INPLASY PROTOCOL

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None declared.

The effectiveness of Salvianolate injection for in-stent restenosis after percutaneous coronary intervention: a meta-analysis and systematic review

Zhang, M[1]; Yuan, Y[2]; Gao, Y[3]; Lu, RZ[4]; Deng, Y[5].

Review question / Objective: **The study aims to evaluate the effectiveness of Salvianolate injection for use in the treatment of ISR.**
Information sources: **We will search the following databases from their inception to February 27, 2022: The Cochrane Library, Embase, PubMed, Web of Science, China National Knowledge Infrastructure Database (CNKI), Wan-fang Database (wan-fang), Chinese Scientific Journals Database (VIP), and Chinese Biomedicine Database (CBM). The publishing language will be restricted to Chinese and English. The following subject words were used: ("percutaneous coronary intervention" or "percutaneous coronary artery intervention " or "PCI" or "restenosis" or "in-stent restenosis" or "ISR") and ("Salvianolate injection" or "depside salt from salvia miltiorrhiza" or "Dan shen duofen suan yan" or "Danshen polyphenolate injection") and ("randomized controlled trial" or "randomized" or "trial ").**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 February 2022 and was last updated on 27 February 2022 (registration number INPLASY202220117).

INTRODUCTION

Review question / Objective: **The study aims to evaluate the effectiveness of Salvianolate injection for use in the treatment of ISR.**

Condition being studied: **The educational background, age and professional structure of the project team are reasonable. The members are young and middle-aged talents with rich clinical and scientific research experience. The**

personnel the composition can meet the requirements of completing the project.

METHODS

Participant or population: All patients must meet the diagnostic criteria for adult CHD established by the American College of Cardiology/American Heart Association. All patients must have undergone PCI and have a diagnosis of ISR after PCI. There will be no limits on basic patient characteristics (including region, race, and sex).

Intervention: In the intervention group patients received Salvianolate injection or combined with another intervention.

Comparator: In the control group, patients received another intervention or no treatment.

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

Eligibility criteria: Inclusion criteria were: (1) studies that were randomized controlled trials (RCTs) comparing Salvianolate injection with a control group; (2) patients in the studies had coronary atherosclerosis disease diagnosed by coronary arteriography and had successfully undergone PCI; (3) patients were randomized to either the Salvianolate injection group or a control group; (4) the primary outcome was angiographic restenosis, defined as stenosis >50% of the diameter, and secondary outcomes were major adverse cardiac events (MACEs), consisting of MI, repeated angioplasty, coronary artery bypass surgery, and death; (5) patients were followed for at least 6 months.

Information sources: We will search the following databases from their inception to February 27, 2022: The Cochrane Library, Embase, PubMed, Web of Science, China National Knowledge Infrastructure Database (CNKI), Wan-fang Database (wan-fang), Chinese Scientific Journals Database (VIP), and Chinese Biomedicine Database (CBM). The publishing language will be restricted to Chinese and English. The following subject words were used: ("percutaneous coronary intervention" or "percutaneous coronary artery intervention " or "PCI" or "restenosis" or "in-stent restenosis" or "ISR") and ("Salvianolate injection" or "depside salt from salvia miltiorrhiza" or "Dan shen duofen suan yan" or "Danshen polyphenolate injection") and ("randomized controlled trial" or "randomized" or "trial ").

Main outcome(s): The primary outcome measures will be the restenosis rate.

Additional outcome(s): The secondary outcomes will include the angina recurrence rate and major adverse cardiac events (MACEs).

Quality assessment / Risk of bias analysis: Two review authors (ZM and GY) will independently evaluate each included study and follow the domain-based evaluation developed by the Cochrane Handbook for Systematic Reviews of Interventions. They will assess the following domains: (1) selection bias (random sequence generation and allocation concealment), (2) performance bias (blinding of participants and personnel), (3) detection bias (blinding of outcome assessment), (4) attrition bias (incomplete outcome data), (5) reporting bias (selective reporting), (6) other bias (such as pre-sample size estimation, early stop of trial). Each domain will be divided into three categories: low risk of bias, unclear bias and high risk of bias. Any discrepancies will be resolved by reviewing the original article and discussed with the third author (YY) to reach a consensus.

Strategy of data synthesis: We will analyze the data with RevMan V.5.4 software provided by The Cochrane Collaboration. A meta-analysis using random or fixed effects models will be conducted to summarize the data. Continuous data will be pooled and presented as mean differences or standardized mean differences with 95% CI. Dichotomous data will be pooled and expressed as a risk ratio with their 95% CI. We will interpret it using the following criteria: I2 values of 25% are

considered low levels of heterogeneity, 50% indicated moderate levels, and 75% indicated high levels. Since low or moderate heterogeneity suggests little variability among these studies, the data will be analyzed in a fixed-effects model. When significant heterogeneity occurs among the studies (P < .05, I2≥ 50%), a random effect model will be performed to analyze the data.

Subgroup analysis: We plan to carry out the following subgroup analyses to explore possible sources of heterogeneity: type of PCI. The qualitative synthesis will be conducted instead of quantitative synthesis if the data is insufficient.

Sensitivity analysis: Sensitivity analysis will be performed to examine the robustness of the results by eliminating low quality trials.

Country(ies) involved: China.

Keywords: Percutaneous coronary intervention; In-stent restenosis; Salvianolate injection; coronary heart disease; protocol; systematic review.

Contributions of each author:

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