INPLASY

PCSK9i in addition to statin regulating coronary artery plaque regression in chronic/acute coronary syndrome: a meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202550027

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 May 2025 and was last updated on 12 May 2025.

INTRODUCTION

Review question / Objective Statins are the standard treatment for coronary atherosclerosis, but somepatients require additional therapies for optimal plaque regression. PCSK9 inhibitors,including monoclonal antibodies (mAbs) and siRNA, have shown promise as adjunctsto statins, though their efficacy for coronary plaque regression, as assessed byintravascular imaging, remains uncertain.

Rationale This meta-analysis aims to synthesize the available data on the impact of this combination therapy on plaque volume, composition, and adverse events, as well as to identify potential effect modifiers and sources of heterogeneity. The findings of this study will provide valuable insights into the role of statin plus PCSK9 inhibitor therapy in the management of coronary atherosclerosis and guide future research in this field.

Condition being studied Statin therapy has long been the cornerstone for treating coronary atherosclerosis. However, a significant number of patients still face a high risk of cardiovascular events despite its use. PCSK9 inhibitors have emerged as a potential adjunct to statins. This study aims to comprehensively assess the efficacy of combining PCSK9 inhibitors with statins in promoting coronary plaque regression through a meta – analysis, providing crucial insights for better management of this condition.

METHODS

Search strategy We will search the following electronic databases from inception to August 31st 2024: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and ClinicalTrials.gov. The search strategy will be developed in collaboration with a medical librarian and will include a combination of keywords and controlled vocabulary terms (e.g., MeSH terms)

related to statins, PCSK9 inhibitors, coronary atherosclerosis, and intravascular imaging.

Participant or population Participants: adults (≥18 years) with coronary atherosclerosis confirmed by coronary angiography or other imaging modalities.

Intervention Interventions: statin therapy combined with PCSK9 inhibitors (monoclonal antibodies or siRNA).

Comparator Comparators: statin therapy alone or statin therapy plus placebo.

Study designs to be included Study design: parallel-group or crossover trial with a minimum follow-up duration of 3 months.

Eligibility criteria We will exclude observational studies, animal studies, and studies not published in English.

Information sources We will search the following electronic databases from inception to August 31st 2024: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and ClinicalTrials.gov. We will also manually search the reference lists of relevant reviews and included studies to identify additional eligible trials. If necessary, we will contact study authors for additional information or unpublished data.

Main outcome(s) Outcomes: reporting the follow-up outcomes of intra-vascular imaging including IVUS, OCT or NIRS, as well as changes in lipid profiles.

Quality assessment / Risk of bias analysis Publication bias will be assessed visually using funnel plots and statistically using Egger's test.

Strategy of data synthesis We will perform a qualitative synthesis of the included studies by summarizing their characteristics, participants, interventions, comparators, and outcomes in tables and text. If the included studies are sufficiently homogeneous in terms of design, population, interventions, and outcomes, we will conduct a quantitative synthesis using random-effects meta-analyses. For the parameter of plaque burden, we will calculate the mean difference (MD) and its 95% confidence interval (CI) between the intervention and control groups. If plaque volume is reported using different scales or units across studies, we will use the standardized mean difference (SMD) instead. For continuous variables (e.g., changes in lipid profiles), we will also use the MD or SMD and their 95% CIs.

Subgroup analysis We will conduct sensitivity analyses by excluding studies with high risk of bias to assess the robustness of our findings. We will also conduct sensitivity analyses by removing one study at a time to evaluate the impact of individual studies on the pooled results.

Sensitivity analysis None.

Language restriction Yes, studies will be limited to English language only.

Country(ies) involved China.

Keywords Coronary Atherosclerosis, Statin, PCSK9 Inhibitor, Plaque regression, Meta-analysis.

Dissemination plans Results will be disseminated through publication in a peer-reviewed journal and presentation at relevant scientific conferences.

Contributions of each author

Author 1 - Dexiao Yuan carried out the studies, participated in collecting data, and drafted the manuscript.
Email: 2700547988@qq.com
Author 2 - Ting Cheng performed the statistical analysis and participated in its design.
Author 3 - Zhihua Cao participated in collecting data.
Author 4 - Fang Wang helped to draft the manuscript.
Author 5 - Yongpeng Wang read, provided feedback and approved the final manuscript.