

INPLASY PROTOCOL

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None declared.

Effect of Sodium Tanshinone IIA Sulfonate Injection as Adjuvant Therapy on Hemorheology in Patients with Coronary Heart Disease: A Systematic Review and Meta-analysis

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Review question / Objective: As a strong risk factor of coronary heart disease (CHD), abnormal blood rheology is the mechanism basis of coronary atherosclerosis and plaque rupture. Numerous studies have shown that Sodium Tanshinone IIA Sulfonate Injection (STS) has the effect of improving hemorheology while reducing major cardiovascular events in patients with CHD. However, to the extent of our knowledge, there is no meta-analysis on the effect of STS on hemorheology in patients with CHD. The meta-analysis method was used to systematically evaluate the effect of STS on hemorheology in patients with CHD.

Information sources: A computerized search of published relevant studies on STS in the treatment of CHD was performed. PubMed, Cochrane Library, Web of Science, Embase, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Chinese Scientific Journals Database (VIP) and Wanfang database were searched.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 August 2022 and was last updated on 08 August 2022 (registration number INPLASY202280031).

INTRODUCTION

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Sulfonate Injection (STS) has the effect of improving hemorheology while reducing major cardiovascular events in patients with CHD. However, to the extent of our knowledge, there is no meta-analysis on the effect of STS on hemorheology in patients with CHD. The meta-analysis method was used to systematically evaluate the effect

of STS on hemorheology in patients with CHD.

Condition being studied: Coronary heart disease(CHD) is one of the most common cardiovascular diseases, and its morbidity and mortality are increasing year by year. Characterized by acuteness, repeated relapse, and severe clinical symptoms, if not timely treated,it may induce heart failure and myocardial infarction.Its pathogenesis is related to myocardial ischemia and injury caused by imbalance of blood supply and demand in coronary vessels.In recent years, With the rapid development of Clinical Medicine, many studies on the correlation between hemorheology and coronary heart disease have been reported. Abnormal hemorheology is considered to be the key factor for early clinical diagnosis and clinical prognosis of patients with CHD.Since the change of hemorheology often occurs earlier than clinical symptoms, early attention to hemorheology can effectively reduce the occurrence and development of CHD.

METHODS

Participant or population: Patients with CHD, with or without angina pectoris(AP).

Intervention: Sodium Tanshinone IISulfonate+conventional medicine (CM).

Comparator: CM.CM includes statins, aspirin, beta blockers,nitrates and angiotensin-converting enzyme inhibitor(AECI).

Study designs to be included: Published randomized controlled trial (RCT).

Eligibility criteria: Inclusion criteria: (1) Types of studies:Published randomized controlled trial (RCT); (2) Types of participants:Patients with CHD, with or without angina pectoris(AP); (3)Types of interventions:STS+conventional medicine (CM);CM includes statins, aspirin, beta blockers,nitrates and angiotensin-converting enzyme inhibitor(AECI); (4) Types of comparators: CM;The application

and dose of CM in the observation and control groups were the same; (5) Types of outcome indicators: blood viscosity(including HSBV,LSBV,PV),Fb, HCT and Platelet function indicators(including PAR,CD63,CD42b,PAC-1). Exclusion Criteria: (1) Study types as following: reviews, meta-analysis,cluster RCTs, animal experiments, expert experience, or case-control studies; (2) Diagnostic assessment criteria was not mentioned; (3) Duplicate publications; (4) Literature with obvious statistical errors.

Information sources: A computerized search of published relevant studies on STS in the treatment of CHD was performed. PubMed, Cochrane Library, Web of Science, Embase, China National Knowledge Infrastructure(CNKI), Chinese Biomedical Literature Database(CBM), Chinese Scientific Journals Database(VIP) and Wanfang database were searched.

Main outcome(s): blood viscosity(including HSBV,LSBV,PV),Fb, HCT and Platelet function indicators(including PAR,CD63,CD42b,PAC-1).

Quality assessment / Risk of bias analysis: The assessment of risk of bias literatures was evaluated by 2 investigators according to the risk of bias assessment tool in Cochrane Reviewers Handbook 6.1.0, mainly including the following 7 aspects: random sequence generation; allocation concealment; implementation of blind method for patients and trial personnel; implementation of blind method for outcome assessors; incomplete result data; selective reporting; and other biases (such as potential bias related to special study design in studies, false statement, etc.). Eventually, it is necessary to make a judgment on "low risk", "high risk" and "unclear risk" in the literatures. Disagreement will be settled by team discussion. Review manager V.5.4 will be used to make the risk of bias diagram.

Strategy of data synthesis: We used Review manager V.5.4 and Stata V.16.0 for statistical analysis.Because the indicators to be analyzed are all continuous variables,

we chose the mean difference (MD) as the effect scale. All results were presented with 95% confidence intervals (CI). Heterogeneity among trials was assessed by Cochrane's Q test and I-squared statistic. When $I^2 < 50\%$, it means that the heterogeneity among studies is small, and the fixed effect model is used for analysis; If $I^2 \geq 50\%$, the random effect model is used. Furthermore, The sensitivity analysis was also performed by removing each study one at a time to evaluate the stability of the results. Subgroup analysis was performed according to different duration of intervention, doses of STS and whether accompanied by AP. The publication bias was evaluated by the funnel plot, the Begger's test and the Egger's test. Sensitivity analysis, subgroup analysis and publication bias were performed only for outcome indicators with more than 10 pieces of literature.

Subgroup analysis: To explore the sources of heterogeneity and improve the persuasiveness of the evidence, we conducted a subgroup analysis based on the study characteristics (duration of treatment, dose of STS and whether accompanied by AP).

Sensitivity analysis: To further confirm the stability of the results of the meta-analysis, sensitivity analysis was conducted by excluding the studies from the analysis one by one. We only analyzed the outcome indicators of > 10 literatures.

Country(ies) involved: China.

Keywords: Coronary heart disease, sodium tanshinone IIA sulfonate, adjunctive therapy, hemorheology, meta-analysis, systematic review.

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