INPLASY

INPLASY2026110049

doi: 10.37766/inplasy2026.11.0049

Received: 12 November 2026

Published: 12 November 2026

Efficacy and safety of Xuefu Zhuyu Tang as an adjunctive therapy for acute myocardial infarction: a systematic review and meta-analysis of clinical and preclinical studies

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ADMINISTRATIVE INFORMATION

Support - No support.

Review stage at the time of initial registration - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2026110049

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 November 2026 and was last updated on 12 November 2026.

INTRODUCTION

Review question / Objective The objective of this systematic review and meta-analysis is to comprehensively evaluate the efficacy and safety of Xuefu Zhuyu Tang (XFZYT) as an adjunctive therapy for acute myocardial infarction (AMI) by integrating clinical and preclinical evidence.

The review question is structured according to the PICOS framework:

P (Population): Patients clinically diagnosed with AMI in clinical studies, and animals subjected to coronary artery ligation or myocardial ischemia/reperfusion models in preclinical studies.

I (Intervention): In clinical studies, XFZYT (original or modified formulas) combined with conventional medical treatment; in animal studies, XFZYT administered at various doses.

C (Comparator): In clinical studies, conventional medical treatment without XFZYT; in animal studies, normal saline, distilled water, or equivalent vehicle controls.

O (Outcomes): Clinical outcomes include major adverse cardiovascular events (MACE), cardiac function, myocardial injury biomarkers, inflammatory and oxidative stress markers, endothelial function, lipid profiles, clinical response rate, and adverse drug reactions. Animal outcomes include myocardial apoptosis, cardiac function, myocardial injury, inflammatory and oxidative stress markers, endothelial function, angiogenesis-related indicators, and ST-segment changes.

S (Study design): Randomized controlled trials (RCTs) and preclinical animal studies.

This review aims to determine whether adjunctive XFZYT improves clinical outcomes and cardiac function, reduces myocardial injury and associated pathological responses, and whether its potential

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cardioprotective effects are supported by preclinical evidence.

Condition being studied Acute myocardial infarction (AMI) is a serious cardiovascular disease characterized by myocardial necrosis resulting from acute and sustained myocardial ischemia and hypoxia, usually caused by an abrupt reduction or interruption of coronary blood flow. It remains a major contributor to cardiovascular mortality and disease burden worldwide.

Although early reperfusion therapies, including percutaneous coronary intervention (PCI), together with antiplatelet, anticoagulant, and lipid-lowering treatments, have substantially improved the management of AMI, patients remain at risk of subsequent cardiovascular complications, including recurrent myocardial infarction, heart failure, angina, and arrhythmias. Furthermore, myocardial ischemia/reperfusion injury may aggravate myocardial damage through inflammatory responses, oxidative stress, endothelial dysfunction, and cardiomyocyte apoptosis.

Therefore, improving cardiac function, reducing myocardial injury, and preventing subsequent cardiovascular events remain important therapeutic goals in AMI. This review focuses on AMI and its associated pathological processes, integrating clinical evidence from patients and preclinical evidence from animal models of coronary artery ligation and myocardial ischemia/reperfusion to evaluate the potential therapeutic effects and safety of Xuefu Zhuyu Tang (XFZYT) as an adjunctive treatment.

METHODS

Participant or population Clinical studies: Patients clinically diagnosed with acute myocardial infarction (AMI), without restrictions on age, sex, or disease subtype, provided that the diagnostic criteria were clearly reported.

Preclinical studies: Experimental animals subjected to coronary artery ligation models or myocardial ischemia/reperfusion (I/R) models, regardless of animal species, sex, or body weight.

Intervention Clinical studies: The experimental group receives Xuefu Zhuyu Tang (XFZYT), either the original or modified formula, in combination with conventional Western medical treatment. Studies involving additional adjunctive interventions are eligible only when these interventions are administered equally to both groups and the primary difference between groups is the use of XFZYT.

Animal studies: The experimental group receives XFZYT at various doses.

Comparator Clinical studies: The control group receives the same conventional Western medical treatment as the experimental group, without XFZYT.

Animal studies: The control group receives normal saline or distilled water.

Study designs to be included Randomized controlled trials (RCTs) investigating XFZYT as an adjunctive treatment for AMI, and preclinical animal studies using coronary artery ligation or myocardial ischemia/reperfusion models.Clinical randomized controlled trials (RCTs) and controlled preclinical animal studies meeting the predefined eligibility criteria will be included.

Eligibility criteria Exclusion Criteria: Duplicate publications; reviews, systematic reviews, meta-analyses, clinical protocols, comments, editorials, and case reports; studies not involving XFZYT as an intervention; studies combining XFZYT with other traditional Chinese medicine interventions that were not equally administered to both groups; studies without a control group; studies using animal models unrelated to AMI, including coronary artery ligation or myocardial ischemia/reperfusion models; and studies for which relevant data could not be obtained even after contacting the original authors.

Information sources A comprehensive literature search was conducted in eight electronic databases: China National Knowledge Infrastructure (CNKI), Wanfang Data, VIP Database, Chinese Biomedical Literature Database (CBM), PubMed, Embase, Web of Science, and the Cochrane Library. All databases were searched from their inception to November 2026, without language restrictions. In addition, the reference lists of relevant articles were manually screened to identify potentially eligible studies. Search strategies combining controlled vocabulary and free-text terms were adapted to the specific requirements of each database.

Main outcome(s) Clinical outcomes: The primary outcome was major adverse cardiovascular events (MACE), including the incidence of recurrent myocardial infarction, heart failure, angina, and arrhythmias. Secondary outcomes included other serious complications (e.g., cardiogenic shock);

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cardiac function (LVEF, LVEDD, and LVESD); myocardial injury and cardiac function-related biomarkers (cTnI, CK-MB, BNP, and NT-proBNP); inflammatory and oxidative stress markers (hs-CRP, TNF-α, IL-6, MDA, and SOD); endothelial function (NO, ET-1, FMD, and vWF); lipid profiles (TC, TG, HDL-C, and LDL-C); total clinical effective rate (TCER); and adverse drug reactions/events.

Animal outcomes included myocardial apoptosis index (AI); cardiac function (LVEF and LVFS); myocardial injury markers (LDH, CK, and CK-MB); inflammatory and oxidative stress markers (TNF-α, IL-6, SOD, and MDA); endothelial function and angiogenesis-related indicators (NO, ET-1, VEGF, bFGF, and MVD); and ST-segment changes.

Quality assessment / Risk of bias analysis The methodological quality and risk of bias of the included studies were independently assessed by two reviewers (Yahao Zhang and Adilay Abdulikim). For clinical randomized controlled trials, the Cochrane Risk of Bias 2 (RoB 2) tool was used to assess five domains: the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Each domain was judged as having a low risk of bias, some concerns, or a high risk of bias. For animal studies, the SYRCLE risk of bias tool was used to assess ten domains, including sequence generation, baseline characteristics, allocation concealment, random housing, blinding of caregivers and investigators, random outcome assessment, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and other potential sources of bias. Disagreements between reviewers were resolved through discussion, with a third reviewer (Mukamengjiang Juaiti) consulted when necessary.

Strategy of data synthesis Statistical analyses were performed using RevMan 5.4 and STATA 18.0. Dichotomous outcomes were expressed as risk ratios (RRs) with 95% confidence intervals (CIs). For continuous outcomes, mean differences (MDs) with 95% CIs were used when studies employed the same measurement methods and units, whereas standardized mean differences (SMDs) with 95% CIs were applied when different measurement methods or units were used. Clinical continuous outcomes were analyzed using post-treatment values at the end of the treatment period.

Statistical heterogeneity was assessed using the I^2 statistic. A fixed-effect model was applied when $I^2 \leq 50\%$, while a random-effects model was used when $I^2 > 50\%$, after checking the accuracy of data extraction and coding. Sensitivity analyses were performed using the leave-one-out method and, where appropriate, by excluding studies with a high risk of bias. When more than ten studies were available for an outcome, publication bias was assessed using funnel plots, Begg's test, Egger's test, and the trim-and-fill method. The certainty of evidence was evaluated using the GRADE approach, and trial sequential analysis (TSA) was conducted to assess the robustness and sufficiency of the cumulative evidence.

Subgroup analysis Subgroup analyses were performed when a sufficient number of studies and comparable data were available to explore potential sources of heterogeneity. For clinical studies, subgroup analyses were conducted according to treatment duration. For animal studies, subgroup analyses were performed according to different experimental models, including coronary artery ligation and myocardial ischemia/reperfusion models.

Sensitivity analysis Sensitivity analyses were performed to evaluate the robustness of the pooled results and identify potential sources of heterogeneity. The leave-one-out method was used by sequentially excluding each individual study to assess its influence on the overall effect estimates and heterogeneity. For outcomes involving studies with a high risk of bias, additional sensitivity analyses were conducted by excluding these studies to examine the stability of the results.

Language restriction No language restrictions will be imposed.

Country(ies) involved China.

Keywords Xuefu Zhuyu Tang; acute myocardial infarction; meta-analysis; trial sequential analysis; cardiac function.

Contributions of each author

Author 1 - Yahao Zhang - Study determination and scheme design; Literature screening and data extraction; Data analysis and interpretation; Article writing; Article review and final approval.

Author 2 - Filkati Yushanjiang - Study determination and scheme design; Literature screening and data extraction; Data analysis and interpretation.

Author 3 - Adilay Abdulikim - Article review and final approval.

Author 4 - Yan Gao - Article review and final approval.

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Author 5 - Mukamengjiang Juaiti - Literature screening and data extraction; Article review and finalapproval.

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