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

Informed Consent Form

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Dear Patient,

You have been diagnosed with Acute Coronary Syndrome (ACS). We invite you to participate voluntarily in a multicenter, randomized, double-blind, placebo-controlled clinical study and molecular mechanism exploration of the intervention of Xuesaitong soft capsules in post-intervention ACS patients. We sincerely thank you for your participation. Before deciding whether to participate, it is necessary for you to understand the purpose of this study, the trial medication, the potential risks, what will be expected from you during the trial, and your rights as a participant. Please read this participant information carefully.

1. Study Background

Despite significant improvements in clinical outcomes for ACS patients through coronary intervention and the use of antiplatelet and lipid-regulating drugs, there remains a high risk of adverse cardiovascular events and bleeding risks from long-term antiplatelet therapy, with a one-year adverse event rate of about 10%. This remains a major cause of mortality and disability from cardiovascular disease.

On the basis of previous research, this study aims to leverage the advantages of traditional Chinese medicine (TCM) for promoting blood circulation and removing blood stasis to develop a combined TCM and Western medicine approach that can further reduce adverse cardiovascular events and bleeding risks in post-intervention ACS patients. Our previous clinical and basic research demonstrated that Xuesaitong soft capsules, which are composed of Panax notoginseng saponins (PNS), can enhance the antithrombotic effects of dual antiplatelet drugs and reduce the risk of gastrointestinal and cerebral hemorrhage.

Based on the medical need and our prior work, this study adheres to evidence-based medicine research standards to objectively evaluate the efficacy, safety, and mechanisms of Xuesaitong soft capsules in high-risk post-intervention ACS patients.

2. Study Introduction

This study is funded by the 2024 Chinese Academy of Traditional Chinese Medicine Xiyuan Hospital's Project for Leading Research (No. XYZX0204-02) and follows the Helsinki Declaration. The study protocol has been approved by the Ethics Committee of Xiyuan Hospital of the Chinese Academy of Traditional Chinese Medicine.

The study will be led by Xiyuan Hospital of the Chinese Academy of Traditional Chinese Medicine and is expected to involve 50 voluntary patients.

This is an open-label exploratory clinical trial, enrolling 50 patients. Participants will take Xuesaitong soft capsules for 4 weeks without follow-up observation.

3. Eligibility Criteria

Inclusion Criteria:

- Diagnosed with "post-intervention acute coronary syndrome."
- Aged between 18 and 80 years, irrespective of gender.

- Willing to participate voluntarily, with informed consent signed.

Exclusion Criteria:

- Uncontrolled hypertension (systolic BP >180 mmHg or diastolic BP >110 mmHg).
- Increased bleeding risk: history of hemorrhagic stroke, intracranial aneurysm, recent major surgery or trauma, active bleeding disorders.
- History of gastrointestinal ulcers or significant gastrointestinal bleeding.
- Severe organic heart disease (LVEF <35% or NYHA/Killip class IV).
- History of malignant arrhythmias requiring medical intervention or resuscitation.
- Severe liver or kidney dysfunction (ALT or AST ≥3× ULN, TBIL ≥2× ULN, or Ccr <30 ml/min).
- Pregnant or breastfeeding women.
- Recent history of significant blood loss or donation.
- History of alcohol abuse or drug dependence.
- Recent participation in other clinical trials.
- Allergic to aspirin or P2Y12 receptor inhibitors.
- Any condition deemed unsuitable for the study by the investigator.

4. Study Process

If you decide to participate, the following steps will be taken:

- Detailed screening to confirm eligibility and consent signing.
- Blood tests, ECG, platelet function, liver and kidney function tests at baseline and after 4 weeks of medication.
- Collection of blood (serum and plasma), saliva, and stool samples for multi-omics analysis.
- Regular monitoring and follow-up to assess symptoms and treatment adherence.
- Free medication and related medical tests for study participants.

5. Participant Rights and Benefits

Participation is voluntary, and you can withdraw at any time without affecting your medical care or relationship with the doctor. You will receive appropriate medical services during the study period, and any costs related to the study will be covered. If adverse reactions occur, necessary medical treatment and economic compensation will be provided by Xiyuan Hospital of the Chinese Academy of Traditional Chinese Medicine.

6. Confidentiality

All your personal information, including medical history and test results, will be kept confidential within legal boundaries. Only authorized personnel, ethics committees, and regulatory agencies will have access to your medical records without disclosing your personal identity.

7. Publication

The results of the study, regardless of the outcome, will be published while maintaining confidentiality.

8. Consent

I have read the information provided about this study and have had the opportunity to discuss it with the doctor and ask questions. I understand the potential risks and benefits of participating. I voluntarily agree to participate in this study.

Participant Signature: _____ ID Number: _____ Date: _____

Guardian/Legal Representative Signature: _____ ID Number: _____ Date: _____

Doctor Signature: _____ Date: _____

Thank you for reading the above information. If you decide to participate, please inform your doctor, who will arrange all related matters for the clinical study. Please keep this document.