INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Shenfu injection for cardiogenic shock: Protocol for a systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **The efficacy and safety of Shenfu injection for cardiogenic shock.**
Condition being studied: **Cardiogenic shock (CS) is a disease with high mortality worldwide. Shenfu injection (SFI) can effectively improve end-organ hypoperfusion and hypoxia; thus, its role in alternative therapy for CS has received widespread attention. However, a systematic review or meta-analysis has not been conducted on the treatment of CS with SFI. Therefore, we designed a protocol for the systematic review and meta-analysis of the efficacy and safety of SFI in the treatment of CS.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 May 2022 and was last updated on 07 May 2022 (registration number INPLASY202250041).

INTRODUCTION

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for the systematic review and meta-analysis of the efficacy and safety of SFI in the treatment of CS.

METHODS

Search strategy: We will retrieve articles from the following databases: PubMed, Embase, Web of Science, The Cochrane Library, the Chinese National Knowledge Infrastructure, The Chinese Medicine Database and the China Science and Technology Journal Database, Wanfang, Chongqing VIP information.We will also undertake a targeted gray literature search on Clinical Trials.gov and the International Clinical Trials Registry Platform search portal to identify in-progress and completed trials. We anticipate that the databases will be searched from their respective dates of inception to May 2022.

Participant or population: Hospitalized adults (≥18 years old) with a diagnosis of cardiogenic shock as defined by study authors.

Intervention: Shenfu injection alone or combined with conventional medical treatment.

Comparator: Conventional medical treatment.

Study designs to be included: We will include randomized trials to assess the beneficial effects and side effect of Shenfu injection combined with routine chemotherapy versus routine chemotherapy alone on cardiogenic shock.RCT.

Eligibility criteria: Hospitalized adults (≥18 years old) with a diagnosis of cardiogenic shock as defined by study authors.

Information sources: electronic databases, contact with authors, trial registers, or grey literature.

Main outcome(s): We will include randomized trials to assess the beneficial effects and side effect of Shenfu injection combined with routine chemotherapy versus routine chemotherapy alone on cardiogenic shock.

Additional outcome(s): The secondary outcome measures included systolic blood pressure, heart rate, heart function indicators：such as left ventricular ejection fraction (LVEF) or cardiac index(CI).

Data management: The titles and abstracts of the studies retrieved using the search strategy will be screened independently by two review authors to identify studies that potentially meet the inclusion criteria outlined above. The full texts of these potentially eligible studies will then be retrieved and independently assessed for eligibility by two review team members. Any disagreements between them over the inclusion/exclusion of particular studies will be resolved through discussion and consensus. A standardised, pilot-tested form will be used to extract data from the included studies for assessment of study quality and evidence synthesis. The extracted information will include: 1)publication information: first author, publication year, journal and publication country ;2) general characteristics of patients : disease name, sample size, gender, age, eligibility criteria, baseline condition and numbers of dropouts;3) details of intervention and control therapy: drug names, dosages and treatment;4) details of outcomes 5) bias risk assessment information: quality of included studies and research sites.

Quality assessment / Risk of bias analysis: Cochrane risk assessment tool was use to evaluate the quality of RCTs. Q test and I^2 statistic were used to estimate the heterogeneity of the pooled data.

Strategy of data synthesis: The meta-analysis is performed by Review Manager 5.3 software (Cochrane Collaboration, Oxford, UK). For outcome measures, dichotomous variables are presented as risk ratio (RR) with 95% confidence intervals (CI), while continuous outcomes are expressed as mean difference (MD) with 95% CI. As a quantitative measure of

inconsistency, the I^2 (I^2) statistic is used to assess heterogeneity. Fixed effect model is performed with minor heterogeneity when I^2 was less than 50%. Random effect model is applied when I^2 was over 50 %. Publication bias is explored applying a funnel plot analysis if more than 10 trials are identified.

Subgroup analysis: Subgroup analyses will be done for different outcome measures if the necessary data are available.

Sensitivity analysis: Sensitivity analysis will be conducted to explore the robustness of the meta-analysis results.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Shenfu injection; cardiogenic shock; Protocol; meta-analysis; randomized controlled trials.

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