

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

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Registration date 27/06/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/02/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

320697

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

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

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