Informed Consent Form

2024.05

Study Name: Multi-center Prospective Cohort Study on the Evaluation of Carotid Plaque Vulnerability and Prediction of Cardiovascular and Cerebrovascular Event Risks via Ultrasound Imaging

Organizing Institution: Department of Ultrasound Medicine, Shanghai First People's Hospital

Dear Sir/Madam:

We are inviting you to participate in the "Multi-center Prospective Cohort Study on the Evaluation of Carotid Plaque Vulnerability and Prediction of Cardiovascular and Cerebrovascular Event Risks via Ultrasound Imaging" initiated by the Department of Ultrasound Medicine, Shanghai First People's Hospital.

This informed consent form aims to help you decide whether to participate in this clinical study. This document explains the purpose, procedures, potential risks and benefits, discomfort, and considerations of participating in the study. It also explains your right to withdraw from the study at any time. Before making a decision, please read this informed consent form carefully and ensure that you fully understand it. Please ensure that your questions are answered to your satisfaction. If you have any questions, please consult the attending physician or research staff at any time. However, please note that we cannot make any promises about the results of the study.

If you participate in this study, you will receive a copy of the informed consent form signed by you and the researcher.

Purpose of the Study

Current imaging techniques for detecting carotid plaques mainly include high-resolution MRI enhancement imaging, CT enhancement imaging, optical coherence tomography, PET-CT imaging, etc. However, due to factors such as insufficient spatial resolution, high cost, long duration, poor patient tolerance, and allergic reactions to contrast agents, these imaging methods have not yet become routine screening methods.

Ultrasound examination remains the most commonly used method for screening carotid plaques, as it has the advantages of convenient operation, good reproducibility, non-invasiveness, and no radiation. This study aims to collect an ultrasound imaging dataset of patients with carotid plaques and establish a plaque vulnerability assessment model based on ultrasound imaging indicators, clinical history, and laboratory indicators. Based on the occurrence of cardiovascular and cerebrovascular events and ischemic stroke in patients during the 3-year follow-up period, we will

explore the value of ultrasound imaging in assessing the vulnerability of carotid plaques and predicting the risk of cardiovascular diseases such as myocardial ischemia and stroke. Furthermore, we will establish a cardiovascular and cerebrovascular risk prediction model for patients with plaques based on multi-dimensional data indicators such as clinical data and ultrasound imaging data, forming a risk warning tool suitable for clinical use.

Project Introduction

This is a prospective multi-center cohort study aiming to collect 600 patients with carotid plaques from six participating centers. The follow-up period is 36 months, starting from the collection of cases. We will observe whether patients develop or recur with cardiovascular and cerebrovascular diseases to explore the value of ultrasound imaging in assessing the vulnerability of carotid plaques and predicting the risk of cardiovascular and cerebrovascular events. Based on this, we will establish a cardiovascular and cerebrovascular risk prediction model for patients with carotid plaques, forming a risk warning tool suitable for clinical use.

Who will be invited to participate in this study?

The study population for this research includes outpatient and inpatient patients requiring carotid ultrasound examinations at participating research centers during the study period.

Inclusion criteria:

(1) Have a full understanding of the purpose and significance of this experiment, voluntarily participate, and sign the informed consent form;

(2) Patients over 40 years of age;

(3) Patients who meet the criteria of having a carotid plaque ≥1.5mm on routine ultrasound and who undergo routine ultrasound, ultrasound elastography, and three-dimensional ultrasound imaging.

Exclusion criteria:

(1) Severe cardiopulmonary insufficiency; allergy to sulfur hexafluoride; pregnancy and lactation; patients with advanced cancer;

(2) Poor ultrasound image quality;

(3) Patients who have previously undergone carotid artery stenting or endarterectomy on the same side as the carotid plaque.

How many people will participate in this study?

It is initially planned that 600 eligible patients will participate in this study.

How will the study be conducted?

During the initial visit, if you meet the inclusion criteria, the research doctor will explain the study to you in detail, and you will need to sign the informed consent form to participate. We will perform ultrasound imaging examinations such as routine

ultrasound, contrast-enhanced ultrasound, ultrasound elastography, and three-dimensional ultrasound imaging on eligible patients and record whether there is a cardiovascular or cerebrovascular event within 2 weeks. Starting from the collection of cases, the research doctor will follow up with you at 12, 24, and 36 months until a cardiovascular or cerebrovascular event occurs or the follow-up period reaches 36 months. Outpatient or telephone follow-up visits will be conducted at 12 and 24 months for clinical assessment, and a carotid ultrasound examination and clinical assessment will be performed during the 36-month follow-up visit. After completing the follow-up for all enrolled patients, we will organize and analyze the data to explore the value of ultrasound imaging in assessing the vulnerability of carotid plaques and predicting cardiovascular and cerebrovascular events. Based on this, we will establish a cardiovascular and cerebrovascular risk prediction model for patients with carotid plaques, forming a risk warning tool suitable for clinical use.

What are the potential risks involved in participating in this study?

Your research doctor will monitor treatment-related adverse reactions. If you experience any adverse reactions or discomfort during the study, it is crucial that you report them immediately to the research doctor. If you or your research doctor believe that you cannot tolerate these adverse reactions, you may withdraw from the study.

Risks related to ultrasound examinations:

Overall, ultrasound examinations have minimal adverse reactions that are transient, self-resolving, and without lasting effects. The most common are local allergic reactions at the injection site, headache, and nausea during ultrasound contrast examinations. However, different patients may have individual differences, and the following risks exist:

(1) Ultrasound examinations are generally safe and non-invasive.

(2) Although studies have shown that ultrasound contrast examinations are very safe, unexpected complications may occur during the examination, especially for critically ill patients, patients with poor cardiopulmonary function, and those with a history of cardiovascular and cerebrovascular diseases.

The research doctor has provided me or my authorized representative with detailed explanations and explanations of the potential risks associated with the above examinations. I or my authorized representative have a clear understanding of the information provided by the doctor and are fully prepared. If any of these risks occur, we understand that they are medically unavoidable accidents and complications. We trust that the medical staff will do their utmost to provide treatment. I or my authorized representative will actively cooperate with the medical staff's treatment and pay all required expenses.

Potential Benefits of Participating in the Study

Assessing the vulnerability of carotid artery plaques through ultrasound imaging is conducive to risk management of carotid artery plaques, early clinical intervention, and prevention of strokes.

What Do I Need to Do If I Participate in the Study?

(1) You will need to undergo follow-up visits with the doctor. Starting from the collection of case data, the research doctor will conduct follow-up visits with you at the 12th, 24th, and 36th months, or until a cardiovascular and cerebrovascular event occurs or the follow-up period reaches 36 months. Outpatient or telephone follow-up visits will be conducted at the 12th and 24th months, while an outpatient follow-up visit will be conducted at the 36th month, including carotid ultrasound examination and clinical assessment.

(2) If you plan to participate in another clinical study, please inform your research doctor promptly.

(3) If there are any changes to your address, phone number, or other contact information, please inform your research doctor.

In addition, your research doctor will collect relevant information about you (such as date of birth, ethnicity, marital status, past medical history, family history, and investigation of stroke-related risk factors) and assess whether you are suitable for participating in this study. After completing these tests and evaluations, the doctor may find that you are not suitable for participating in this study. Your research doctor will determine if there is a possibility of re-screening (i.e., completing some tests again). If you re-enter the screening period, you will still need to re-sign the informed consent form. Whether you are ultimately enrolled or not, it will not affect your clinical treatment plan.

Regarding Fees

After the clinical physician issues a medical order, if you agree to participate in this study during routine examinations, you will need to pay for the clinically prescribed examination items. If the number of your examinations increases during the follow-up period, after obtaining your consent, we will be responsible for the relevant examination fees. If the patient experiences adverse reactions due to this trial for non-personal reasons, the researchers will be responsible for bearing the costs of handling the adverse reactions in accordance with laws and regulations.

Compensation for Potential Study-Related Injuries

If your health is harmed due to participating in this study, please inform your research doctor (Zhang Luni, phone number: 19542782907). We will take necessary medical measures and actively treat you. Depending on the severity of your injury and relevant laws and regulations, you will receive appropriate compensation.

Participation and Termination of the Study

You may refuse to participate in or withdraw from this study at any time, without any reason. When you decide to no longer participate in this study, we hope you will inform your research doctor promptly.

You have the right to inquire about any issues related to this trial at any time. During the study, your research doctor or research staff will answer any questions you have about this trial. If you have any questions about your rights as a clinical trial participant, please contact our hospital's ethics committee at 021-36123569.

Apart from withdrawal due to your own willingness, there are also the following situations where you may be required to terminate this study:

(1) If your research doctor believes that stopping the study is most beneficial to your recovery

(2) If your behavior does not meet the requirements of the protocol

(3) If your research doctor requests your withdrawal from the study for other medical reasons

(4) If any party of the sponsor or ethics committee decides to stop the study

Is personal information kept confidential?

The information you provide for this study will be recorded in your medical record as required. The personnel authorized to access your medical record and the information collected in this study include: research doctors, the State Food and Drug Administration, the hospital ethics committee, and other authorized representatives. Your personal information and all information that reveals your identity in this study will be kept strictly confidential and will not be made public. If the results of this study are published, your identity will be kept confidential. By signing the attached consent form, you authorize relevant researchers and management agencies to access these confidential materials.

By signing this written informed consent form, you authorize the research doctor in charge and their research center staff to collect and process your personal information, including: your date of birth, age, family history, personal data regarding your physical and psychological conditions, as well as any personal information and results obtained from your participation in this study and any follow-up/examination.

Please note that the results of this study may be published in medical journals/conferences, but your name will not be disclosed.

You may not receive financial benefits from participating in this study, but the results obtained from this study will enable timely diagnosis and treatment of your disease and will benefit human health and society.

Questions and Consultation

If you have any questions about this study, including issues related to subject rights or information related to this verification, you can contact the doctor in charge of this study, Dr. Zhang Luni, at 19542782907. You can also contact the Ethics Committee of Shanghai First People's Hospital at 021-36126254.

Thank you for reading the above information. If you decide to participate in this study, please inform your doctor, and he/she will arrange all related matters for your participation in this study.

Informed Consent Signature Page

Study Name: Multi-center Prospective Cohort Study on Ultrasound Imaging Evaluation of Carotid Plaque Vulnerability and Prediction of Cardiovascular and Cerebrovascular Event Risk

Clinical Research Responsible Unit: Shanghai General Hospital

Participant's Statement of Consent:

I have read the introduction to this study mentioned above and have had the opportunity to discuss this study with the doctor and ask questions. All my questions have been satisfactorily answered.

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

(1) I can consult the doctor for more information at any time.

(2) I can withdraw from this study at any time without affecting my medical treatment and rights.

(3) I also understand that if I withdraw from the study, informing the doctor of any changes in my condition and completing relevant physical and biochemical examinations will be beneficial to both myself and the study.

(4) If I need to take any other adjunctive treatments due to changes in my condition, I will seek the doctor's advice beforehand or inform the doctor truthfully afterwards.

(5) I agree to allow the drug regulatory authorities, ethics committees, or other authorized representatives to access my research data.

(6) I will receive a signed and dated copy of this informed consent form.

Finally, I have decided to participate in this study and promise to follow the doctor's advice as much as possible.

Participant's Signature: _____ Date: _____ Contact Number: _____

Legal Representative (Fill in if applicable)

Representative's Signature: _____ Date: _____ Contact Number: _____

Investigator's Statement

I have carefully introduced the above information to the participant. Therefore, I ensure that I have clearly explained the nature, requirements, risks, and benefits of the clinical study, as well as the legality of her/his signature, using all my professional knowledge. No medical, language, or educational barriers have hindered the participant's understanding of these issues. This informed consent form is in duplicate, with one copy kept by the researcher and one copy kept by the participant. According to national laws and the study protocol, I will accurately conduct the clinical study and take necessary measures to protect the rights and safety of the participant.

Signature: _____ Date: _____ Contact Number: _____