

INPLASY PROTOCOL

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

Conflicts of interest:
None.

Efficacy and safety of Danlou tablets combined with western medicine for patients undergoing PCI : a protocol for systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: Is Danlou tablets combined with western medicine effective and safe Treating Coronary Heart Disease after PCI?

Condition being studied: Coronary heart disease are selecting interventional therapy.

Information sources: A literature search will be performed in four Chinese(Chinese Biomedical Literature Database, China National Knowledge Infrastructure, Wanfang, and VIP) and three English(PubMed, Emase, Cochrane Library) electronic databases from their inception to December 30 2020.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 8 January 2021 and was last updated on 8 January 2021 (registration number INPLASY202110023).

INTRODUCTION

Review question / Objective: Is Danlou tablets combined with western medicine effective and safe Treating Coronary Heart Disease after PCI?

Rationale: In the past decade, cardiovascular disease has become the most important cause of death worldwide. Percutaneous coronary intervention (PCI) is an established treatment for coronary heart disease (CHD). An increasing number of patients with coronary heart disease are

selecting interventional therapy. PCI is known to effectively improve the prognosis of patients with CHD, particularly those with acute coronary syndrome. However, little further improvements in symptoms of CHD have been achieved after PCI. Traditional Chinese medicine is widely used for CHD in China. Danlou tablet (DLT) Danlou tablet, a kind of Chinese patent medicine, has been widely used in the treatment of CHD. But the effect and safety of Danlou tablets combined with western medicine for patients undergoing PCI has not been systematically evaluated.

Condition being studied: Coronary heart disease are selecting interventional therapy.

METHODS

Search strategy: The search strategy consisted with the following terms:“Danlou tablet”[MeSH Terms] AND “Percutaneous coronary intervention”[MeSH Terms] AND“Randomized Controlled Trial” [ptyp].

Participant or population: The randomized controlled trials will be contained. Danlou tablet combined with western medicine for patients with CHD after PCI. without the limitations of age, sex or ethnicity.

Intervention: Danlou tablet combined with routine drug for patients with CHD after PCI will be included as trial group, the control group should be treated with western medicine or western medicine combined with placebo.

Comparator: The control group should be treated with western medicine or western medicine combined with placebo, including vasodilator, ACEI/ARB, calcium antagonist, beta blocker, antiplatelet aggregation, anticoagulation and lipid regulation.

Study designs to be included: The randomized controlled trials will be contained.

Eligibility criteria: Type of studies:The randomized controlled trials will be contained. Danlou tablet combined with

routine drug for patients with CHD after PCI will be included . Patients diagnosed with CHD after PCI. without the limitations of age, sex or ethnicity.

Information sources: A literature search will be performed in four Chinese(Chinese Biomedical Literature Database, China National Knowledge Infrastructure, Wanfang, and VIP) and three English(PubMed, Embase, Cochrane Library) electronic databases from their inception to December 30 2020.

Main outcome(s): The primary outcomes are improvements in angina symptoms, frequency of angina attacks, and the duration of chest pain or angina pectoris.

Additional outcome(s): The secondary outcomes will be include HsCRP, Number of ST segment descending leads in ECGT, wave low-level (or inverted) lead number , and adverse events ,et al.

Data management: Data from included studies will be extracted following structured forms with the relevant information (e.g.,author's name, publication year, study design, sample size, characteristics of the patients, type of intervention, treatment course, outcomes, adverse events).

Quality assessment / Risk of bias analysis: Two reviewers will use the Cochrane Collaboration's tool to evaluate the risk of bias of included RCTs. The tool includes six aspects such as selection bias(random sequence generation, allocation concealment), performance bias(blinding of participants and researchers), detection bias(blinding of outcome assessment), attrition bias (incomplete outcome data),reporting bias(selective reporting)and other bias to assess quality. Other more,The corresponding author will be contacted to examine issues if necessary. The included studies will be assessed either as low, high , or unclear risk.

Strategy of data synthesis: RevMan 5.3.5 software from the Cochrane Collaboration

will be used to synthesize and analyze the included data. The continuous data will be analyzed by using mean difference with 95% Confidence interval(CI), while the analysis of dichotomous data will be analyzed by adopting relative risk ratios with 95% CI. The heterogeneity will be assessed based on the results of standard χ^2 test, if I² value is more than 50% indicating high heterogeneous, the random-effect model will be used to pool the data. Otherwise, a fixed-effect model will be applied for data synthesis when I² value is less than 50%.

Subgroup analysis: Subgroup analysis will be performed to assess possible biasing factors of meta results following the factors of age, sex, type of coronary heart disease.

Sensitivity analysis: Sensitivity analyses will be conducted at factors may be strongly influence the results. For instance, whether the results are different when excluding the low-quality articles.

Country(ies) involved: The systematic review will be carried out in China.

Keywords: Danlou tablet, Percutaneous coronary intervention, meta-analysis, randomized controlled trials, Chinese medicine.

Contributions of each author:

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