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Mapping the inside and outside of the heart for patients with recurring atrial fibrillation

Submission date 21/06/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/06/2023	**Overall study status** Ongoing	
Last Edited 26/02/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is the most common sustained abnormal heart rhythm which can increase the likelihood of other illnesses and death. This has been treated in the past with medication and resetting the heart rhythm with an electrical impulse in a process known as cardioversion, with mixed long-term success. An advance was the realisation that short-circuits in the electrical pathways in the heart that caused the abnormal rhythms could be broken by introducing a small scar across these pathways on the inside of the heart in a process known as cardiac ablation. However, symptoms can still reoccur and the aim of this study is to assess if ablation to the inside and outside of the heart in both upper chambers of the heart can decrease the chances of AF reoccurring.

Who can participate?
Adults aged over 18 years old who have persistent AF and are suitable for catheter ablation

What does the study involve?
If suitable for the procedure the patient will have catheter ablation to both the inside and outside of the heart in areas of the upper heart chambers where there is evidence of reconnection of abnormal pathways. The patient will then be followed up at 6 months and 12 months to assess if there has been any reoccurrence of AF. An MRI scan prior to the procedure and at 12 months are optional and dependent on the participant's consent.

What are the possible benefits and risks of participating?
Patients could benefit from there being less chance of their AF recurring. The additional risks of taking part in this study are inflammation and pain from the mapping and ablation of the outside of the heart, called pericarditis (1-2 in 100 people). This can sometimes occur with ablation to only the inside of the heart (1 in 200). There is also a risk of introducing infection into the outside space of the heart (1 in 100 people). We will administer antibiotics before the procedure and steroids after the procedure to minimise the risk of inflammation/pericarditis and infection.

Where is the study run from?
The Royal Sussex County Hospital, Brighton, UK

When is the study starting and how long is it expected to run for?
October 2022 to December 2025

Who is funding the study?
Abbott Medical UK Ltd

Who is the main contact?
Dr Karthick Manoharan, karthick.manoharan1@nhs.net (UK)

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320697

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55518, IRAS 320697

Study information

Scientific Title
Simultaneous Endo-Epicardial Mapping Of REcurrent Atrial Fibrillation 2 (SEE MORE AF 2)

Acronym
SEE MORE AF 2

Study objectives
The hypothesis is that connections on the inside and outside of both upper chambers of the heart could be responsible for recurring and persistent atrial fibrillation, which may explain why treating only those areas inside the heart does not always work in maintaining normal heart rhythm.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/04/2023, London - Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)2071048088; surrey.rec@hra.nhs.uk), ref: 23/LO/0213

Study design
Non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
We plan on undertaking pre and post-procedural research magnetic resonance imaging (MRI). This will be an optional part of the study for patients. This will help establish atrial scar burden and help establish the efficacy of MRI at predicting areas of scar identified at endo and epicardial mapping. MRI data has already established that scarring has a significant contribution to recurrent atrial fibrillation (AF) post-ablation. This can help to establish the role of MRI in predicting the need for epicardial ablation, to help improve the success rates. Post-procedural MRIs will help establish the impact of ablation on bi-atrial function, which will be correlated with electrical data. This will allow help to understand if there is an improvement in heart function following ablation.

The procedure will be performed by a Consultant Cardiologist or Specialist Registrar with experience in catheter ablation for AF, and experience of techniques to gain access to the epicardial space. All patients recruited will have a clinical indication for AF ablation. This involves the placement of catheters within the cardiac chamber. All procedures will be conducted under general anaesthesia.

STANDARD CLINICAL PROCEDURE: Following general anaesthesia, an ultrasound probe is inserted down the oesophagus to ensure that there are no blood clots within the heart. Small tubes will be placed in the femoral veins to allow specialised catheters to be placed inside the chambers of the heart. Access into the left atrium, where the majority of AF ablation is undertaken, is carried out using a standard technique called a transseptal puncture. This involves a fine needle being used to create a small hole from the right atrium into the left atrium to allow passage of catheters. Following this, treatment can be delivered by making a series of small burn marks to restore the normal heart rhythm. During the procedure it is common that patients require the heart rhythm to be restored to normal with a specially timed electrical shock, called a cardioversion.

RESEARCH PROTOCOL: The research protocol represents only a small modification of the standard clinical procedure. Ordinarily, access to the outside of the heart is not undertaken and would represent an additional step. To allow access to the outside of the heart, a small tube is inserted underneath the breastbone and within the space between the pericardium (sac surrounding the heart) and the heart. Specialised catheters can be introduced through this tube to allow electrical maps of the outside of the heart to be created. Areas of interest on the

outside of the heart can be treated with ablation in addition to the areas inside the heart chamber with the aim of improving success rates. This will prolong the procedure by around 30-60 minutes. A standard procedure without the research protocol takes between 2 and 4 hours.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Recurrence of atrial fibrillation measured using cardiac rhythm monitors at 3, 6 and 12 months follow up

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
06/10/2022

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Documented persistent AF
2. Suitable for clinically indicated catheter ablation
3. Aged > 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 22; UK Sample Size: 22

Key exclusion criteria
1. Pregnancy
2. Current enrolment in another trial
3. Clinically unsuitable
4. Patients lacking capacity

Date of first enrolment
23/07/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
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Sponsor information

Organisation
University Hospitals Sussex NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.uhsussex.nhs.uk/

ROR
https://ror.org/03wvsyq85

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories

Alternative Name(s)
Abbott, Abbott U.S., Abbott Alkaloidal Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Trial results will be released in several manuscripts providing outcomes of the trial as a whole

Intention to publish date
31/03/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date