Title: Clinical Study on the Intervention of Xuesaitong Soft Capsules in Post-Intervention Patients with Acute Coronary Syndrome and Exploration of Molecular Mechanisms Clinical Research Protocol

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Clinical Research Protocol

Title	Clinical Study and Molecular Mechanism of Xuesaitong Soft Capsule in the Treatment of Acute Coronary Syndrome After Percutaneous Coronary Intervention
Version Number	2024XLA098-2
Responsible Institution	Xiyuan Hospital of China Academy of Chinese Medical Sciences
Target Population	Patients with Acute Coronary Syndrome (ACS) after Percutaneous Coronary Intervention (PCI), both male and female, aged between 18 and 80 years.
Objective	To interpret the microcosmic manifestations of ACS development using multi-omics technologies, explore key biomarkers and the correlation Objective between disease and syndrome, and elucidate the macro and microcosmic manifestations and biological basis of Xuesaitong soft capsule in the treatment of ACS from multiple perspectives.
Study Design	Single-center, open-label, exploratory clinical study.
Sample Size	50 ACS patients post-PCI in an open-label group.
Study Duration	From October 13, 2024, to December 1, 2026.
Inclusion Criteria	(1) Patients diagnosed with acute ST-segment elevation myocardial infarction, acute non-ST-segment elevation myocardial infarction, or unstable angina according to Western medical standards. Inclusion Criteria. (2) Within 4 weeks post-PCI. (3) Aged between 18 and 80 years, both male and female. (4) Voluntarily participating in the clinical trial, having signed the informed consent form.

Exclusion Criteria	(1) Uncontrolled hypertension after medication (systolic BP > 180mmHg or diastolic BP > 110mmHg). (2) Increased bleeding risk: history of hemorrhagic stroke; intracranial aneurysm; major trauma or surgery within the past month (including Exclusion Criteria bypass surgery); active bleeding disorders. (3) History of gastrointestinal ulcers or significant gastrointestinal bleeding. (4) Severe organic heart disease, such as LVEF < 35% or NYHA/Killip heart function grade IV. (5) History of malignant arrhythmias within the past year (arrhythmias affecting hemodynamics requiring medication or electrical cardioversion, or requiring CPR), congenital heart disease, or malignant tumors. (6) Severe liver or kidney dysfunction: ALT or AST ≥ 3×ULN, TBIL ≥ 2×ULN, or creatinine clearance < 30ml/min. (7) Pregnant or lactating women. (8) Recent blood donation or significant blood loss within the past 3 months (≥400ml). (9) History of alcohol abuse (≥28 standard units/week for males, ≥21 standard units/week for females) or frequent alcohol consumption in the past 6 months (≥14 standard units/week). (10) History of drug abuse or dependence within the past year. Participation in other clinical trials and taking trial drugs within the past 3 months. (11) Allergy or intolerance to aspirin or P2Y12 receptor inhibitors. (12) Allergy to any components of the trial drug. (13) Other conditions deemed inappropriate for participation by the investigator.

Medication Information	Trial Drug: Xuesaitong Soft Capsule. Main Component: Panax Notoginseng Saponins. Dosage Form: Capsule. Dosage and Administration: Orally after meals, 0.33g per capsule, 2 capsules per dose, twice daily. Storage Conditions: Room temperature, cool, dry place.
Medication Regimen	Conventional Western medical treatment (oral medication and standard PCI) combined with Xuesaitong soft capsule, 0.33g per capsule, 2 capsules per dose, twice daily for 4 weeks.
Study Procedure	Participants who meet the diagnostic criteria, inclusion, and exclusion criteria, and have signed the informed consent form will be included in the study. The open-label study period is 4 weeks, including 2 visits: Visit 1 (-1D to 0D) and Visit 2 (4w ± 3d), with no follow-up period.
Evaluation Criteria	(1) General Information: Demographic data, physical examination, medical history, allergy history, smoking and alcohol history, concomitant medications. (2) Multi-omics Analysis: Including platelet transcriptomics, metabolomics, proteomics, microbiomics. (3) Platelet Function: platelet granule markers (PF4 and β-TG), surface activation markers (P-selectin/CD62P, GPIIb/IIIa complex/CD41/CD61), platelet-leukocyte aggregation (CD41 and CD15). (4) Safety Indicators: Routine blood, urine, and stool tests (including occult blood), liver and kidney function tests, ECG, coagulation function, and adverse event recording.
Statistical Analysis Plan	1. Analysis Data Sets 1.1 Full Analysis Set (FAS): Defined according to the ITT principle, including all enrolled participants who received at least one treatment.

	1.2 Per-Protocol Set (PPS): Includes participants who met inclusion criteria, completed treatment and follow-up, had medication compliance between 80-120%, did not use concomitant medications affecting efficacy evaluation, had complete main outcome data, and no major protocol violations. 1.3 Safety Set (SS): Includes all enrolled participants who received at least one treatment. Baseline data analysis will be conducted separately for FAS and PPS. Efficacy indicators will be analyzed for both FAS and PPS. Safety and adverse events will be analyzed for SS. 2. Statistical Method Description 2.1 Enrollment Analysis: List the number of enrolled and completed cases, and determine the analysis data sets (PPS, SS). 2.2 Demographic and Baseline Analysis: Descriptive statistics for demographic data and other baseline characteristics: Continuous variables: Calculate the number, mean, standard deviation, median, minimum, and maximum values. Categorical and ordinal data: Calculate frequencies and proportions. Inferential statistical results (P-values) will be listed as descriptive results. Age factors should be considered in data analysis, and data should be stratified or grouped by different age groups. 2.3 Efficacy Analysis: Primary Efficacy Indicators: Evaluate treatment effects through multi-omics analysis and platelet function indicators. Use descriptive and inferential statistical methods such as t-tests, chi-square tests, and Cox regression analysis to compare pre- and post-treatment differences. Secondary Efficacy Indicators: Include safety indicators and adverse event records. Use descriptive statistical methods such as frequency analysis and percentage calculations to describe the incidence and severity of adverse events.

	2.4 Safety Analysis: Number and rate of laboratory indicators or physical examination abnormalities after treatment. List abnormal laboratory indicators, abnormal physical examination cases, and clinical interpretations. 2.5 Laboratory Data: Analyze changes in laboratory test results before and after treatment using paired t-tests or Wilcoxon signed-rank tests. 2.6 Adverse Events: Describe the types, frequencies, and severities of adverse events using chi-square tests or Fisher's exact tests for comparisons. 2.7 Multiple Comparison Adjustments: For multivariable statistical analyses, use Bonferroni correction or Holm-Bonferroni method to adjust significance levels and control type I error rates. 2.8 Critical Assumption Verification: Certain statistical methods require critical assumptions such as normality and homogeneity of variance. Verification methods include: Normality Test: Shapiro-Wilk test or Kolmogorov-Smirnov test. Homogeneity of Variance Test: Levene's test or Bartlett's test. This statistical analysis plan ensures the scientific rigor and reliability of data analysis. All statistical analyses will be performed using SAS or R software by professional statisticians