Study Title: CARTO SOUND™ FAM-Guided Pulsed Field Ablation for Paroxysmal Atrial Fibrillation: An Exploratory Study

NCT Number: Not yet assigned

Document Date: April 2, 2026

We invite you to participate in the study **"CARTO SOUND™ FAM-Guided Pulsed Field Ablation for Paroxysmal Atrial Fibrillation: An Exploratory Study"** initiated by Fuwai Hospital, Chinese Academy of Medical Sciences. This study has been approved by the Ethics Committee of Fuwai Hospital, Chinese Academy of Medical Sciences (Tel: +86-10-88396281, +86-10-88396282). Please read this information carefully to understand your rights and obligations in this study, as well as the nature, content, and risks of the research. Your participation is entirely voluntary. Whether or not you choose to participate will not affect your routine treatment or other legal rights at our hospital. You may ask questions at any time during the explanation and discussion of this consent form, and you may request clarification on anything you do not understand. You will have sufficient time to discuss participation with your family, friends, and your doctor. Please make your decision after full consideration.

If you are currently participating in another clinical study, please inform the study staff.

Funding source: Johnson.

Multi-center study: The lead site is Fuwai Hospital, Chinese Academy of Medical Sciences, and the Principal Investigator is Zheng Lihui at that site. The Principal Investigator at this site is also Zheng Lihui, Chief Physician, Arrhythmia Center.

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1. Why is this study being conducted?

Study objective: To evaluate the effectiveness and safety of pulmonary vein isolation (PVI) using Varipulse™ after left atrial model reconstruction guided by CARTO SOUND™ FAM in patients with paroxysmal atrial fibrillation (PAF).

Background: The prevalence of atrial fibrillation (AF) is increasing. Catheter ablation is strongly recommended when antiarrhythmic drugs are not tolerated or fail. Moreover, a growing number of studies have shown that not only paroxysmal AF but also persistent AF (with or without heart failure) can benefit from catheter ablation. This has led to a surge in the number of ablation procedures, which is expected to continue increasing in the coming years. Pulsed field ablation (PFA) is increasingly used due to its safety and efficacy. Its advantages include minimal thermal energy delivery to target tissue, higher sensitivity of myocardial cells to electric fields, and creation of transmural, continuous lesions through irreversible electroporation. Although PFA offers improved safety (e.g., reduced thermal injury), its effectiveness depends heavily on precise catheter positioning relative to dynamic anatomy.

Accurate reconstruction of the left atrium (LA), pulmonary veins (PVs), and left atrial appendage (LAA) is essential for safe and effective AF ablation. Current methods for LA reconstruction mainly rely on fast anatomical mapping (FAM) and cardiac CT-MRI fusion (Carto Merge). However, both methods have significant limitations.

CARTO SOUND™ FAM (UG-5400-008H (01A)) addresses these challenges: (1) It reconstructs a 3D anatomy of the left atrium (LA body, LAA, left superior PV, left inferior PV, right superior PV, right inferior PV) from 2D ICE image frames acquired from the right atrium (fossa ovalis) and right ventricular outflow tract; (2) It generates automated 2D contours on real-time ultrasound images; (3) It achieves AI-based automatic segmentation of left atrial substructures. Compared to traditional methods, LA mapping time is reduced by ⩾60% (the algorithm reconstructs LA anatomy with a mean computation time of 65 seconds; in our

center's prior experience, LA mapping time was 4.5±1.0 minutes), and resolution in high-risk areas (e.g., the ridge/crista) is improved.

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2. What does this study involve?

This study (CARTO SOUND™ FAM-guided PFA for PVI) is a prospective, multicenter, non-randomized, observational study. It will be led by Fuwai Hospital and conducted at three centers in China with extensive experience in PVI for paroxysmal AF. A total of 70 PAF patients will be enrolled.

Compared to conventional FAM-based workflows or CT/MRI fusion, CARTO SOUND™ FAM offers the following advantages: (1) minimal use of X-ray; (2) easier operation; (3) fast and more accurate LA reconstruction. In our center's prior experience, LA mapping time was 4.5±1.0 minutes with greater accuracy.

However, despite its theoretical advantages, the synergy of CARTO SOUND™ FAM with PFA has not yet been explored. This preliminary study is the first to apply CARTO SOUND™ FAM-guided PFA to PAF, aiming to improve safety and efficacy while expanding accessibility for PAF patients.

The study procedures are expected to include:

(1) Enrollment and signed informed consent;

(2) Baseline assessments and necessary examinations;

(3) Standardized femoral vein puncture and ICE catheter insertion;

(4) 3D model reconstruction of the left atrium and pulmonary veins using CARTO SOUND™ FAM;

(5) PVI and voltage mapping using Varipulse™;

(6) Post-procedural safety and effectiveness evaluation;

(7) Follow-up visit on day 30 (window: day 25 to day 35) after the procedure.

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3. Who will be invited to participate?

You will be invited to participate if you meet the following criteria:

- (1) Voluntarily agree to participate and sign the informed consent form;
- (2) Diagnosed with paroxysmal AF and have an indication for catheter ablation;
- (3) Age between 18 and 80 years;
- (4) Able and willing to comply with all pre-procedure, post-procedure, and follow-up visits and requirements.

You **cannot** participate if:

- (1) You have valvular AF, untreated/uncontrolled thyroid disease, acute coronary syndrome, or AF secondary to cardiomyopathy;
- (2) You have any contraindication to catheter ablation (e.g., left atrial thrombus, coagulopathy preventing anticoagulation, severe hepatic/renal dysfunction, psychiatric illness);
- (3) You are pregnant or breastfeeding;
- (4) You have a malignancy, cachexia, severe ascites, BMI >40 kg/m², or severe sleep apnea syndrome;
- (5) You are participating in another clinical study;
- (6) The investigator considers any other condition makes you unsuitable for

participation;

- (7) You have contraindications to any study device as specified in the respective instructions for use (IFU).

We will review your pre-study transthoracic echocardiography, left atrial CT or transesophageal echocardiography, ECG, 24-hour Holter, and relevant laboratory tests (liver/kidney function, electrolytes, blood count, coagulation function) as well as the protocol's inclusion/exclusion criteria to determine your eligibility.

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4. Duration of the study and number of participants

This is a multi-center study planning to enroll a total of 70 participants across 3 sites. About 50 participants will be enrolled at this site.

The study is planned to run from June 2026 to June 2027. Your expected participation lasts approximately 1 month, from the procedure until the 1-month follow-up.

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5. How will participation affect my daily life?

Before being enrolled, you will undergo the following assessments to determine eligibility:

Transthoracic echocardiography, left atrial CT or transesophageal echocardiography, ECG, 24-hour Holter, and relevant laboratory tests (liver/kidney function, electrolytes, blood count, coagulation function). The doctor may also ask about your medical history, perform a physical examination, and document your comorbidities and treatments.

You will be required to attend a follow-up visit 1 month after the procedure.

Please carefully consider the potential impact of these assessments and follow-up visits on your daily work and family life, including travel time and costs.

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6. Risks and adverse events for participants

This study does not impose any risks beyond routine clinical care. All examinations you will undergo are standard clinical practice. No additional blood samples are collected solely for research purposes, and no extra examinations or procedures are added.

If you become pregnant or suspect that you might be pregnant during the study, you must immediately inform the study staff. This is crucial. If you become pregnant, you will be withdrawn from the study.

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7. Are there direct benefits from participating?

You may not receive direct benefit from participation. Your medical condition may or may not improve. Your participation may help us understand the pathogenesis of the disease, advance medical knowledge, and develop safer or more effective diagnostic and treatment methods, thereby promoting new scientific knowledge.

You may receive the benefit of having your doctor provide optimal treatment recommendations, and follow-up staff may give additional health care advice based on your condition.

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8. What alternative treatments are available if I do not participate?

You may choose not to participate, and this will not affect your access to routine treatment. You may discuss alternative treatment options with your doctor. If you decide not to

participate, you have the right to choose other treatments, such as conventional catheter ablation using FAM-based or CT/MRI fusion-based workflows. Your study doctor will discuss with you the potential risks of participation and the advantages/disadvantages of other treatments, and will recommend a suitable treatment plan based on your condition.

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9. Costs and compensation for participation

Your study uses the latest ablation catheter and modeling system. Compared to standard surgery, there is no significant increase or reduction in surgical costs. You will not need to pay any additional costs related to the research.

The study does not provide any remuneration or compensation.

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10. Management of research-related injury

If your health condition is affected by a research-related injury, please inform the investigator (Dr. Liu Lei, contact: 15215607933). We will promptly take necessary medical measures. Compensation or liability will be determined in accordance with relevant Chinese laws and regulations.

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11. Will my information be kept confidential?

If you decide to participate, your participation and all personal data collected during the study will be kept confidential. When your data are used for this study, your personal information will be protected. All information will be properly stored and used only for this study.

All data and samples will be strictly anonymized, removing any personally identifiable information. Information that could identify you will not be disclosed to anyone outside the research team.

To ensure the study is conducted properly, the Ethics Committee, regulatory authorities (e.g., drug administration, health department) may access your original medical records for study verification, without violating confidentiality principles or relevant regulations.

If the study results are published, your personal information will not appear in any public materials or publications, nor will it be disclosed to any third party.

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12. What are my rights during the study?

Participation is voluntary. You are free to decide whether or not to participate. Whether you agree or refuse will not affect your routine clinical care at our hospital.

You may refuse to participate at any time or withdraw from the study at any stage without giving a reason, and without discrimination or retaliation. Your medical treatment and rights will not be affected.

If you wish to withdraw from the study, please inform the study staff, complete the required pre-withdrawal assessments, and finish the withdrawal procedures in writing as requested. After withdrawal, the study staff will no longer collect or use your data; however, data that were anonymized before your withdrawal cannot be deleted or revoked. If new information related to your health and rights becomes available after you withdraw, we may contact you again.

If you decide to participate, you must carefully read this consent form, confirm that you fully understand the relevant issues, and sign this form. Signing this form does not waive any of

your legal rights.
During the study, you have the right to receive new information about the study and to obtain the informed consent form and any updated version.

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13. Under what circumstances might I be terminated from the study?

You may be asked to withdraw from the study if any of the following occur:

- (1) You experience a serious adverse event that makes continued participation inappropriate;
- (2) You are non-adherent to study procedures;
- (3) The investigator believes it is necessary for your safety (with detailed documentation of the reason).

The sponsor or regulatory authorities may also terminate the study early. If the study is terminated early, we will notify you in a timely manner. Your study doctor will provide recommendations for your future treatment plan. For participants who withdraw, we have a final follow-up plan, but you have the right to decline. If new information about your health and rights becomes available after your withdrawal, we may contact you again.
After withdrawal, no new data related to you will be collected. The investigator will securely store the data collected before your withdrawal until final destruction, and will not continue to use or disclose them, except in rare circumstances where government supervisory authorities need to review all study information for oversight, inspection, or statistical purposes.

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14. Who should I contact if I have questions or problems?

You may raise any questions regarding this study at any time and receive answers. For any discomfort during the study, please contact Dr. Liu Lei (study staff) at **13151411023**.
If you have any concerns about your rights, please contact the Ethics Committee of Fuwai Hospital at **+86-10-88396281** or **+86-10-88396282**.
Thank you for taking the time to read this consent form. If, after full consideration, you agree to participate, we hope you will follow the study staff's instructions. Before participating, please complete and sign the last page (signature page) together with your study staff. You will receive one signed copy, and our hospital will retain the other.

SIGNATURE PAGE

Statement of the Research Participant

I have carefully read, understood, and agree to all the terms of this informed consent form.
I have been informed of the study's purpose, content, procedures, potential risks, compensation, and my rights. I have had sufficient time and opportunity to ask questions and have received satisfactory answers.
I agree to participate in this study and authorize the hospital to collect my biological samples and research data for this study.
I promise that the information I provide is truthful. If any false information is provided, I accept the consequences.
I have also been informed of who to contact if I have questions or need further information.
I confirm that the contact information provided at signature is my valid personal contact

information. If my contact information changes, I will promptly notify the hospital; otherwise, I accept the consequences of being unreachable.

I understand that I may withdraw at any time without affecting my medical treatment and rights, and that the investigator may suspend or terminate my participation.

I will receive one original copy of this informed consent form, with both my signature and the investigator's signature.

I agree to participate in this study.

Research participant's name: _____

Signature: _____

Date: _____

(If the participant is a minor or lacks capacity, the guardian must sign. Leave blank if the participant has full capacity.)

Guardian's name: _____

Signature: _____

Relationship to participant: _____

Date: _____

(If the participant or guardian is illiterate, an impartial witness must read the consent form and other written materials to the participant/guardian and witness the consent process. Leave blank if the participant/guardian is literate.)

I confirm that the information in the informed consent form has been correctly explained and that the participant or guardian understands the information. The participant voluntarily agrees to participate.

Impartial witness's name: _____

Signature: _____

Date: _____

Statement of the Investigator

I confirm that I have explained the details of this study to the research participant, including their rights, benefits, and risks. I have answered the participant's questions, provided a signed copy of the consent form, and verified that the participant voluntarily agrees to participate.

Investigator's name: _____

Signature: _____

Date: _____