

INPLASY PROTOCOL

To cite: Huang et al. Efficacy and safety of Shenmai injection combined with levocarnitine in the treatment of heart failure with ischemic cardiomyopathy: a systematic review and meta-analysis. Inplasy protocol 2022110052. doi: 10.37766/inplasy2022.11.0052

Received: 11 November 2022

Published: 12 November 2022

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Support: Self-financing.

Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest:
None declared.

Efficacy and safety of Shenmai injection combined with levocarnitine in the treatment of heart failure with ischemic cardiomyopathy: a systematic review and meta-analysis

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Review question / Objective: To perform a systematic review and meta-analysis to assess the efficacy and safety of Shenmai injection combined with levocarnitine in the treatment of heart failure with ischemic cardiomyopathy.

Condition being studied: Heart failure with ischemic cardiomyopathy; Shenmai injection ; and levocarnitine.

Information sources: PubMed, Embase, the Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Database, China Science and Technology Journal Database(VIP),and SinoMed.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 November 2022 and was last updated on 12 November 2022 (registration number INPLASY2022110052).

INTRODUCTION

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METHODS

Participant or population: Participants who were diagnosed with heart failure with

ischemic cardiomyopathy were included. No limitations of location, educational background, and gender were imposed.

Intervention: Combination of shenmai injection and levocarnitine on the basis of conventional western medicine treatment.

Comparator: Conventional western medicine treatment.

Study designs to be included: Published randomized controlled trials (RCTs).

Eligibility criteria: The detailed inclusion criteria were summarized using PICOS approach (patients, intervention, comparisons, outcome, and study design type).

Information sources: PubMed, Embase, the Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Database, China Science and Technology Journal Database (VIP), and SinoMed.

Main outcome(s): The primary outcomes included the clinical effective rate and LVEF level. The clinical effective rate was calculated by the following formula: (number o f remarkable recovery participants + number of basic recovery participants)/total number of participants × 100%.

Additional outcome(s): The secondary outcomes included BNP level and the potency of lengthening the distance of 6-min walk test (6MWT), and adverse events.

Quality assessment / Risk of bias analysis: Cochrane risk of bias tool.

Strategy of data synthesis: This study will use RevMan 5.3 software to pool and analyze extracted data. We will use I^2 test to identify heterogeneity across trials. We defined it as follows: $I^2 \leq 50\%$ means acceptable heterogeneity, while $I^2 > 50\%$ suggests obvious heterogeneity. If $I^2 \leq 50\%$, we will pool the data using a fixed-effects model. If minor heterogeneity is

identified across trials, we will conduct a meta-analysis based on the sufficient similarity in study and patient characteristics, treatment and controls, and outcome indicators. If $I^2 > 50\%$, we will pool the data using a random-effects model, and we will perform a subgroup analysis to examine the sources of obvious heterogeneity.

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

Sensitivity analysis: Sensitivity analysis will be performed to verify the stability and robustness of study findings by removing studies with low quality.

Country(ies) involved: China.

Keywords: Shenmai injection; levocarnitine; ischemic cardiomyopathy; heart failure; efficacy; safety; Systematic review; Meta-analysis.

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