

# INPLASY

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## Danggui Sini Decoction combined with conventional western medicine in the treatment of coronary heart disease and angina pectoris: a Systematic review and meta-analysis based on Randomized controlled trial

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## ADMINISTRATIVE INFORMATION

**Support** - No funding was provided for this study.

**Review Stage at time of this submission** - Completed but not published.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202390078

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 September 2023 and was last updated on 24 September 2023.

## INTRODUCTION

**Review question / Objective** To systematically evaluate the effectiveness and safety of Danggui Sini Decoction combined with conventional Western medicine for the treatment of coronary heart disease with angina pectoris.

**Condition being studied** Coronary arteriosclerotic heart disease, also known as coronary heart disease, is a cardiac condition caused by atherosclerotic lesions in the coronary arteries, leading to narrowing and blockage of the vessel lumen, resulting in myocardial ischemia or necrosis.

## METHODS

**Participant or population** Comply with the diagnostic criteria for UA established in the Guidelines for the Diagnosis and Treatment of Unstable Angina and Non-ST-Segment Elevation

Myocardial Infarction and the Guidelines for the Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes (2016 Edition) or the diagnosis of SA-related criteria in the Guidelines for the Diagnosis and Treatment of Chronic Stable Angina.

**Intervention** The experimental group was treated with Danggui Sini Soup on the basis of the treatment in the control group.

**Comparator** Danggui Sini Soup.

**Study designs to be included** Publicly published randomised controlled trials (RCTs) in China and abroad, in Chinese and English languages, with no restriction on whether blinding was used.

**Eligibility criteria** Exclusion Criteria :① Repeated publications, reviews and conference papers; ② Animal experiments or individual case reports; ③ Literature with incomplete data or unavailable

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outcome indicators; ④ Literature whose interventions did not meet the inclusion criteria.

**Information sources** China Knowledge Information Network (CNKI), WanFang database (WanFang), Wipro Chinese Journals (VIP), Chinese Biomedical Literature Database (SinoMed), as well as in the databases such as Pubmed, Embase, Cochrane, Web of Science.

**Main outcome(s)** The primary efficacy outcomes included the clinical effective rate (angina pectoris effective rate, electrocardiogram effective rate, nitroglycerin dosage reduction rate, and traditional Chinese medicine syndrome effective rate).

**Additional outcome(s)** The secondary outcome measures included traditional Chinese medicine syndrome score (based on the criteria outlined in the "Guidelines for Clinical Research of New Chinese Medicines" ), cardiac function indicators [cardiac output (CO), left ventricular ejection fraction (LVEF), left ventricular end-diastolic diameter (LVEDD)], angina pectoris episodes (frequency and duration of angina attacks), Seattle Angina Questionnaire (SAQ) score, and inflammatory factors [interleukin-6 (IL-6), tumor necrosis factor-alpha (TNF- $\alpha$ ), and high-sensitivity C-reactive protein (hs-CRP)].

**Quality assessment / Risk of bias analysis** The Cochrane Handbook 5.1 "Risk of bias assessment" tool was used to evaluate the quality of the literature. Ten [11-18,20,22] studies were randomised by the randomised numeric table method, and three [19,21,23] studies did not explicitly describe the specific randomisation method; all the studies did not mention whether the allocation plan was hidden or blinded, so they were evaluated to be at unknown risk; all the results were complete, and there was no selective reporting of the results of the studies and no other sources of bias, so they were evaluated to be at low risk. The results are shown in Figures 2 and 3.

**Strategy of data synthesis** Meta-analysis was performed using RevMan 5.4 software. Effect indicators: ratio ratio (OR) or risk ratio (RR) was used for count data, and mean difference (MD) or standardised mean difference (SMD) was used for measure data, and their 95% confidence intervals (CI) were calculated. Heterogeneity analysis needed to be determined according to the size of  $I^2$ ; if  $P > 0.10$  and  $I^2 \leq 50\%$ , a fixed-effects model was used; if  $P \leq 0.10$  and  $I^2 > 50\%$ , a random-effects model was used and subgroup analysis or sensitivity analysis was performed, and when more than 10 outcome indicators were included in the

study, a funnel plot was used to assess its publication bias.

**Subgroup analysis** No subgroup analyses were performed.

**Sensitivity analysis** No sensitivity analyses were performed.

**Country(ies) involved** China.

**Keywords** Danggui Sini Decoction; conventional Western medicine; angina pectoris; meta-analysis; systematic review.

#### **Contributions of each author**

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