Informed Consent Form • Information Page

Dear Sir/Madam:

You are invited to participate in a clinical trial entitled "A Study on the Efficacy and Safety of Chinese Herbal Compound Qidan XiaoKe Granules in Patients After Coronary Revascularization."

Before you decide whether to take part, please read the following information carefully. It will help you understand the purpose, procedures, potential benefits, risks, and discomforts of the study. This study has been reviewed and approved by the Medical Ethics Committee of the Third Affiliated Hospital of Zhejiang Chinese Medical University and complies with relevant Chinese regulations and the ethical principles of the Declaration of Helsinki for the protection of research subjects.

Introduction

1. Study Background

You have received coronary stent implantation (medically termed percutaneous coronary intervention, PCI) for coronary heart disease. This is an effective procedure to restore blood flow to the heart and save lives. However, after surgery, some patients may still experience recurrent chest pain, chest tightness, or another cardiac event. Standard conventional drug treatment is very important, but combining traditional Chinese medicine (TCM) for holistic regulation may bring additional benefits for post- operative recovery.

Our team’s preliminary research has found that a TCM compound named "Qidan XiaoKe Granules" (composed of Astragalus, Pheretima, Salvia, etc.) may help relieve residual symptoms after stenting and potentially reduce the risk of adverse cardiac events. This conclusion, however, needs to be confirmed through more rigorous scientific research. Therefore, we are conducting this clinical study to scientifically evaluate whether this Chinese herbal medicine, together with conventional Western medicine, is safe and effective for patients like you after stenting.

2. Study Purpose

The main purpose of this study is to see whether adding Qidan XiaoKe Granules or an identical- looking/tasting placebo (containing no active drug) to your current conventional Western medicine regimen can better reduce the risk of serious heart problems (such as recurrent heart attack or repeat surgery) within one year after surgery. At the same time, we will also assess the effects of this Chinese medicine on your symptoms, quality of life, and various physical

parameters, as well as its safety.

3. What will I need to do if I participate?

(1) The coordinating center of this study is located in the Department of Cardiovascular Medicine, the Third Affiliated Hospital of Zhejiang Chinese Medical University (Zhejiang Zhongshan Hospital). Approximately 164 participants are expected to voluntarily enroll. Eligible patients will be randomly assigned by the doctor to either the experimental group or the control group:

• Group A: Receive conventional Western medicine + Qidan XiaoKe Granules.

• Group B: Receive conventional Western medicine + matching placebo (identical appearance and taste).

Neither you nor your study doctor will know which group you are assigned to until the study ends. This ensures the objectivity of the results.

The entire study lasts about 48 weeks (approximately 11 months), including a 12-week treatment period and a 36-week follow-up period. You will need to complete a total of 6 visits (Day 0, Week 6, Week 12, Week 24, Week 36, Week 48). At each visit, the doctor will ask about your health, perform a TCM symptom assessment, ask you to complete a quality-of-life questionnaire, and conduct blood tests, echocardiography, and Holter monitoring as scheduled. You will need to take the study medication (granules dissolved in warm water, twice daily) on time every day and keep the packages for verification.

Through a rigorous multicenter, randomized, double-blind, placebo-controlled trial, we aim to evaluate the efficacy and safety of Qidan XiaoKe Granules in patients after coronary revascularization, develop a TCM rehabilitation plan and evaluation system, and provide high-level evidence-based support for TCM prevention and treatment of coronary heart disease.

4. What are the main eligibility criteria for participants?

(1) Inclusion criteria (all must be met):

① Age 18–80 years;

② Both sexes;

③ Meet diagnostic criteria for coronary heart disease;

④ Have undergone successful PCI;

⑤ Voluntarily sign informed consent.

(2) Exclusion criteria (any one will exclude participation):

① Severe liver or kidney dysfunction;

② Severe electrolyte imbalance;
③ Severe hematologic disease or malignancy;
④ Pregnancy or breastfeeding;
⑤ Psychiatric disorder;
⑥ Cognitive impairment (e.g., dementia, post- stroke cognitive impairment) preventing normal communication;
⑦ Planned repeat revascularization in the near future;
⑧ Other severe cardiovascular diseases: uncontrolled hypertension, angina, tachyarrhythmias, high- degree or complete AV block (without pacemaker), severe aortic stenosis, decompensated heart failure (NYHA IV), deep vein thrombosis, obstructive hypertrophic cardiomyopathy, acute pericarditis/myocarditis, infective endocarditis, acute aortic dissection, etc.;
⑨ Acute pulmonary embolism or chronic lung disease with dyspnea at rest or on minimal exertion;
⑩ Bleeding risk within 1 month: history of bleeding, active bleeding, bleeding diathesis, current use of anticoagulants;
⑪ Participation in another interventional clinical trial within the last 1 month;
⑫ Known allergy to any ingredient of Qidan XiaoKe Granules;
⑬ Any other condition judged by the investigator as unsuitable for participation.

5. Are there alternative treatments available?

For patients after coronary stenting, the standard treatment is long- term use of guideline- directed conventional drugs (e.g., aspirin, statins), which are effective in preventing thrombosis and controlling lipids. The advantage is proven efficacy; the disadvantage is that some patients still have residual symptoms. Other alternatives include other TCM formulas, acupuncture, and rehabilitation exercises (e.g., Baduanjin). They can be used as adjuncts, but the level of evidence for their efficacy varies among individuals.

The approach used in this study is the addition of the investigational Chinese herb Qidan XiaoKe Granules to standard Western medicine. Potential benefits include additional heart protection and symptom relief; potential disadvantages are that the efficacy is still being validated, and there may be a small risk of unknown adverse reactions from taking an extra medication.

6. If I participate, what will I need to do?

This is a multicenter, prospective, randomized, double- blind,

placebo-controlled, superiority trial. A computer-generated randomization list with stratified block randomization (stratified by center) will be used. You have a 50% chance of being assigned to the experimental group or the control group. Neither you nor your study doctor will know your assignment (unless emergency unblinding is required), which ensures objectivity.
If you agree to participate, you will need to:
①Medication: Take the study medication (granules dissolved in warm water, twice daily) and your conventional Western medicine on time every day for 12 weeks.
②Visits: Come to the hospital for 6 visits: Day 0, Week 6, Week 12, Week 24, Week 36, and Week 48.
③ Assessments:
-At each visit: record your physical condition and symptoms, complete TCM symptom scores and the Minnesota Living with Heart Failure Questionnaire (MLHFQ).
-At selected visits (V0, V2, V5): blood tests (complete blood count, liver/kidney function, cardiac enzymes, lipids, glucose), echocardiography, and 24-hour Holter monitoring.
④Medication record: Keep the medication packages and bring them back at the next visit so that your adherence can be checked.
⑤Cooperation: Inform the study doctor immediately if you experience any discomfort during the study. If an adverse event occurs, you will need to cooperate with the doctor for follow-up and management.

7. What are the potential benefits of participating?

(1) You will receive free study-related medical examinations (including blood tests, echocardiography, Holter monitoring at specified time points).
(2) During the study, you will receive closer attention and follow-up from the research team.
(3) The study medication (Qidan XiaoKe Granules or placebo) is provided free of charge.
(4) Your participation will provide important scientific evidence for the use of TCM in improving post-stenting rehabilitation and may benefit you and future patients. Please note, however, that participation does not guarantee that your condition will improve.

8. What are the risks of participating?

(1) Risks related to the study medication: Qidan XiaoKe Granules are composed of commonly used Chinese herbs, and previous studies

suggest good safety. However, individual differences may occur, such as mild gastrointestinal discomfort (e.g., stomach upset, bloating), dry mouth, or rash. The placebo may also cause psychological discomfort.
(2) Risks related to study procedures: Repeated blood draws may cause local pain, bruising, and, rarely, infection or fainting.
(3) Risks related to the underlying disease: Your coronary heart disease itself carries a risk of cardiac events. Participating in this study will not increase that risk, and the research team will closely monitor and manage any abnormalities.
If you experience any discomfort at any time during the study, please inform your study doctor immediately.

9. Will participating increase my medical costs?

No. All study-related direct expenses (including the scheduled examinations and study medication/placebo) are covered by the research grant. Your routine conventional drugs for coronary heart disease and medical costs for other illnesses will still be paid according to your insurance or out-of-pocket policies.

10. Under what circumstances may the trial be terminated?

① Found after enrollment not to meet inclusion/exclusion criteria;
② Severe adverse reaction or event during treatment, judged by the investigator as requiring termination;
③ Failure to adhere to the protocol (e.g., compliance <80%);
④ Voluntary withdrawal of consent;
⑤ Lost to follow-up;
⑥ Decision by the sponsor or ethics committee to stop the trial.

11. Will I have to pay any costs for participating?

No increase in your medical costs. Study-related examinations and the study medication/placebo are free. Your routine conventional drugs for coronary heart disease and other medical expenses are your own responsibility (insurance or self-pay).
As a token of appreciation for your time and travel expenses, you will receive 40 RMB per completed visit. There are 6 visits in total, so if you complete all visits, you will receive 240 RMB. The compensation will be paid proportionally according to the number of visits you actually complete.

12. Compensation for injury

If you suffer an injury related to this study, confirmed by the Hangzhou Medical Association to be related to the study, we will provide compensation. Compensation will be paid as scheduled and proportionally.

13. Will my personal information be kept confidential?

All information collected during the study will be recorded in the medical records/case report forms (CRF). Your test results (including personal data and laboratory reports) will be kept confidential to the extent permitted by law. Your name will not appear on the CRF; only your initials and subject number will be used. In any publications or presentations, only your initials and subject number will appear if necessary.

When required by law, regulatory authorities, ethics committees, or study sponsors may inspect your study records, but they are also obligated to maintain confidentiality.

14. Do I have to participate?

Participation is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

15. How can I obtain more information?

(1) General inquiries: You may ask questions about the study at any time. Please contact your study doctor, Wang Yanfei, at 15869195971.

(2) Information updates: If any important new information becomes available that might affect your willingness to continue, the doctor will notify you promptly.

(3) Contact for rights and complaints:

For general study information or questions about your rights, you may contact the overall principal investigator, Professor Liu Qiang, at 13588121905.

If you have any complaints, suggestions, or wish to make an independent inquiry about your rights and welfare, you may contact the Medical Ethics Committee of the Third Affiliated Hospital of Zhejiang Chinese Medical University (Tel: 0571-87238255, address: No. 219 Moganshan Road, Xihu District, Hangzhou).

In case of study- related injury, please immediately contact your study doctor, Wang Yanfei (Tel: 15869195971), who will assess and arrange necessary medical care.

16. Medical Ethics Committee

If you have any dissatisfaction with the study, please contact the Medical Ethics Committee of the Third Affiliated Hospital of Zhejiang Chinese Medical University.

Tel: 0571-87238255.

Thank you for reading this information. If you decide to participate, please inform your doctor, who will arrange everything for the study.

Please keep this document for your records.

Informed Consent Form • Signature Page

Statement of Consent

1.I have read this informed consent form, and the study personnel have fully explained the purpose, procedures, risks, and benefits to me.
2.I have had the opportunity to discuss and ask questions about the study, and I am satisfied with the answers.
3.I have had sufficient time to make my decision.
4.I voluntarily agree to participate in this clinical study as described.
5.If I withdraw early because of the study product, I will promptly notify the doctor of any changes in my condition.
6.If my condition changes and I need any other treatment, I will consult the study doctor beforehand or truthfully inform him/her afterward.
7.I agree that regulatory authorities, ethics committees, or study sponsors may access my research records for verification purposes.
8.I will receive a signed and dated copy of this informed consent form.

Finally, I decide to participate in this study and will follow the doctor's instructions.
Signature of subject: _____
Date:_____ month _____ day_____ year
Subject's telephone: _____

Investigator's Statement
I confirm that I have explained the details of this study, including the subject's rights and the potential benefits and risks, and I have given the subject a signed copy of the informed consent form.
Signature of doctor: _____
Date: _____ year _____ month _____ day
Study doctor's contact information: _____
(This page is an essential part of the informed consent form. A valid consent form must have the signature and date of both the subject (or legal representative) and the study doctor.)