Microvascular Angina Intervention with Compound Danshen Dripping Pill(MAIDS)

Informed Notice Page

Dear patient:

We will invite you to participate in a clinical study . This research protocol has been reviewed by the ethics committee and approved for clinical research.

Please read the following as carefully as possible before you decide whether to participate in this study. It can help you understand the study and why it is being conducted, the procedures and duration of the study, and the possible benefits, risks, and discomforts that may occur to you if you take part in the study. If you want, you can also discuss it with your relatives and friends, or ask a doctor to explain it to help you make a decision.

1. Research background and research purpose

1.1 Disease burden and current treatment status

Coronary microvascular disease is one of the important causes of angina pectoris and acute cardiovascular events. Long-term repeated angina pectoris attacks affect the patient's quality of life. Patients with significantly reduced coronary blood flow reserve or myocardial perfusion reserve, especially female patients, may have a higher incidence of adverse cardiovascular events. However, there is currently a lack of specific drugs for coronary microvascular angina, and drugs such as beta-blockers and nitrates are generally used to treat angina. Basic and clinical studies of the traditional Chinese medicine Compound Danshen Dripping Pill have found that it can improve vascular endothelial function and relieve angina pectoris, and is widely used in clinical practice. However, its effect on coronary reserve function and angina pectoris in coronary microvascular disease needs further clinical research to confirm.

1.2 Purpose of this study

This study is a randomized, double-blind, placebo-controlled, multi-center clinical study. Based on previous studies, it deeply explores the effect of Compound Danshen Dropping Pills on coronary blood flow reserve and the efficacy of angina in patients with microvascular angina. The implementation of this study will help further reveal the effect of Compound Danshen Dropping Pills on coronary microvascular disease and

provide new basis for the treatment of coronary microvascular disease. We look forward to having you join us.

2. Who is suitable to participate in the study?

This study plans to enroll a total of 100 patients with chest pain who have no obvious coronary artery stenosis on coronary angiography or coronary CT examination.

All subjects must meet the following conditions :

①Have typical symptoms of exertional angina;

② Coronary artery CTA or angiography examination shows normal coronary artery or stenosis <50%;

③Ischemic downward shift of the ST segment is found in the electrocardiogram at rest or during exercise stress (horizontal or downsloping downward shift behind the J point >0.1mv, lasting 0.08s);

④ Transthoracic ultrasound examination before and after intravenous adenosine injection to check the anterior descending coronary artery blood flow reserve test CFR <2.5;

⑤The patient agrees to participate in this study.

3. Who should not participate in research?

1. Aged less than 30 years old or older than 75 years old;

2. Have a history of carotid endarterectomy or stent implantation, or have a history of stroke;

3. Patients with angina pectoris with coronary artery stenosis >50%;

4. Myocarditis, pericardial disease, valvular disease, cardiomyopathy;

5. Difficult to control diabetes (fasting blood glucose >7.0 mmol/L);

6. Hypertension (SBP>180 mmHg and/or DBP>110 mmHg);

7. familial hypercholesterolemia;

8. Takayasu arteritis;

9. Those who are pregnant or lactating, or those who intend to have a child within one year, or those who have not taken effective contraceptive measures during the childbearing age;

10. Abnormal liver function (serum GPT level exceeds 3.0 times the upper limit of normal) or renal function abnormality (serum creatinine level exceeds 2 mg/dl);

11. Other clinically significant respiratory, digestive, blood, infection, immune, endocrine, neuropsychiatric, tumor diseases, etc., which may cause serious danger to patients ;

12. Patients who require anticoagulant treatment with warfarin; taking nitrates, K channel openers, CCB, ACEI drugs and traditional Chinese medicine preparations that activate blood circulation and remove blood stasis to improve microcirculation ;

13. Those who are allergic to intra-arterial injection of contrast media, blood, or blood products;

14. Patients who are participating in other clinical studies.

4. What will you need to do if you participate in the study?

1. Before you are enrolled in the study, the doctor will ask and record your medical history and coronary angiography or coronary CTA examination, and conduct a physical examination and blood biochemical tests. If you are a qualified participant, you can voluntarily participate in the study and sign the informed consent form. If you do not want to participate in the study, we will treat you according to your wishes.

2. If you voluntarily participate in the research, you will follow the following steps:

(1) Selection stage

This study was divided into a Danshen Dropping Pills treatment group and a placebo group according to a randomized, double-blind, placebo-controlled method. After signing the informed consent form, we will provide your initials, gender, age and other general information to the central random

system, the system will give you a random number based on its random number in the test, and we will give it to you accordingly.

medicine. Dosage of Compound Danshen Dropping Pills or Placebo: 3 times a day, 20 pills each time, taken after meals. The follow-up period was 6 months. Compound Danshen Dropping Pills and placebo have the same appearance, with the main ingredient being starch. Both are produced by Tasly Pharmaceutical Group Co., Ltd.

(2) Follow-up stage

You will be followed up once every 2, 4, and 6 months after you are enrolled in this study. We will ask about your medication status and new symptoms after taking the medication, conduct routine physical examinations, record clinical events, laboratory tests, and ultrasound examinations.

In order to monitor the safety of medication, we will collect blood and urine samples in the 2nd and 4th months after your enrollment in this study and at the end of the study to measure blood and urine routine, liver and kidney function, and blood sugar indicators; Ask about and record adverse reactions and their severity in the medical history. Carry out corresponding laboratory tests when necessary.

In order to observe the endpoint indicators and evaluate the efficacy, we will conduct an exercise test when you are enrolled, and at 2, 4, and 6 months, measure the left anterior descending coronary flow reserve (CFR) by ultrasound, and calculate the difference, and compare the groups. difference between.

3. Other matters requiring your cooperation

You must bring your used drug packaging boxes and relevant medical records to the hospital for treatment at the follow-up time agreed by the doctor and you (during the follow-up period, the doctor may learn about your situation through phone calls or door-to-door visits). Your follow-up visits are very important because your doctor will determine whether the treatment you are receiving is actually working and provide you with timely guidance. You must take medication according to the doctor's instructions, and please fill in your medication records promptly and objectively. You must return unused medicines and their packaging at each follow-up visit, and bring any other medicines you are taking, including medicines you have to continue taking if you have other comorbidities.

5. Possible adverse reactions, risks, discomfort and inconvenience of participating in the study

Possible adverse reactions of the contrast-enhanced adenosine test: When adenosine is applied intravenously, it mainly dilates the coronary arteries, but it also has a dilation effect on peripheral blood vessels. It may cause a drop in blood pressure, dizziness, fatigue and other discomforts, which generally occurs when the application

is relatively difficult. Patients with large doses of adenosine or with low basal blood pressure. When adverse reactions occur, aminophylline can be used to antagonize them. Gastrointestinal discomfort may occasionally occur when taking Compound Danshen Dropping Pills, and the symptoms may disappear after stopping the medication.

If you experience any discomfort during the study, or new changes in your condition, or any unexpected circumstances, whether related to the study or not, you should notify your doctor in time, and he/she will make a judgment and provide appropriate medical treatment. deal with.

During the study period, you need to go to the hospital for follow-up visits and do some examinations on time, which will take up some of your time and may also cause you trouble or inconvenience.

6. Explanation of fees for participating in the trial

During your participation in this trial, laboratory tests (including blood routine, urine routine, prothrombin time, fasting blood glucose, alanine aminotransferase, aspartate aminotransferase, CK, urea nitrogen, creatinine, troponin, high-sensitivity C-reactive protein, troponin, serum creatine kinase, plasma total cholesterol, triglycerides, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol), echocardiography, Exercise stress test, drug stress electrocardiogram and other examinations. There is no need to pay for the expenses incurred by the above related examinations and the transportation expenses incurred by you for timely follow-up visits.

7. Is personal information confidential?

Your medical records (research medical records /CFR , laboratory test orders, etc.) will be completely kept at the hospital where you visited. Your doctor will record the test results in your medical record. The relevant researchers and statisticians of this study will analyze the data related to your participation in this study and will only use it for the publication of research results related to this study. Researchers, ethics committees, and drug regulatory authorities will be allowed access to your medical records. Any public reporting of the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information to the extent permitted by law.

8. How to get more information?

You can ask any questions about this study at any time and have them answered

accordingly. If any important new information becomes available during the study that may affect your willingness to continue participating in the study, your doctor will notify you promptly.

9. You can voluntarily choose to participate in the research and withdraw from the research midway

It is entirely up to you whether you want to take part in a study. You can refuse to participate in this study, or withdraw from this study at any time during the study. This will not affect the relationship between you and the doctor, nor will it affect the loss of your medical treatment or other benefits. For your best interests, the doctor or researcher may discontinue your participation in this study at any time during the study.

If you withdraw from the study for any reason, you may be asked about your use of the study drug. You may also be asked to undergo laboratory tests and a physical examination if your doctor deems it necessary.

10. What to do now?

It is up to you (and your family) to decide whether to take part in this study. Before you make a decision to participate in a study, ask your doctor as many questions as possible.

Thank you for reading the above material. If you decide to participate in this study, please tell your doctor and he or she will make all study-related arrangements for you. Please keep this information.

Informed consent form . Consent signature page

Clinical research project name:Microvascular Angina Intervention with Compound Danshen Dripping Pill(MAIDS)

Project undertaking unit : Qilu Hospital of Shandong University

Statement of consent

I have read the above description of this study and have had the opportunity to discuss and ask questions about this study with my doctor. All of my questions were answered satisfactorily.

I understand the possible risks and benefits of participating in this study. I understand that participation in the research is voluntary, I confirm that I have given sufficient time to consider this, and understand that:

- I can always ask my doctor for more information.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I also know that if I withdraw from the study midway, especially if I withdraw from the study due to drug reasons, it will be very beneficial to the entire study if I tell the doctor about the changes in my condition and complete the corresponding physical examination and physical and chemical examinations.

If I need to take any other medication due to changes in my condition, I will seek the doctor's advice in advance or truthfully tell the doctor afterwards.

I consent to the ethics committee of the drug regulatory authority or the sponsor's representative having access to my research data.

I will be given a copy of the signed and dated informed consent form.

Finally, I decided to agree to participate in this study and promised to follow the doctor's instructions as much as possible.

Patient’s signature: _____Date : ____month_ _day____year

Contact number: _____

I confirm that the details of this trial, including its rights and possible benefits and risks, have been explained to the patient and that I have given the patient a copy of the signed informed consent form.

Doctor’s signature: _____Date : ____month__day, year

Doctor’s work pho*ne number:*_____