

INPLASY202650004

doi: 10.37766/inplasy2026.5.0004

Received: 1 May 2026

Published: 1 May 2026

Zhou, CH; Chang, TY; Guo, JJ.

Corresponding author:

Jiajuan Guo

gj-2005@163.com

Author Affiliation:

Changchun University of Chinese Medicine, Changchun, China.

ADMINISTRATIVE INFORMATION

Support - 1.Evidence-based Capacity Enhancement Program for the Affiliated Hospital of Changchun University of Chinese Medicine (2024) 2.Development of Danzhi Tongmai Granule, a hospital preparation for the treatment of coronary atherosclerotic heart disease, No. 2024C012-4, Industrial Technology Research and Development Project of Jilin Provincial Development and Reform Commission.

Review Stage at time of this submission - Data analysis.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202650004**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 1 May 2026 and was last updated on 1 May 2026.**INTRODUCTION**

Review question / Objective Based on the PICOS framework, this systematic review and meta-analysis was conducted to comprehensively evaluate the efficacy and safety of monascus preparations in patients with carotid atherosclerotic plaque, and to further clarify the intervention effect and application prospect of monascus preparations for carotid plaques.

Condition being studied Carotid atherosclerosis is a common chronic vascular disease, with carotid atherosclerotic plaque as its main pathological manifestation. The continuous progression of plaques can lead to arterial stenosis and insufficient cerebral perfusion, thereby elevating the risk of ischemic stroke and adverse cardio-cerebrovascular events. Monascus preparations have lipid-regulating and anti-atherosclerotic properties and are widely applied in the clinical

intervention of carotid plaques. However, the conclusions regarding their efficacy and safety in improving plaque morphology and stabilizing plaques remain inconsistent, and relevant evidence lacks systematic integration. Therefore, based on the PICOS framework, this systematic review and meta-analysis will comprehensively evaluate the clinical efficacy of monascus preparations, so as to provide evidence-based references for clinical application.

METHODS

Search strategy Literature will be retrieved from Chinese databases including CNKI, VIP, Wanfang and SinoMed, as well as English databases including PubMed, EMBASE, Cochrane Library and Web of Science. Randomized controlled trials focusing on monascus preparations for carotid atherosclerotic plaque will be included. The search terms will mainly cover “Xuezhikang”, “Zhibituo”

and “atherosclerotic plaque”. Unpublished literature will be excluded.

Participant or population Adult patients with confirmed carotid atherosclerotic plaque, without restrictions on gender, age or race.

Intervention The included patients was given basic treatment. On this basis, the treatment group was treated with Xuezhikang, Zhibituo, Xuezhikang combined with statins, or Zhibituo combined with statins.

Comparator The included patients was given basic treatment. On this basis, the control group was treated with the above basic treatment alone, or additional statin therapy.

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

Eligibility criteria

(1)Inclusion criteria:

The study design is randomized controlled trials (RCTs) ;

Study subjects met clear diagnostic criteria for carotid atherosclerotic plaque formation;

Interventions were monascus preparations (Xuezhikang, Zhibituo), administered alone or in combination with statins for the treatment of carotid plaques;

Studies with a control group;

Intervention duration was at least 2 weeks;

Studies with complete data available for carotid plaque-related outcome indicators;

Studies provided mean±standard deviation (SD) at baseline and at the end of treatment, as well as 95% confidence intervals (CI) for the corresponding outcomes.

(2)Exclusion criteria:

In vitro or animal experiments;

Nonrandomized controlled trials, cohort studies, case reports, literature reviews, meeting abstracts, or studies with inappropriate intervention or control groups;

Studies lacking sufficient data or with unclear presentations;

In cases of duplicated studies, we only included the most recent or the most comprehensive ones.

Information sources Literature will be retrieved from eight electronic databases, including CNKI, VIP, Wanfang, SinoMed, PubMed, Embase, Cochrane Library and Web of Science.

Main outcome(s) The primary outcomes of this review mainly include intima-media thickness,

maximum plaque thickness, the number of plaques, plaque score, and plaque area.

Data management The two researchers extracted data from the included literature simultaneously, mainly including the authors, publication year, patient age, intervention measures, control measures, outcome indicators, course of disease, and course of treatment. They used Excel spreadsheet tools to record and check each other carefully, and the third researcher would help solve any differences.

Quality assessment / Risk of bias analysis Using the risk bias assessment tool in Cochrane Systematic Review Manual 5.1, the risk of bias was evaluated from the following seven aspects: the generation of random sequence, the implementation of allocation hiding, whether subjects used blindness, whether researchers used blindness, the completeness of outcome indicators, the generation of selective reports, and the existence of other biases.

Strategy of data synthesis Revman 5.4 software was used for analysis. Relative risk (RR) and mean difference (MD) were used as efficacy indicators for counting data and continuity variables. If the numerical units were inconsistent, standardized mean difference (SMD) was used for analysis. The χ^2 test was used to test the heterogeneity of results. If $I^2 \leq 50\%$ and $P \geq 0.1$, it was considered that the heterogeneity among studies was small, and the fixed effect model was used; if $P > 50\%$, it was considered that there is great heterogeneity among studies, and the source of heterogeneity should be further evaluated through subgroup analysis or sensitivity analysis. The results show that $P < 0.05$ is statistically significant through forest map. If the combined analysis is not viable, the descriptive analysis should be utilized. Inverted funnel plots were used to determine potential publication bias when more than 10 studies were included in the meta-analysis.

Subgroup analysis Subgroup analysis will be conducted based on different control measures. Included studies will be stratified by control types, including conventional basic treatment and statin agents.

Sensitivity analysis Sensitivity analysis will be performed via RevMan 5.4 to evaluate the stability and reliability of the meta-analysis results. Specifically, leave-one-out analysis will be conducted by sequentially omitting each individual study to observe changes in the pooled effect size and 95% confidence interval. Studies with a high

risk of bias or incomplete data will be excluded to explore the influence of low-quality literature on the overall outcomes. Meanwhile, differences in pooled estimates between the fixed-effect model and random-effect model will be compared. No significant fluctuation in the pooled results indicates strong robustness of the findings; otherwise, the potential influencing factors will be further discussed and explained.

Language restriction English; Chinese.

Country(ies) involved China.

Keywords Carotid Plaque, Atherosclerotic; Humans; Drugs, Chinese Herbal; Monascus preparations; Xuezhikang; Zhibituo.

Contributions of each author

Author 1 - Chuhan Zhou.

Author 2 - Tianying Chang.

Author 3 - Jiajuan Guo.