ID: 2019ZY003-MERIDIAN

Research name:

A study on the heat transport characteristics of meridian phenomenon for the heart and lung meridians based on patients with stable angina pectoris

Date: March 25, 2019

Informed consent · Informed page

Dear patients:

It is our pleasure to invite you to participate in a clinical research entitled ‘A study on the heat transport characteristics of meridian phenomenon for the heart and lung meridians based on patients with stable angina pectoris’.

Please read the following contents carefully, which will help you understand the details of the study. If you wish, you can discuss it with your relatives and friends, or ask your doctor to give an explanation to help you make a decision.

1. Research introduction

Meridian theory is one of the core contents for traditional Chinese medicine basic theories, which guides almost all clinical practices of acupuncture and moxibustion. The study of meridian theory is of great significance both in theory and clinical application.

The meridian research in China originated in the 1950s and 1960s, mainly exploring the essence of the meridians. With the development of the meridian research, various meridian hypotheses have been put forward, such as neurohumoral regulating hypothesis, vascular and lymphatic hypothesis, double reflex hypothesis, third equilibrium system hypothesis and low flow obstruction channel hypothesis. However, these hypotheses required further improved and verified. Much more efforts are needed before we find the essence of meridians. At present, acupuncture has been widely used in more than 180 countries and regions in the world. Foreign counterparts have also made some achievements in meridian researches. Researchers in South Korea tried to explore the essence of meridians by putting forward the concept of original pipeline system. France was the first country to use infrared thermal imaging technology to investigate the meridians. The optical characteristics of meridians was studied by polarizing detection technique in the former Soviet Union.In England, magnetic detection electrical impedance tomography (MDEIT) was creatively used to show the meridians in three-dimensional images.

To summary, although some important progresses were made in the field of the meridian research, no breakthroughs have been achieved. The essence of meridians

remains unclear and current achievements in meridian researches are not enough to guild clinical practice of acupuncture and moxibustion.Besides,there are some problems in meridian researches, such as disconnection between meridian structure research and meridian functional research, disconnection between basic researches and clinical researches. The research results of meridian phenomena, such as meridian sensation transmission, involve lots of subjective elements.Researches that use scientific techniques to investigate the biological characteristics of meridian phenomenon are urgently needed.

Thus, this project focus on the core theory that meridians reflect the the connection between different regions of the body and choose the Heart and Lung Meridians as the breakthrough point. By including patients with chronic stable angina pectoris (CSAP) and healthy volunteer, we aim to explore the heat transport characteristics of meridian phenomenon for heart and lung meridians by using infrared thermal imaging. In addition, the relative specificity of the two meridians will be investigated. We will explore the relationship between different regions of the body reflected by meridians to summary the characteristics and rules of the relationship.

The results of this study could not only bring new scientific explanations of the meridian theories, but also provide scientific foundation for traditional meridian theories, even raise the reestablishment of theories and promote the development of the discipline of acupuncture and moxibustion.

2. Research objectives

(1)This study aims to assess the heat transport characteristics of meridian phenomenon of Heart and Lung in healthy volunteers and patients with CSAP by using infrared thermal imaging. Thus, the biological characteristics of meridian phenomenon could be presented objectively in a scientific methodology. Besides, the relative specificity of the two meridians will be investigated.

(2)This study aims to build standardized techniques and schemes for detecting the heat transport characteristics of meridian phenomenon for Heart and Lung in different conditions, which includes physiology state and pathological state. Besides,

it could lead to the formation of a standardized, effective clinical therapeutic regimen for treating diseases relevant to Heart and Lung meridians. The results of this study could provide scientific foundation for traditional meridian theories, even raise the reestablishment of theories.

3. What should I do if I participant in this study?

If you meets the inclusion criteria and agree to participant in the study, you will receive a near infrared spectroscopy examination along the meridians. You will be asked to stabilize for 15 minutes in a supine position in the experimental room before formal detection. You need to keep silent and normal breath and avoid limb movement during the whole measuring period. Infrared thermal images and acupoint temperature will be will be recorded for 5 minutes.

4. What is the inclusion and exclusion criteria?

4.1 Inclusion criteria

4.1.1. Inclusion criteria for CSAP

(1) Patients should meet the diagnostic criteria of coronary heart disease, which includes the following items: 1)confirmed old myocardial infarction (MI), or a history of percutaneous coronary intervention(PCI), or coronary artery bypass grafting; 2)50% or more luminal stenosis in at least one coronary artery or major branch segment confirmed by coronary angiogram or CT angiography; 3) myocardial ischemia indicted by exercise stress radionuclide myocardial imaging; 4) treadmill exercise testing is positive (for male patients);

(2) Patients should meet the diagnostic criteria of CSAP and the Canadian Cardiovascular Society(CCS) classification for CSAP is level II or III;

(3) The medical history of angina pectoris ≥3 months, with at least 2 episodes per week in the last month;

(4) 35 ≤ age ≤65 years, male or female;

(5) Patients have clear consciousness and could communicate with others normally;

(6) Patients could understand the full study protocol and have high

adherence .Written informed consent is signed by themselves or their lineal kin.

4.1.2 Inclusion criteria for health volunteers

(1) Healthy volunteers who could provide a recent (in the past 3 month) medical examination report to confirm they have not any cardiovascular, respiratory, digestive, urinary, hematological, endocrine and neurological disease;

(2) 35 ≤ age ≤65 years, male or female;

(3) Participants have clear consciousness and could communicate with others normally;

(4) Participants could understand the full study protocol and have high adherence .Written informed consent is signed by themselves or their lineal kin.

4.2 Exclusion criteria

4.2.1 Exclusion criteria for CSAP

(1) Patients with acute coronary syndrome (including acute myocardial infarction and unstable angina) and severe arrhythmias (such as severe atrioventricular block, ventricular tachycardia, supraventricular tachycardia, frequent premature beats and premature ventricular contraction);

(2) Patients' chest pain is caused by valvular heart disease, hypertrophic cardiomyopathy and dilated cardiomyopathy;

(3) Patients' chest pain is caused by non-cardiac disease (such as severe neurosis, climacteric syndrome, cervical spondylosis, and esophageal/pulmonary/chest wall lesions);

(4) Patients have concomitant conditions of lung diseases, such as COPD;

(5) Patients have serious concomitant conditions and and fail to treat them effectively, such as diseases of the digestive, urinary, respiratory, hematological and nervous system;

(6) Patients have mental illness, severe depression, alcohol dependence or history of drug abuse;

(7) Pregnant or lactating patients;

(8) Patients are participating in other trials.

4.2.2 Exclusion criteria of health volunteers

(1) Participants have sudden severe diseases during the trial, such as cardiovascular diseases, liver diseases, kidney diseases, urinary diseases and hematological diseases.

(2) Participants have mental illness, severe depression, alcohol dependence or history of drug abuse;

(3) Pregnant or lactating participants ;

(4) Participants are participating in other trials.

5. What are the benefits if I participate in the study?

If you participate in this study, it will make you be aware of the health conditions of the Heart and Lung meridians.

6. What is the risk if I participant in this study?

This study will just adopt infrared thermal imaging to assess the heat transport characteristics of meridian phenomenon for Heart and Lung. It will not give participants any other intervention. Thus, generally speaking, adverse events rarely occur during the study and the study will not bring you any risk. Anyway, you could tell the researchers immediately if you feel any uncomfortable during the trial. The researchers will deal with your discomfort as soon as possible.

7. Will my medical expenses increase if I participate in this study?

No. We do not charge any fees in this study. All examinations on the biological characteristics of meridian phenomenon are free.

8. What is the compensation if I participant in the study?

We will offer you 50 yuan each time as traffic expenses at your each visit.

9. What is the compensation if I suffer from serious adverse events during the study?

If you suffer from any serious adverse events due to this study, the researchers will compensate you according to relevant laws and regulations of China.

10. Is personal information confidential ?

Your personal information will be kept in the study record and case report forms. All test results (including your personal information, laboratory test report, etc.) will be kept completely confidential. Your name will not appear directly in the case report

form or published papers, instead, only the abbreviation of your name and the assigned code will appear.

If necessary, members from the drug administration department, ethics committee, or the funding authority of the study will have access to your research material according to relevant regulations.However, without permission, they don't have the right to use the data of your personal information for other purpose or disclose it to other organizations.

11. How to obtain more information ?

You can submit any questions about this study at any time and consult Dr. Hu. His mobile number is 86-18667103032. During the study, the researchers will inform you of any new information promptly that may affect your willingness to continue participating in the study.

12. Will I be forced to take part in the study?

It is your own right to decide whether you want to participate in the study. You could refuse to participate in this study for any reason.

13. Could I quit the study at anytime during the study?

You have the right to withdraw from this study at any time during the research, which will not affect your rights and you will not be discriminated or retaliated against.If you choose to participate in this study, we hope that you will be able to complete the entire research process.

For your best interest and benefits, a physician or researcher may suspend your participation in the study at any time during the study.

If you withdraw from the study due to any reasons, you may be asked relevant information.If the physician thinks it is necessary, you may also be asked to carry out a laboratory examination and physical examination. You may also refuse the request and you will not be discriminated or retaliated against.

14. What should I do now?

Whether to participate in this study is decided by yourself.You can also discuss it with your family or friends before making a final decision. Before you make your decision, please ask your doctor about more details so that you could completely

understand the study.

15. How to contact the ethics committee?

If you have any problems or complaints during the study, please contact the Ethics Committee of Zhejiang Chinese Medical University.

Address: No.548, Binwen road, Binjiang district, Hangzhou city, Zhejiang province.

Tel: 0571-86613536

Officers: Yingyin Mao

Thank you for reading the informed consent form. If you decide to participate in this study, please tell the researchers, they will arrange all the matters for you. Please keep this informed consent form by yourself.

Informed consent · Signature page

Patient’s statement

1. I have read this informed consent form, and the doctor has explained the purpose, contents, risks and benefits of this experiment to me in details.
2. I have discussed and asked relevant questions about this study and I am satisfied with the answers.
3. Plenty of time is offered to me for making a decision on whether I should participant in this study.
4. I participate in this clinical study on my own decision.
5. If I withdraw from the trial due to the reasons related to the study, I will inform the doctors of the change of my health condition in time.
6. If I receive any additional treatments due to the change of my health condition, I will seek for the doctor's advice in advance or tell the doctors afterwards.
7. I allow members from the drug administration department, ethics committee, or the funding authority of the study to have access to my research materials.
8. I will receive a copy of the signed informed consent with the date written on it.

Finally, I have decided to participate in this study.

Patient’ signature:

Date：

Contact number:

Doctor's statement

I confirm that the details of the trial have been explained to the patients, including its right, possible benefits and risks. A copy of the informed consent has been signed to the patient.

Researcher's signature:

Date：

Contact number: