Informed Consent Form

CPVI Alone Versus CPVI Plus Low-Voltage Areas Ablation During SR Versus CPVI Plus Low-Voltage Areas Ablation During AF for the Treatment of CAF

The affiliated Yantai Yuhuangding Hospital of Qingdao University

NCT:ChiCTR2400084841

3/23/2024

Informed Consent Form

Dear Mr. / Ms,

We invite you to participate in the study approved by Yantai Yuhuangding Hospital of Qingdao University on the efficacy of radiofrequency ablation of persistent atrial fibrillation under low voltage guidance under different rhythm of sinus and atrial fibrillation-a prospective, multicenter, randomized controlled study. This study is conducted by Professor Chu Hongxia, Director of Cardiovascular Internal Medicine, and will be carried out jointly in four hospitals, including Yuhuangding Hospital in Yantai and the people of Guangdong Province. It is estimated that 150 subjects will participate voluntarily, and the center plans to include 30 subjects. This study has been reviewed and approved by the Ethics Committee of Yuhuangding Hospital in Yantai. Ethics Review No.: 2024-226.

Why is this study carried out? (brief introduction of research background and purpose)

Atrial fibrillation (Atrial Fibrillation,AF) is a kind of common atrial arrhythmia. At present, the rhythm control of symptomatic patients by radio frequency ablation has become a first-line treatment for patients with atrial fibrillation. The pathophysiological mechanism of atrial fibrillation is complicated. The formation of atrial fibrosis marked by atrial low voltage area (low voltage areas,LVAs) is a key factor in the occurrence and development of atrial fibrillation. Clinically, the scar area of left atrial fibrosis can be detected by delayed contrast-enhanced MRI, and the decrease of local voltage in this region can also be recorded by endocardial voltage mapping, which can be correlated and confirmed. Electrolytic anatomy can provide information about local abnormal voltage and reflect atrial fibrosis to a certain extent. Studies have confirmed that ablation in low voltage area can improve the success rate of patients with paroxysmal atrial fibrillation. In most studies, mapping was performed under sinus rhythm, while ANDRÉS performed preoperative mapping in patients with persistent atrial fibrillation under atrial fibrillation rhythm. QURESHI and other studies have shown that the corresponding relationship between LVAs obtained under atrial fibrillation rhythm and sinus rhythm and LVAs obtained by delayed contrast-enhanced MRI is also different. Low voltage areas are more common in patients with persistent atrial fibrillation, and low voltage ablation may also be effective for persistent atrial fibrillation. However, the ablation of low voltage area according to sinus rhythm or atrial fibrillation rhythm is still not confirmed by large-scale randomized and controlled studies. Therefore, this study will be based on this randomized, controlled study to determine the advantages and disadvantages of radiofrequency ablation in low voltage area compared with simple pulmonary vein ablation in sinus rhythm and atrial fibrillation rhythm.

Who is suitable (not) suitable to participate in the study? (inform the main selection criteria and exclusion criteria)

The main Inclusion criteria for this study include:

1. Patients age is 18-80 years;
2. Patients with non-paroxysmal AF; non-paroxysmal AF will be defined as a sustained episode lasting > 7 days;
3. Patients can sign the written informed consent for the study;
4. Patients can endure the required follow-up.

The main Exclusion criteria for this study include:

5. Patients who had previously undergone atrial fibrillation, atrial tachycardia, or atypical atrial flutter ablation;
6. Preoperative combined atrial tachycardia (≥30S) and atypical atrial flutter;
7. Left atrial diameter >55mm;
8. Left ventricular ejection fraction <35%;
9. Left atrial thrombus;
10. Postoperative cardiac surgery;
11. After valve replacement;
12. After permanent pacemaker implantation;
13. hypertrophic cardiomyopathy;
14. Patients with moderate-to-severe aortic valve disease, moderate-to-severe mitral stenosis, and severe other valvular disease;
15. Hemorrhagic stroke within 6 months;
16. Transient ischemic attack or ischemic stroke within 1 month;
17. Mental disorder or history of mental illness and inability to cooperate voluntarily;
18. Breastfeeding, pregnancy and women planning or likely to become pregnant;
19. Life expectancy <12 months;
20. Participating in other interventional clinical trials;
21. The researchers judged that it was not suitable for inclusion in this study.

What do you need to do if you participate in the research? (mainly to inform the research methods, processes, steps and matters needing attention in detail)

If you are willing to participate in this study, we will adopt the central simple random grouping method, so there is a 33.3% chance that you will receive the following three treatment regimens. The study group is divided into two groups, one group is circumferential pulmonary vein isolation (CPVI) + sinus rhythm (SR) LVAs ablation group, the other group is CPVI + AF rhythm LVAs ablation group, the control group is simple CPVI group. The above three groups of treatments are commonly used surgical methods at present, and we will conduct outpatient follow-up within 18 months after the end of the operation (1 month, 3 months, 6 months, 12 months, 18 months respectively). The follow-up included symptoms, ECG, cardiac ultrasound, dynamic ECG, atrial fibrillation monitoring and so on.) it will take you about 18 months to participate in this study. In the above treatment / examination, all examinations are routine examinations in clinical diagnosis and treatment.

What are the advantages of participating in the research? (objectively inform the subjects of their direct or indirect benefits and social benefits)
By participating in this study, your condition may or may not be improved, and this study will also help determine which treatment is more safe and effective to treat other patients with similar conditions.

What are the risks of participating in the study? (inform all trial drugs, adverse reactions of control drugs or test equipment, risks of trial therapy and countermeasures)

All radiofrequency ablation procedures have associated risks including: hemorrhage, hematoma, pseudoaneurysm, arteriovenous fistula, macrovascular injury (incidence 1.31%); thromboembolism, stroke, cerebral hemorrhage (0.17%); cardiac macrovascular rupture, pericardial tamponade requiring surgical thoracotomy or puncture drainage (incidence 0.78%); pulmonary vein stenosis, occlusion, embolism; left atrioesophageal fistula. Death, disability (0.05%); heart valve injury; pneumothorax, hemopneumothorax, hemothorax; diaphragm paralysis, phrenic nerve injury; catheter discount, rupture, shedding; unsuccessful or recurrent treatment of atrial fibrillation; gastrointestinal function injury / gastroparesis; vomiting; esophageal and adjacent organ injury; urethra, digestive tract, skin and mucosa bleeding; infection, etc. We will observe the possible side effects / adverse reactions caused by this study (drug treatment) through hematological examination and echocardiography in a regular and timely manner. and take timely stop of related drugs, pericardiocentesis, thoracic drainage, plus the use of stomach-protecting drugs, anti-infection and other ways to prevent and cure (give risk prevention and control guidance if necessary). If there are any discomfort or adverse reactions, please contact your research doctor in time. As the drugs and instruments used in this study are routine surgical treatments for atrial fibrillation, even if you do not participate in this clinical study, as long as you accept this treatment, these side effects / adverse reactions may occur. In addition, any treatment may be ineffective, and the disease may continue to develop due to ineffective treatment or other diseases.

Do you have to pay a fee to participate in the study? (specify the compensation plan and amount)

The catheter treatments involved in this study are all routine clinical treatments, so they are not free of charge. The postoperative follow-up of the subjects was routine regular follow-up without additional financial subsidy. Except for a very small number of people who are unable to follow up with real financial difficulties, this study will reimburse the subsidy for round-trip fares. If the test-related damage occurs, the corresponding treatment and compensation will be provided in accordance with the relevant provisions of the state.

Is personal information confidential?

Your medical records will be kept in the hospital, and researchers, research authorities, and ethics committees will be allowed to access your medical records. Any public reports 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 within the limits permitted by law.

What other treatments are there if you do not participate in this study? (mainly to provide detailed information about alternative treatments and potential risks and benefits)

If you do not participate in this study, or drop out of the study, there are many alternative treatments, such as antiarrhythmic drug therapy or frequent ablation therapy, the potential risks and benefits of which are described above.

Do I have to participate in the study?

Participation in this study is completely voluntary, you can refuse to participate in the study, or withdraw from this study at any time in the course of the study, which will not affect your doctor's treatment of you. If you decide to withdraw from this study, please contact your doctor and you may be asked to have a relevant examination, which is beneficial to protect your health.

If you have any questions related to personal rights and interests, please contact the Ethics Committee of our hospital at 025-68306360

The subject declared: I have read the above introduction to this study and am fully aware of the risks and benefits that may arise from participating in this study. I volunteered to participate in this study. I will get a copy of this informed consent form with the name and date of signature.

I agree□ or reject □ the use of my medical records and clinical specimens related to this study by other studies.

Subject signature:

Date:

Contact number of the subject:

Cell-phone number:

(where applicable) signature of guardian:

Date:

Contact number of the guardian:

Cell-phone number:

(where applicable) signature of the witness:

Date:

Contact number of the witness:

Cell-phone number:

The researcher stated: "I confirm that I have explained the details of this study to the subjects, especially the possible risks and benefits of participating in this study, and answered all the relevant questions of the subjects, who voluntarily agreed to participate in this study." The informed consent form was in duplicate, and the researcher and the subjects each left a signed informed consent form.

Study the signature of the doctor: **Date:**

Research the doctor's work phone number: **Cell-phone number:**