INPLASY PROTOCOL

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Corresponding author:
Ying Chen

192669938@qq.com

Author Affiliation:
Affiliated Hospital of Changchun University of Chinese Medicine, Branch of National Clinical Research Center for Chinese Medicine Cardiology.

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Conflicts of interest:
None declared.

Acupuncture combined with Qishen Yiqi Dripping Pills in the treatment of acute coronary syndrome in remission period A protocol for systematic review and meta-analysis

Li, Y[1]; Zhang, Y[2]; Wang, J[3]; Yang, M[4]; Chen, Y[5].

Review question / Objective: **To systematically evaluate the efficacy and safety of acupuncture combined with Qishen Yiqi 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 (NTSE-ACS). NSTE-ACS can be subdivided into two types, One is unstable angina pectoris (UPA) and the other is non ST segment elevation myocardial infarction (NSTENI). 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 31 March 2022 and was last updated on 31 March 2022 (registration number INPLASY202230176).

INTRODUCTION

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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 (NTSE-ACS). NSTE-ACS can be subdivided into two types, One is unstable angina pectoris (UPA) and the other is non ST segment elevation myocardial infarction (NSTENI). 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.

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 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.

Intervention: The patients in the treatment 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 treatment group was loaded with acupuncture combined with Qishen Yiqi Dripping Pills based on the above conventional western medicine, with unlimited dosage and course of treatment.

Comparator: The control group was treated with conventional western medicine.

Study designs to be included: 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 Qishen Yiqi 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. 2.2.2 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 w.

Eligibility criteria: (1) The data is incomplete or there are obvious errors, and the research of statistical analysis cannot be carried out. (2) Study on intervention measures containing traditional Chinese medicine preparations with similar effect to Qishen Yiqi Dripping Pills. (3) Reprinted literature. (4) Those who cannot obtain the full text through electronic retrieval or manual retrieval.

Information sources: The main databases we searched include PubMed, web of science, MEDLINE, EMBASE, Cochrane Library, CNKI, China Science Journal Database, Wan fang Data and China biomedical literature database. The key words searched were “Qishen Yiqi Dripping Pills”; “acupuncture”; “acute coronary syndrome”; "randomized control" ; "unstable angina pectoris" and "acute myocardial infarction”. The retrieval time is from the beginning to March 2022. To avoid data loss, we will also manually retrieve references to documents that meet the standards. In terms of literature, we only search publishers in Chinese or English,

which has nothing to do with the quality of publications.If there is a lack of relevant data, we will contact the author of the article by telephone or e-mail.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.

Quality assessment / Risk of bias 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.

Strategy of 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 I2 > 50%, P <. 1, it means that the difference has significant statistical significance. At this time, the random effect model is used.

Subgroup analysis: The heterogeneity between included studies was analyzed by chi square test. If P > 0.1 and I2 < 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 I2 ≥ 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.

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: Qishen Yiqi Dripping Pills; acupuncture; acute coronary syndrome; meta-analysis; protocol; systematic review.

Contributions of each author:

Author 1 - Yuhui Li.
Email: 363110918@qq.com
Author 2 - Ye Zhang.
Author 3 - Jiale Wang.
Author 4 - Min Yang.
Author 5 - Ying Chen.
Email: 192669938@qq.com