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Hybrid ablation of atrial fibrillation in heart failure

Submission date 03/11/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/11/2025	**Overall study status** Ongoing	
Last Edited 05/11/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation is associated with significant symptoms, impairment of quality of life and morbidity, particularly when it co-exists with impaired left ventricular function (heart failure). At present, patients with AF who are candidates for AF ablation can be offered either Hybrid AF ablation or catheter ablation as part of their usual care. The objective of this study is to evaluate the safety and efficacy of convergent hybrid ablation when compared to standard catheter ablation. As part of the trial, patients will be randomly allocated to one treatment, and data will be collected to ascertain whether one procedure is superior.

Who can participate?
Adult patients with persistent AF who would be routinely referred for AF ablation as part of their usual care.

What does the study involve?
Participants will undergo AF ablation either with Convergent Hybrid AF ablation (two-stage, epicardial and endocardial ablation) or with standard catheter ablation (single-stage, groin-only). The interventions that are being performed within this trial are the same as the routinely offered procedures to patients in clinical care. Following the procedure, data will be collected for up to 24 months to ascertain the response to treatment.

What are the possible benefits and risks of participating?
The treatments are the same as those received as part of usual care. Patients will benefit from contact with a dedicated research team and follow-up.

Where is the study run from?
St George's University Hospital, UK.

When is the study starting and how long is it expected to run for?
July 2021 to May 2027

Who is funding the study?
Investigator initiated and funded. Supported by Atricure

Who is the main contact?
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05411614

Integrated Research Application System (IRAS)
291145

Study information

Scientific Title
A randomised controlled trial comparing hybrid convergent ablation to standard catheter ablation in patients with non-paroxysmal atrial fibrillation and heart failure

Acronym
HALT AF

Study objectives
The objective of this randomised study is to evaluate the safety and efficacy of Convergent hybrid ablation when compared to standard catheter ablation in patients with non-paroxysmal AF and impaired left ventricular systolic function.
The hypothesis being tested is: Convergent Hybrid Ablation is superior to standard catheter ablation for the rhythm control of persistent AF in patients with reduced left ventricular ejection fraction

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/07/2021, South West – Cornwall and Plymouth Research Ethics Committee (Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)2071048033; cornwallandplymouth.rec@hra.nhs.uk), ref: 21/SW/0082

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Safety, Treatment

Health condition(s) or problem(s) studied
Persistent atrial fibrillation, heart failure

Interventions
Randomisation will utilise a centralised, anonymised, secure web-based application termed REDCap (Research Electronic Data Capture) that allows for longitudinal data collection with audit trails to ensure data integrity. It will be accessed via a secure server stored within St

George's University, London, UK. Once enrolled, a patient identification number (PIN) will be generated by registering the patient for an eCRF (electronic case report file). Authorised and trained staff will be allocated a username and password. Once informed consent and eligibility are confirmed, a staff member can enter the subject's details, and the software will automatically randomly assign the subject to a trial arm.

Trials arms:
1. Convergent Hybrid Ablation +/- Left Atrial Appendage Exclusion. Consisting of two stages:
Stage 1 - Minimally-Invasive Surgical Epicardial Ablation Procedure +/- concomitant left atrial appendage (LAA) exclusion.
Stage 2 - Endocardial Catheter Ablation

2. Standard Endocardial Catheter Ablation

Intervention Type
Procedure/Surgery

Primary outcome(s)
Freedom from persistent atrial arrhythmia as recorded on prolonged Holter electrocardiogram (ECG) monitoring after a single procedure (either the completed hybrid ablation or catheter ablation), off Class I or III medications up to 12 months post-ablation

Key secondary outcome(s))
1. Safety endpoint of severe and non-severe complications, as defined in the protocol, measured up to 30 days post procedure (early), and up to 12 months (late)
2. Freedom from any atrial arrhythmia lasting > 30 seconds on prolonged Holter electrocardiogram (ECG) monitoring after a single completed procedure on class I/III medications up to 12 months post-ablation
3. Freedom from atrial arrhythmias on prolonged Holter electrocardiogram (ECG) monitoring after any redo procedures (on or off class I or III medications) up to 12 months post-ablation post-ablation
4. Left ventricular structural remodelling and change in ventricular function in response to either procedure from baseline, measured on echocardiography up to 12 months post-ablation post-ablation
5. Left atrial remodelling in response to either technique from baseline, measured on echocardiography up to 12 months post-ablation
6. Patient's symptoms and quality of life measured using the change in European Heart Rhythm Association Score (EHRA Score) from baseline up to 12 months post-ablation
7. Patient's symptoms and quality of life measured using the change in New York Heart Association Functional Classification (NYHA Class) from baseline up to 12 months post-ablation
8. Quality of life measured using the change in EuroQoL 5-Dimension Questionnaire (EQ-5D) from baseline up to 12 months post-ablation
9. Quality of life measured using the change in Atrial Fibrillation Effect on Quality-of-Life Questionnaire (AFEQT) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ) from baseline up to 12 months post-ablation

Completion date
01/05/2027

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Persistent or Long-standing Persistent AF
3. Dilated left atrium
4. Suitable for either procedure
5. LVEF < 50%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Not yet optimised from a medical or lifestyle perspective for AF or heart failure
2. Unable to provide written consent
3. Previous open-heart surgery
4. Active infection, oesophageal ulcer stricture or oesophageal varices
5. Prior catheter ablation of atrial fibrillation (prior ablation for atrial flutter / supraventricular tachycardia or ventricular arrhythmia acceptable)
6. Contraindication to anticoagulation, or active thrombus in the left atrium despite therapeutic anticoagulation
7. Severe valvular heart disease
8. Unstable coronary artery disease
9. Uncontrolled ventricular arrhythmia
10. Heart attack or stroke within the last 90 days
11. Pregnant, breastfeeding, or women of childbearing age who plan to get pregnant within six months
12. Severe concomitant condition or presence of an implanted device that would preclude the patient from undergoing trial procedures

Date of first enrolment
01/05/2022

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
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Study participating centre
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Sponsor information

Organisation
City St George's, University of London

ROR
https://ror.org/047ybhc09

Funder(s)

Funder type
Industry

Funder Name
AtriCure

Alternative Name(s)
AtriCure, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published (where feasible) as a supplement to the results publication or will be made available upon reasonable request to the corresponding author (Dr Riyaz A Kaba, rkaba@sgul.ac.uk) or trial sponsor

IPD sharing plan summary

Available on request, Published as a supplement to the results publication