INPLASY PROTOCOL

To cite: Xu et al. Danlou tablets as an adjunctive treatment for patients with coronary heart disease after percutaneous coronary intervention: a systematic review and meta-analysis of randomised controlled trials. Inplasy protocol 202110023. doi: 10.37766/inplasy2021.1.0023

Received: 8 January 2021

Published: 8 January 2021

Corresponding author:
Jingqing Hu

gcp306@126.com

Author Affiliation:
The First Affiliated Hospital of Anhui University of Traditional Chinese Medicine

Support: **HAVE.**

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

Conflicts of interest:
None.

Danlou tablets as an adjunctive treatment for patients with coronary heart disease after percutaneous coronary intervention: a systematic review and meta-analysis of randomised controlled trials

Xu, G[1]; Lin, M[2]; Dai, X[3]; Hu, J[4].

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 six electronic databases: the China National Knowledge Infrastructure, WanFang Database, VIP database, PubMed, Embase, and Web of Science. The databases will be searched from their inception to 30 December, 2020. Furthermore, supplementary searches will be carried out in Google Academic. Searches were restricted to studies published in English or Chinese language.**

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 14 April 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: (i) The studies were randomised clinical trials (RCTs). (ii) The studies included adults aged ≥ 18years and the literature search placed no limits on the sex or ethnicity of subjects. (iii) Subjects underwent PCI treatment for coronary heart disease. (iv) The experimental groups were co-treated with DLT and conventional therapy (antiplatelet drugs, anticoagulants, β-receptor blockers, or nitrate drugs, and so on), whereas the control groups were treated with conventional therapy with or without a placebo. (v) The studies reported at least one of the following outcome measures: relief of angina symptoms, frequency of angina attacks, duration of chest pain or angina pectoris, high-sensitivity C-reactive protein (hs-CRP), number of ST segment descending leads in electrocardiogram (ECG), T-wave low-level (or inverted) lead number, and blood lipid profile (total cholesterol [TC], low-density lipoprotein-cholesterol [LDL-C], high-density lipoprotein-cholesterol [HDL-C], and triglyceride [TG] levels).

Information sources: A literature search will be performed six electronic databases: the China National Knowledge Infrastructure, WanFang Database, VIP database, PubMed, Embase, and Web of Science. The databases will be searched from their inception to 30 December, 2020. Furthermore, supplementary searches will be carried out in Google Academic. Searches were restricted to studies published in English or Chinese language.

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 χ2 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.

Sensibility 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:
Author 1 - Guiqin Xu.
Author 2 - Mingxin Lin.
Author 3 - Xueli Dai.
Author 4 - Jingqing Hu.