Multi-center study on new cardiovascular remodeling and function parameters in hypertension （Observational study）

Informed Consent

Dear patient:

You are evaluated as a patient with primary hypertension. We will invite you to participate in a national multi-center research project on hypertensive cardiac remodeling and prognosis. This study is a follow-up observational study to observe the prognosis of outpatient and hospital patients. This research scheme has been reviewed by the Ethics Committee of Qilu Hospital of Shandong University and approved for clinical research.

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

Background and objective

1. Current disease situation

Hypertension is the most important risk factor for the morbidity and mortality of cardiovascular and cerebrovascular diseases in China. According to the latest data of China Hypertension Survey, the prevalence rate of hypertension among residents aged over 18 years in China from 2012 to 2015 was 27.9% (the standardized rate was 23.2%). Compared with the five nationwide hypertension sampling surveys conducted in 1958-1959, 1979-1980, 1991, 2002 and 2012, although the total number, age and diagnostic criteria of each survey were not completely consistent, the prevalence rate was

generally increasing. However, the awareness rate, treatment rate and control rate (gross rate) of hypertension patients in China have improved significantly in recent years, but they are still at a low level, reaching 51.6%, 45.8% and 16.8% respectively. At present, the most important complication of hypertension in China is stroke, and the incidence of coronary heart disease has also increased significantly. Other complications include heart failure, left ventricular hypertrophy, atrial fibrillation, and end-stage renal disease. The population monitoring data in China shows that the death rate of cardiovascular and cerebrovascular diseases accounts for more than 40% of the total deaths, the annual incidence rate of stroke is 250/100000, and the annual incidence rate of coronary heart disease events is 50/100000. Hemodynamic overload caused by hypertension can lead to left ventricular remodeling, functional changes and left atrial enlargement, usually manifested as significant changes in the geometry of the left ventricle, such as concentric hypertrophy (CH) and eccentric hypertrophy (EH). Left ventricular hypertrophy is an adaptive process after the increase of hemodynamic load, and is also a manifestation of target organ damage. Epidemiological studies have confirmed that changes in the geometry of the left ventricle may be harmful and have the risk of increasing the incidence rate and mortality of cardiovascular disease. Hypertension, left atrial enlargement, atrial fibrillation and cerebral embolism constitute an important event chain that is easy to be ignored. There are few studies on hypertension remodeling and prognosis, and many studies have shown that there are differences in cardiac reference parameters among different ethnic groups. The establishment of a large multicenter study on hypertension remodeling and prognosis in China is conducive to understanding the current situation and prognosis of cardiovascular remodeling in the Chinese hypertensive population, guiding the choice of drugs and treatment plans, and helping to improve awareness, treatment and understanding of hypertension in China.

2. Objective

To advance early understanding of the type and outcome of left ventricular remodeling and left atrial enlargement in hypertension in China; To explore the relationship between different configurations of left ventricle in hypertension and cardiovascular events.

1.3 Participate centers and patients

This project is a national multi-center clinical research project. There are 20 hospitals participating in this research project. It is estimated that 2200 patients will be included in this project, with a follow-up period of 4 years.

Who is suitable for participating in the research

All participants must meet the following criteria:

(1) Age 30-75 years old;

(2) No antihypertensive drugs were used and three blood pressure measurements were conducted on different days, with systolic blood pressure ≥ 140 mmHg (1 mmHg=0.133 kPa) and/or diastolic blood pressure ≥ 90 mmHg; or have a history of hypertension and are using antihypertensive drugs, even if the blood pressure is lower than 140/90 mmHg;

(3) Left ventricular ejection fraction was normal (LVEF ≥ 0.5).

(4) All patients agreed to participate in the experiment and signed the informed consent form.

Who should not participate in the research:

(1) Secondary hypertension caused by renal parenchymal diseases, renal vascular diseases, coarctation of aorta and endocrine system diseases;
(2) Severe cardiovascular and cerebrovascular diseases; heart valve disease; persistent atrial fibrillation and severe arrhythmia; previously undergone cardiovascular disease surgery;
(3) Abnormal liver function; abnormal renal function and diabetes;
(4) Pregnant or breastfeeding women;
(5) Expected survival time due to non-cardiovascular disease<4 years;
(6) Patients with poor echocardiographic image quality.

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

(1) If you are enrolled in the study, the doctor will ask and record your medical history, laboratory examination results, and perform physical examination, cardiac color ultrasound, and carotid ultrasound. As 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 according to your wishes.

(2) If you want to participate in the study, you will follow the following steps:

We will introduce the current situation and clinical significance of the study, the benefits of your participation from the research project, the research process cycle, and the follow-up time, matters needing attention (For example, you will get professional guidance and monitoring of blood pressure diagnosis and treatment when you participate in this project. You need to carry out physical examination on the day of enrollment, including measurement of blood pressure and heart rate, ECG examination, blood lipid, blood glucose and other laboratory examinations, carry out two ultrasonic cardiograms and carotid ultrasound examinations with an interval of more than 4 hours, and come to the hospital at 12th months, 24th months, 36th months and 48th months. After enrollment, you should conduct ECG and ultrasound during the follow-up, echocardiogram and carotid artery ultrasound, record blood pressure, heart rate, your medication and other indicators).

(3) Other matters requiring your cooperation

You need to bring all the previous detailed information to the hospital according to the follow-up time (during the follow-up period, the doctor may know your situation by phone or visiting). Your follow-up is very important because your doctor will assess your risk situation and guide your treatment.

This study is a prospective observational study, and your current and future medication will not be affected. If you need other treatment, you can consult the corresponding specialist, but you need to report to us.

(4) If you have any problems with cardiovascular and cerebrovascular diseases, please contact us in time.

Possible benefits of participating in the study

With participating in this study, you can understand the type of cardiac remodeling, peripheral vascular disease and its evolution, and obtain professional advice and suggestions from cardiovascular specialists.

Possible adverse events, risks, discomfort and inconvenience of participating

This study is an observational study. Ultrasound examination is safe, simple, and free from adverse reactions and risks. If you have any discomfort, or new changes in your condition, or any unexpected situation during the study, regardless of whether it is related to the study, you should notify your doctor, who will make a judgment and give appropriate medical advice. During the study period, you need to visit the hospital on time with examinations, which take up some of your time and may also cause you trouble or inconvenience.

Expenses

The examinations you participated in this study (only recording the results of routine laboratory examinations that have been carried out to assess the disease condition, no additional laboratory examinations due to the project, and the first cardiac ultrasound and carotid ultrasound that are required to assess the condition) are all routine items that need to be monitored for standardized management of diseases in the guidelines, and no additional fees are paid for this study. During the study period (the second cardiac and carotid ultrasound examination and follow-up cardiac and carotid ultrasound examination at an interval of 4 hours on the day of enrollment), cardiac and carotid ultrasound can be performed free of charge. The selected follow-up time point is the routine follow-up time to evaluate the changes of hypertension and drug use, and there is no follow-up required for extraneous examinations.

Is personal information confidential?

Your medical records (research medical records/CRF, test sheets, etc.) will be completely saved in the hospital where you visit. The doctor will record the examination results on your medical record. Researchers, ethics committees and

relevant departments are allowed to access your medical records. Any public report on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data to the extent permitted.

How to get more information?

You can ask any questions about this research at any time and get corresponding answers. If there is any important new information during the study that may affect your willingness to continue to participate in the study, your doctor will tell you.

You can choose to participate in the study or withdraw from the study

Whether to participate in the study depends entirely on your wishes. You can refuse to participate in this study, or withdraw from this study at any time, which will not affect the relationship between you and your doctor, nor will it affect the loss of your medical or other benefits.

For your best interests, the doctor or researcher may suspend your participation in this study at any time during the study.

What should I do now?

Participation in this study is up to you (and your family). Before you make a decision to participate in the study, please ask your doctor for relevant questions as much as possible.

Thank you for reading the above materials. If you decide to participate in this study, please tell your doctor that he/she will arrange all the affairs related to the study for you. Please keep this information.

Informed consent form. Consent signature page

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Subject 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 the study with my doctor. All the questions I raised got a satisfactory reply.

I am aware of the possible risks and benefits of participating in this study. I understand that participation in the study is voluntary, I confirm that I have had 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 halfway, if I tell the doctor about the changes in my condition and complete the corresponding physical examination and physical and chemical examination, it will be very beneficial to the whole study.

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

I agree that the ethics committee or researcher representative can access my research materials.

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

In the end, I decided to agree to participate in this study and pledged to do my best to follow my doctor's orders.

Patient signature_____ Date:____, ____

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 given a copy of the signed informed consent.

Doctor's signature:_____ Date:____, ____

Doctor's work phone: _____