

INPLASY PROTOCOL

To cite: Li et al. Acupuncture combined with Compound Danshen Dripping Pills in the treatment of acute coronary syndrome: A protocol for systematic review and meta-analysis. Inplasy protocol 202240081. doi: 10.37766/inplasy2022.4.0081

Received: 14 April 2022

Published: 14 April 2022

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Support: None.

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

Conflicts of interest:
None declared.

Acupuncture combined with Compound Danshen Dripping Pills in the treatment of acute coronary syndrome: A protocol for systematic review and meta-analysis

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Review question / Objective: To systematically evaluate the efficacy and safety of acupuncture combined with Compound Danshen Dripping Pills in the treatment of acute coronary syndrome.

Condition being studied: Acute coronary syndrome (ACS) is a disease related to myocardial infarction and acute myocardial ischemia, The main cause of the disease is the sudden insufficient blood supply to the coronary artery. According to ECG, ACS can be divided into two different types according to whether ST segment is elevated or not, One is ST segment elevation myocardial infarction (STEMI), the other is non ST segment elevation myocardial infarction (NSTEMI-ACS). NSTEMI-ACS can be subdivided into two types, One is unstable angina pectoris (UAP) and the other is non ST segment elevation myocardial infarction (NSTEMI). For STEMI, the most effective treatment is myocardial reperfusion. For NSTEMI, the key means of treatment is antithrombotic and reperfusion. For the current vascular reperfusion, the most effective method is percutaneous coronary intervention (PCI), With the continuous progress of coronary intervention technology and drug reperfusion treatment, the treatment of ACS has made a breakthrough. However, in the process of clinical treatment, the problems of high mortality and poor prognosis have not been well solved.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 April 2022 and was last updated on 14 April 2022 (registration number INPLASY202240081).

INTRODUCTION

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safety of acupuncture combined with Compound Danshen Dripping Pills in the treatment of acute coronary syndrome.

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METHODS

Participant or population: We will include patients who meet the diagnostic criteria of Western medicine for acute coronary syndrome and set the diagnostic criteria of UAP and NSTEMI with reference to the 2016 guidelines for the diagnosis and treatment of Non-ST segment elevation acute coronary syndrome. To formulate the diagnostic criteria of STEMI, refer to the 2019 guidelines for the diagnosis and treatment of acute ST segment elevation myocardial infarction. Treatment, regardless of age, sex, course of disease and race.

Intervention: Based on the standardized treatment of Western medicine, Compound Danshen Dripping Pills were added, orally. Acupuncture points: Xinshu (BL15), Geshu (BL17), Neiguan (PC6), 15~20 mm of straight needles, bring about the desired

sensation, use the reinforcing-reducing method, keep the needles for 20 minutes, 10 minutes once. The patients in the treatment group and the control group were treated with conventional western medicine, including anti ischemia (nitrates), antiplatelet (aspirin), anticoagulant (heparin), lipid-lowering (statins) and other drugs. Individual patients were also treated with antihypertensive or hypoglycemic methods. The control group was treated with conventional western medicine, and the treatment group was loaded with acupuncture combined with Compound Danshen Dripping Pills based on the above conventional western medicine, with unlimited dosage and course of treatment.

Comparator: The patients in the treatment group and the control group were treated with conventional western medicine, including anti ischemia (nitrates), antiplatelet (aspirin), anticoagulant (heparin), lipid-lowering (statins) and other drugs. Individual patients were also treated with antihypertensive or hypoglycemic methods. The control group was treated with conventional western medicine, and the treatment group was loaded with acupuncture combined with Compound Danshen Dripping Pills based on the above conventional western medicine, with unlimited dosage and course of treatment. The patients in the treatment group and the control group were treated with conventional western medicine, including anti ischemia (nitrates), antiplatelet (aspirin), anticoagulant (heparin), lipid-lowering (statins) and other drugs. Individual patients were also treated with antihypertensive or hypoglycemic methods. The control group was treated with conventional western medicine, and the treatment group was loaded with acupuncture combined with Compound Danshen Dripping Pills based on the above conventional western medicine, with unlimited dosage and course of treatment.

Study designs to be included: Acupuncture combined with Compound Danshen Dripping Pills has rapid effect, significant clinical effect and high safety, but there is no relevant systematic evaluation

published at present. Therefore, this study systematically evaluated the clinical efficacy and safety of acupuncture combined with Compound Danshen Dripping Pills in the treatment of acute coronary syndrome, and further collected evidence to provide medical reference for clinical research.

Eligibility criteria: 3.1 Types of studies Our method of collecting the literature did not take into account blinding and whether the distribution was hidden. All randomized controlled trials of acupuncture combined with Compound Danshen Dripping Pills in acute coronary syndrome were included in this study. Our research is not limited by publication time or region, but the language of the literature is limited to Chinese and English. 3.2 Types of participants. We will include patients who meet the diagnostic criteria of Western medicine for acute coronary syndrome and set the diagnostic criteria of UAP and NSTEMI with reference to the 2016 guidelines for the diagnosis and treatment of None-ST segment elevation acute coronary syndrome. To formulate the diagnostic criteria of STEMI, refer to the 2019 guidelines for the diagnosis and treatment of acute ST segment elevation myocardial infarction. Treatment, regardless of age, sex, course of disease and race. 3.3 Types of interventions and comparisons The patients in the treatment group and the control group were treated with conventional western medicine, including anti ischemia (nitrates), antiplatelet (aspirin), anticoagulant (heparin), lipid-lowering (statins) and other drugs. Individual patients were also treated with antihypertensive or hypoglycemic methods. The control group was treated with conventional western medicine, and the treatment group was loaded with acupuncture combined with Compound Danshen Dripping Pills based on the above conventional western medicine, with unlimited dosage and course of treatment.

Information sources: We will use endnote x9 (Thomson Corporation, Stanford, CA) to process all the retrieved literature to delete duplicate research literature. At the same

time, we will draw the flow chart of the screening process (Figure 1) to make the screening process go smoothly. After the screening is completed, we will carefully evaluate all the documents that meet the inclusion criteria and extract data. The literature screening was completed independently by two researchers. Firstly, the unqualified literature was screened by reading the title and abstract of the literature. After reading the full text, the second screening was carried out according to the inclusion and exclusion criteria. If there are different opinions, they should be solved through discussion with the third researcher. We will use consistent data extraction criteria for this process. This process was also completed independently by two researchers, including the first author's name, publication time, thesis title, disease name, sample number of each group, intervention time, intervention methods, outcome indicators, bias risk assessment, etc. after completion, the two researchers cross checked, and if the results are inconsistent, they will discuss or consult the third researcher to reach a consensus. The information extracted in this study mainly includes the basic information of the study, the basic information of participants, the intervention methods and outcome indicators of acute coronary syndrome.

Main outcome(s): (1) To observe the curative effect of angina pectoris (2) The incidence of adverse cardiovascular events (including angina pectoris recurrence, severe arrhythmia, heart failure, non-fatal myocardial infarction, revascularization, in stent restenosis, cardiac death, etc.) was observed.

Strategy of data synthesis: 4.1 Data synthesis. Revman version 5.4 software was used for meta-analysis. Continuous variables use mean difference (MD) or standardized mean difference (SMD) as effect indicators. The efficacy of binary variables is calculated by hypothetical risk ratio (RR) or odds ratio (or), and 95% is set as the confidence interval (95% CI). When $I^2 > 50\%$, $P > 0.1$ and $I^2 < 50\%$, it can be considered that there is no statistical

heterogeneity between included studies, and the fixed effect model can be selected; If $P < 0.1$ and $I^2 \geq 50\%$, select the random effect model, analyze the source of heterogeneity (method heterogeneity, clinical heterogeneity), and conduct subgroup analysis or sensitivity analysis. The source of heterogeneity cannot be judged, and only descriptive qualitative analysis can be used. 4.3 Sensitivity analysis In order to judge the robustness and stability of the review results, we conducted a sensitivity analysis. Through sensitivity analysis, we will delete low-quality studies with small sample size, high risk of bias or missing data one by one. 4.4 Evidence quality assessment. In order to judge the robustness and stability of the review results, we conducted a sensitivity analysis. Through sensitivity analysis, we will delete low-quality studies with small sample size, high risk of bias or missing data one by one. 4.5 Missing data management If there is a lack of relevant data, we will contact the author of the article by telephone or e-mail. 4.6 Ethics and dissemination All data in this study are from published studies. It does not involve the recruitment of patients and has nothing to do with personal privacy. Therefore, it does not need the approval of the ethics committee.

Subgroup analysis: 4.1 Data synthesis. Revman version 5.4 software was used for meta-analysis. Continuous variables use mean difference (MD) or standardized mean difference (SMD) as effect indicators. The efficacy of binary variables is calculated by hypothetical risk ratio (RR) or odds ratio (or), and 95% is set as the confidence interval (95% CI). When $I^2 > 50\%$, $P < 0.1$ and $I^2 < 50\%$, it can be considered that there is no statistical heterogeneity between included studies, and the fixed effect model can be selected; If $P < 0.1$ and $I^2 \geq 50\%$, select the random effect model, analyze the source of heterogeneity (method heterogeneity, clinical heterogeneity), and conduct subgroup analysis or sensitivity analysis. The source of heterogeneity cannot be judged, and only descriptive qualitative analysis can be used. 4.3 Sensitivity

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Sensitivity analysis: In order to judge the robustness and stability of the review results, we conducted a sensitivity analysis. Through sensitivity analysis, we will delete low-quality studies with small sample size, high risk of bias or missing data one by one.

Country(ies) involved: China.

Keywords: Compound Danshen Dripping Pills; acute coronary syndrome; meta-analysis; systematic review.

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