

INPLASY PROTOCOL

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Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: Participants: Ischemic heart disease; Intervention: Growth factor; Control: Placebo; Primary outcomes: All-cause mortality, Major adverse cardiovascular events; Secondary outcome: revascularization, left ventricular ejection fraction, Canadian cardiovascular

Growth factor for therapeutic angiogenesis in ischemic heart disease a meta-analysis of randomized controlled study

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Review question / Objective: Participants: Ischemic heart disease; Intervention: Growth factor; Control: Placebo; Primary outcomes: All-cause mortality, Major adverse cardiovascular events; Secondary outcome: revascularization, left ventricular ejection fraction, Canadian cardiovascular society angina class; Study: randomized controlled trial.

Condition being studied: Ischemic heart disease (IHD) is the major cause of death all over the world according to the report of World Health Organization (WHO). Even though guideline-based medical therapy and percutaneous coronary intervention have been widely used in IHD patients, the 4-year rate of death and myocardial infarction remains about 10%. Lots of patients could not benefit from PCI, and some patients also suffer from refractory angina despite intensive medical therapy.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 November 2022 and was last updated on 09 November 2022 (registration number INPLASY2022110041).

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METHODS

Participant or population: Ischemic heart disease.

Intervention: Growth factor.

Comparator: Placebo.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: (1) RCT study; (2) the patients diagnosed as IHD; (3) reported the outcome including cardiovascular events, cardiovascular mortality, all-cause mortality, cardiac ultrasound at least one.

Information sources: Electronic databases such as PubMed, EMBASE, CENTRAL, and additional records identified through literature review.

Main outcome(s): All-cause mortality, Major adverse cardiovascular events.

Additional outcome(s): Revascularization, left ventricular ejection fraction, Canadian cardiovascular society angina class.

Quality assessment / Risk of bias analysis: The quality of included studies were assessed based on 7 aspects of risk biases, including random sequence generation, allocation concealment, blinding of participants and personnel, blinding for outcome assessment, incomplete outcome data, selective reporting, and other potential sources of bias. Overall, no attrition bias or reporting bias was observed, and the methods of random and blinding were considered to be adequate in this meta-analysis, but there was an unclear risk in allocation concealment.

Strategy of data synthesis: Dichotomous outcomes were analyzed with the relative risk (RR) and 95% confidence interval (CI). Continuous outcomes were analyzed with the weighted mean difference (WMD) and 95% CI. I^2 statistic was used to measure the heterogeneity among the studies. When $I^2 \leq 50\%$, we will consider that the heterogeneity was not significant among the studies, and fixed-effect models will be used. $I^2 > 50\%$ indicated that the heterogeneity among the studies was statistically significant, random-effect models will be applied. Meta-regression analysis was conducted for the factors that affected the research results, such as sex, age and duration of treatment, to observe their impact on outcomes. If necessary, subgroup analysis based on factors such as sex, age and intervention measures was conducted to clarify their impact on outcome. The data were analyzed with Stata (version 12.0) or Cochrane Collaboration software (RevMan 5.3).

Subgroup analysis: Subgroup analyses were performed based on type of IHD, categories of growth factors, injection methods and follow-up duration.

Sensitivity analysis: Sensitivity analysis was used to observe whether the results were reliable after the studies were excluded one by one.

Country(ies) involved: China.

Keywords: Growth factor; revascularization; therapeutic angiogenesis; ischemic heart disease; meta-analysis; randomized controlled study.

Contributions of each author:

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