuretic peptide (NT-pro-BNP). The secondary outcome included safety of TCM and adverse reaction. Adverse events should also be considered.

Information sources We will systematically search electronic databases without restrictions regarding publication status for randomized controlled trials as following: Cochrane Library, PubMed, EMBASE, SinoMed, CNKI, VIP, and Wanfang Data. The search period was from the inception to March 2024.

Main outcome(s) Primary outcomes included cardiovascular events: cardiac death, rehospitalization due to heart failure and hospitalisation duration; heart function left ventricular ejection fraction (LVEF), left ventricular end-diastolic volume (LVEDV), left ventricular end-systolic volume (LVESV), left ventricular end-diastolic dimension (LVEDD), interventricular septum thickness (IVST), and left ventricular posterior wall thickness (LVPWT); NYHA functional classification; serum N-terminal pro-B-type natriuretic peptide (NT-pro-BNP).

Quality assessment / Risk of bias analysis We will use the Cochrane Risk of Bias tool (RoB 2.0) to assess the risk of bias.

Strategy of data synthesis This systematic review will perform and report according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement. We will conduct meta-analyses to pool data for outcomes available from more than two studies. Effect sizes with a confidence interval of 95% were computed based on dichotomous data expressed as relative risk (RR) or continuous data expressed as mean difference (MD) or standardized mean difference (SMD) when different methods were applied to measure the same outcome. Heterogeneity will detect using statistical test recommended by Cochrane handbook.

Subgroup analysis Subgroup analysis will perform according to the pre-specified variables to investigate potential sources of variation: type of Panax quinquefolius saponin preparations, type of control preparation, and intervention duration. When statistical heterogeneity will be identified between included studies ($I2 \geq 30\%$ and $p \leq 0.10$), sources of heterogeneity were analyzed using sensitivity analyses, subgroup analyses, and meta-regression.

Sensitivity analysis Sensitivity analysis will assess by leave-one-out method.

Language restriction None.

Country(ies) involved China.

Keywords Panax quinquefolius saponin; Heart Failure; A systematic review; Meta-analysis.

Contributions of each author

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