INPLASY PROTOCOL

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None declared.

Effects of Compound Danshen Dropping Pills on adverse cardiovascular events and quality of life after percutaneous coronary intervention in patients with coronary heart disease — A protocol for systematic review and meta-analysis

Lv, LN[1]; Yuan, XY[2]; Li, YH[3]; Zhang, DZ[4]; Sun, DW[5]; Jiang, LH[6].

Review question / Objective: **The results of this study will systematically evaluate the effects of Compound Danshen Dropping Pills on adverse cardiovascular events and quality of life after PCI for coronary heart disease.**
Condition being studied: **Percutaneous coronary intervention (PCI) is an important means for the treatment of coronary atherosclerotic heart disease and has effectively reduced the mortality of coronary heart disease. However, reperfusion can also cause certain damage to the vascular endothelium, leading to the occurrence of Conscious Vascular Event (MACE). Compound Danshen Dropping Pill is a Chinese patent medicine preparation. At present, many studies have evaluated the effect of Compound Danshen Dropping Pill in reducing the incidence of adverse cardiovascular events after PCI. This study systematically evaluated the effect of compound Danshen dripping pills on MACE and quality of life after PCI, and provided reference for clinical application andresearch.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 January 2022 and was last updated on 09 January 2022 (registration number INPLASY202210044).

INTRODUCTION

Review question / Objective: **The results of this study will systematically evaluate the effects of Compound Danshen Dropping Pills on adverse cardiovascular events and quality of life after PCI for coronary heart disease.**

Rationale: **This study will provide an objective evidence-based basis for compound Danshen dripping pills to**

reduce adverse cardiovascular events and improve quality of life afterPCI.

Condition being studied: Percutaneous coronary intervention (PCI) is an important means for the treatment of coronary atherosclerotic heart disease and has effectively reduced the mortality of coronary heart disease. However, reperfusion can also cause certain damage to the vascular endothelium, leading to the occurrence of Conscious Vascular Event (MACE). Compound Danshen Dropping Pill is a Chinese patent medicine preparation. At present, many studies have evaluated the effect of Compound Danshen Dropping Pill in reducing the incidence of adverse cardiovascular events after PCI. This study systematically evaluated the effect of compound Danshen dripping pills on MACE and quality of life after PCI, and provided reference for clinical application andresearch.

METHODS

Search strategy: We selected seven databases including PubMed, the Web of Science, Embase, Cochrane Library, the Chinese National Knowledge Infrastructure, the Chinese Science Journal Database, Wanfang Data, and Chinese Biomedical Literature Database for retrieval. We searched for the effects of compound Danshen dripping pills on cardiovascular adverse events and quality of life after percutaneous coronary intervention. The search time was from database establishment to January 2022. Search only Chinese and English literature. The database search was carried out in the form of subject headings combined with free words. The search terms included "Compound Danshen Dropping Pills", "Percutaneous Coronary Intervention", "Standard Balloon Angioplasty", and "Intracoronary Insertion". In addition, references to the included literature were traced back to supplement the acquisition of relevant literature.The main databases we searched were PubMed, the Web of Science, Embase, Cochrane Library, the Chinese National Knowledge Infrastructure, the Chinese Science Journal Database, Wanfang Data, and Chinese Biomedical Literature Database. All randomized controlled trials on the effects of compound Danshen dripping pills on adverse cardiovascular events and quality of life after PCI for coronary heart disease were searched. The search was conducted from inception to January 2022. Data extraction and quality assessment were performed by two reviewers according to the Protocol Guidelines for Systematic Reviews and Meta-analyses Protocols statement guidelines. Meta analysis was performed using Review Manager Version 5.4 software and Stata 16 software.

Participant or population: We will include patients who meet the diagnostic criteria of coronary heart disease and receive percutaneous coronary intervention. There is no restriction on age, sex, course of disease or race.

Intervention: On the basis of routine treatment, the experimental group was treated with compound Danshen dripping pills. The treatment time was after PCI, and the dosage and course of treatment were not limited.

Comparator: The control group received routine treatment. Routine treatment includes antiplatelet drugs, anticoagulants, nitrates, beta blockers, calcium channel blockers, lipid-lowering drugs and so on.

Study designs to be included: Randomised controlled trial.

Eligibility criteria: We will collect all randomized controlled trials about the effects of compound Danshen dripping pills on cardiovascular adverse events and quality of life after percutaneous coronary intervention. The included documents are not restricted by blind method or distribution hiding requirements, but the language of the literature was limited to Chinese and English.

Information sources: We selected seven databases including PubMed, the Web of Science, Embase, Cochrane Library, the Chinese National Knowledge

Infrastructure, the Chinese Science Journal Database, Wanfang Data, and Chinese Biomedical Literature Database for retrieval. In addition, references to the included literature were traced back to supplement the acquisition of relevant literature.

Main outcome(s): The primary outcome measure was adverse cardiovascular events, including recurrent angina, severe arrhythmia, heart failure, non-fatal myocardial infarction, repeat revascularization, in-stent restenosis, and cardiac death.

Additional outcome(s): The Secondary outcome measures included high sensitivity C-reactive protein, left ventricular ejection fraction, 6-minute walking test, and The Seattle Angina scale (degree of physical activity limitation, angina stable state, angina attack, treatment satisfaction, and disease awareness).

Data management: The literature screening was independently completed by two researchers. First, by reading the title and abstract of the literature, the literature that does not meet the standard was screened initially. After reading the full text, the second screening was conducted according to the inclusion and exclusion criteria. In case of disagreement, both parties shall discuss or consult a third party for judgment. Data were extracted independently by two researchers, including name of first author, publication time, title of paper, name of disease, sample size of each group, intervention time, intervention method, outcome indicators, bias risk evaluation, etc. After completion of the cross-check between the two investigators, those with inconsistent results were discussed or the third investigator was consulted to reach a consensus.

Quality assessment / Risk of bias analysis: The risk of bias in the included studies was evaluated by two researchers using the Cochrane Systematic Evaluator's Manual 5.1.0 bias risk assessment tool.[8] Evaluation criteria include random method selection; allocation hiding; blind method, completeness of the result data; whether the evaluator is blind; selectively reporting results; Other Biases 7 entries. According to the specific criteria of the evaluation manual, the researchers identified the included studies as low risk bias, high risk bias or unclear risk of bias. In case of disagreement, it will be resolved through consultation with a third party.

Strategy of data synthesis: Quantitative comprehensive analysis was performed using RevMan version 5.4 software. For continuous variables, mean difference (MD) OR standardized mean difference (SMD) were used as effect indexes, while for dichotomous variables, relative risk (RR), odds ratio (OR) and risk difference (RD) were used as effect indexes, etc. 95% confidence interval was used as effect size, and $P \leq 0.05$ was considered statistically significant.

Subgroup analysis: Chi-square test was used to analyze the heterogeneity among included studies. If $P>0.1$ and $I2<50\%$, it can be considered that there is no statistical heterogeneity among included studies, and the fixed effect model can be used. If $P<0.1$ and $I2 \geq 50\%$, a random-effect model was selected to analyze the source of heterogeneity (methodological heterogeneity, clinical heterogeneity), and subgroup or sensitivity analysis could be performed. If the source of heterogeneity cannot be determined, only descriptive qualitative analysis can be used.

Sensitivity analysis: A random-effect model was selected to analyze the source of heterogeneity (methodological heterogeneity, clinical heterogeneity), and subgroup or sensitivity analysis could be performed. If the source of heterogeneity cannot be determined, only descriptive qualitative analysis can be used.

Language: Search only Chinese and English literature.

Country(ies) involved: China.

Keywords: Compound Danshen Dropping Pills, Percutaneous coronary intervention, Adverse cardiovascular events, meta-analysis, protocol.

Contributions of each author:

Author 1 - Lina Lv - The author Lina Lv proposed the thesis concept, performed formal analysis, data collection, editing, and thesis writing, drafted the manuscript.
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Author 2 - Xianying Yuan - The author performs visual analysis, methodological research, Provides statistical expertise Xianying Yuan for data collection, Visualization, methodological research, Provides statistical expertise.
Author 3 - Yuhui Li - The authors contributed to the development of selection criteria, as well as the risk of bias assessment strategy.
Author 4 - Dongze Zhang - The author organizes the data and searches the literature.
Author 5 - Dongwen Sun - The author organizes the data and searches the literature.
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