INPLASY PROTOCOL

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None declared.

Clinical efficacy and safety of Jingui Baoxin mixture in the treatment of acute coronary syndrome
A protocol for systematic review and meta-analysis

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Review question / Objective: **The aim of this meta-analysis of the clinical efficacy and safety of Jingui Baoxin mixture in the treatment of acute coronary syndrome.**
Condition being studied: **Acute coronary syndrome (ACS) is caused by unstable plaque in the coronary artery, with the rupture of plaque, the patient had severe chest pain in a short time. ACS is divided into three categories: STEMI, NSTENI和 UPA. The treatment of Western medicine is completed through vascular reconstruction and drug assistance, However, traditional Chinese medicine plays a good role in the rehabilitation of patients with acute coronary syndrome in remission. Jingui Baoxin mixture has been used in clinic for many years. It is effective in the treatment of circulatory diseases (such as coronary heart disease, myocardial infarction and arrhythmia), However, the clinical efficacy of Jingui Baoxin mixture in patients with acute coronary syndrome in remission has not been determined.Therefore, the purpose of this study is to conduct meta-analysis to systematically evaluate the clinical efficacy and safety of Jingui Baoxin mixture in the treatment of remission of acute coronary syndrome.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 March 2022 and was last updated on 20 March 2022 (registration number INPLASY202230105).

INTRODUCTION

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Condition being studied: **Acute coronary syndrome (ACS) is caused by unstable plaque in the coronary artery, with the rupture of plaque, the patient had severe chest pain in a short time. ACS is divided**

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METHODS

Participant or population: The research method we collected the literature did not consider whether the blind method and distribution were hidden. All randomized controlled trials of acute coronary syndrome treated with Jingui Baoxin mixture were included in this study. Our research is not limited by the publication time and region, but the language of the literature is limited to Chinese and English. 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 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: 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. Treatment group was loaded with Jingui Baoxin mixture on the basis of the above conventional western medicine, with unlimited dosage and course of treatment.

Comparator: 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.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: The research method we collected the literature did not consider whether the blind method and distribution were hidden. All randomized controlled trials of acute coronary syndrome treated with Jingui Baoxin mixture were included in this study. Our research is not limited by the publication time and region, but the language of the literature is limited to Chinese and English.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.Exclusion 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 jinguibaoxin mixture. (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, Wanfang Data and China biomedical literature database.The key words were "Jingui Baoxin mixture", "acute coronary syndrome" and "randomized control". The retrieval time is from the beginning to March 2022.We searched the literature related to the efficacy and safety of excision therapy in the treatment of migraine, including clinical observation, clinical trial and so on. The key words searched were "jinguibaoxin mixture", "acute coronary syndrome", "unstable angina pectoris" and "acute myocardial infarction". 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.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.(1) Whether the change value of high-sensitivity C-reactive protein (CRP) is better than that of the control group; (2) Whether the fluctuation values of high and low density lipoprotein and triglyceride (TG) exceed the values of the control group. (3) The Seattle angina pectoris questionnaire (SAQ) (4) ECG: (5)SF-36.

Quality assessment / Risk of bias analysis: By 2 researchers according to Cochrane system evaluator manual 5 1. 0 bias risk assessment tool to evaluate the bias risk included in the study. [26] evaluation criteria include random method selection; allocation hiding; blind method, completeness of the result data; whether the evaluator is blind; selectively reporting results; Other bias 7 entries. According to the specific criteria of the evaluation manual, the researchers identified the included study as low-risk bias, high-risk bias or unclear risk of bias. In case of any difference, it shall be settled through negotiation with a third party.

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. 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.

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, USA.

Keywords: Jingui Baoxin mixture; acute coronary syndrome; meta-analysis; protocol; systematic review.

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