INPLASY PROTOCOL

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Support: **Not available.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Efficacy and safety of integrated traditional Chinese medicine and standard western medicine on patients with acute coronary syndrome: A systematic review protocol

Cheng, B[1]; Chen, P[2]; Deng, Y[3].

Review question / Objective: **In the present systematic review, we aim to evaluate the efficacy and safety of adding TCM to standard western medicine to treat patients with ACS.**
Condition being studied: **Acute coronary syndrome (ACS) remains to be a major cause of morbidity and mortality worldwide.**
Eligibility criteria: **The inclusion criteria includes: (1) patients are older than 18 years; (2) patients are treated with conventional western medicine (control group) and combination of Chinese traditional and western medicine (experimental group); (3) studies that report one of the following outcomes clearly: effective rates, cardiovascular function index including left ventricular ejection fraction, early peak flow velocity, and thrombolysis in myocardial infarction, blood lipid levels including total cholesterol, triacylglycerol, and low/high density lipoprotein, and the incidence of adverse cardiovascular events; and (4) studies are randomized controlled trials (RCTs).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 April 2021 and was last updated on 30 April 2021 (registration number INPLASY202140145).

INTRODUCTION

Review question / Objective: **In the present systematic review, we aim to evaluate the efficacy and safety of adding TCM to standard western medicine to treat patients with ACS.**

Condition being studied: **Acute coronary syndrome (ACS) remains to be a major**

cause of morbidity and mortality worldwide.

METHODS

Participant or population: Adult patients with acute coronary syndrome.

Intervention: The combination of traditional Chinese medicine and western medicine.

Comparator: Conventional western medicine.

Study designs to be included: Randomized controlled studies.

Eligibility criteria: The inclusion criteria includes: (1) patients are older than 18 years; (2) patients are treated with conventional western medicine (control group) and combination of Chinese traditional and western medicine (experimental group); (3) studies that report one of the following outcomes clearly: effective rates, cardiovascular function index including left ventricular ejection fraction, early peak flow velocity, and thrombolysis in myocardial infarction, blood lipid levels including total cholesterol, triacylglycerol, and low/high density lipoprotein, and the incidence of adverse cardiovascular events; and (4) studies are randomized controlled trials (RCTs).

Information sources: Not available in the the protocol.

Main outcome(s): The primary outcome is the effective rate and cardiovascular function index (left ventricular ejection fraction, early peak flow velocity, and thrombolysis in myocardial infarction).

Additional outcome(s): The second outcome includes blood lipid level (total cholesterol, triacylglycerol, low/high density lipoprotein) and the incidence of adverse cardiovascular events.

Quality assessment / Risk of bias analysis: The quality of enrolled studies will be assessed using version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB 2).

Strategy of data synthesis: Meta-analyses will be performed if at least two enrolled trials report the corresponding outcomes. Differences will be tested using weighted mean difference (WMD) and relative risk (RR) with 95% confidence interval (CI). Inter group heterogeneity will be tested using Q test, with I2 < 50% and P >0.05 indicating no significant difference. In case of a significant heterogeneity, a random-effect model with DerSimonian–Laird method will be used. Conversely, a fixed-effect model with Mantel–Haenszel method will be used instead. Potential publication bias will be tested by performing funnel plots.

Subgroup analysis: Subgroup analyses will also be performed at last. All the above statistical analyses will be performed using Stata Software (Version 15.0, Stata SE).

Sensitivity analysis: Stability of results will be tested by performing sensitivity analyses through omitting each study sequentially.

Country(ies) involved: China.

Keywords: acute coronary syndrome, traditional Chinese medicine, systematic review.

Contributions of each author:

Author 1 - Bingjie Cheng - Conception and design; collection and assembly of data; data analysis and interpretation; manuscript writing; final approval of manuscript.
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Author 2 - Pei Chen - Provision of study materials or patients; manuscript writing; final approval of manuscript.
Author 3 - Yihui Deng - Administrative support; manuscript writing; final approval of manuscript.