ISRCTN10615430 https://doi.org/10.1186/ISRCTN10615430

Electrical mapping of the inside and outside of the heart during atrial fibrillation ablation procedures

Submission date
25/08/2020

Recruitment status
No longer recruiting

Registration date
01/09/2020

Overall study status
Completed

Last Edited
19/12/2023

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The normal heart rhythm depends on the regular electrical activity of the heart's natural pacemaker cells – the sinus node. The sinus node is in the right upper chamber of the heart and usually 'fires' at about 60-100 beats per minute but it can be faster (during exercise, for example). The electrical impulse spreads through the heart to create a coordinated contraction between the upper and lower chambers. In atrial fibrillation (AF), the normal rhythm is lost due to abnormal electrical activity from an area around the pulmonary veins. This results in a chaotic rhythm in the upper chambers of the heart which stops them from contracting effectively. As the electrical impulse is transmitted to the lower chambers it causes the heart to beat in an irregular, often fast manner that responds poorly to the needs of the body. Atrial fibrillation is the most common heart rhythm disturbance and it is defined as persistent if it lasts for more than 7 days. This can cause unpleasant symptoms such as palpitations, breathlessness, and increases the likelihood of suffering a stroke. Traditionally, it is treated by electric treatment (cardioversion), with long-term medication, or more recently by catheter ablation. Catheter ablation is a procedure which involves passing specialised wires through the blood vessels at the top of the leg to deliver small burn marks (ablation) to regions of the heart that cause AF. However, it has been demonstrated, for different heart rhythm problems, that ablating the outside of the heart as well improves the long term outcome. The aim of this study is to see whether additional electrical maps and ablation of both the inside and the outside of the heart results in improved outcomes in persistent AF. It will help provide valuable information for the management of this condition.

Who can participate?
People who are over 18 years old, have documented persistent AF and are suitable for catheter ablation

What does the study involve?
Many of the tests and procedures involved in the study will be the same as those undertaken for a standard internal ablation procedure and include:
History & clinical examination – this will have been done in the outpatient clinic.

ECG – to check for AF.
Blood tests – blood will be taken for routine tests (blood count, kidney/liver/thyroid function, and blood sugar levels).
Echocardiogram – This is a heart ultrasound scan that looks at the heart muscle and valve function.
Cardiac CT scan – Some, but not all patients will have a CT scan of the heart as part of their routine investigations.
In addition to the standard procedure, there will be an additional mapping and ablation (if required) to the outside of the heart. In order to do this, one additional tube is inserted under the breast bone so that we can access the outside surface of the heart. Taking part in the study will add about 30-60 minutes to the procedure time in order to conduct the research. This extra time is needed for the additional electrical maps and ablation.

What are the possible benefits and risks of participating?
There is a possibility that there will be no benefit for the patient taking part in the study, but it could decrease the likelihood of a recurrence of AF.

Where is the study run from?
Brighton and Sussex University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2020 to December 2022

Who is funding the study?
Abbott Laboratories (USA)

Who is the main contact?
Dr Duncan Fatz
duncan.fatz@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Ian Mann

ORCID ID
https://orcid.org/0000-0002-4793-0673

Contact details
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE
+44 (0)1273 696955
ian.mann2@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
257470

Central Portfolio Management System (CPMS)
45979

Study information

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

Acronym
SEE MORE AF

Study objectives
It is hypothesised that a combination of mapping and ablation to the inside and outside surface of the heart for patients with atrial fibrillation will improve the understanding of the causes of AF, and help improve the quality of ablation lesions, compared to procedures involving mapping and ablation to the inside surface alone. This might result in improved outcomes from ablation with regard to arrhythmia free survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/08/2020, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8102, +44 (0)207 104 8101; cambridgeeast.rec@hra.nhs.uk), REC ref: 20/EE/0178

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Diagnostic

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

Interventions
The procedure will be performed by a Consultant Cardiologist or Specialist Registrar with experience of 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 breast bone and within the space between the pericardium (sac surrounding the heart) and 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

Primary outcome(s)
Recurrence of atrial fibrillation using electrocardiography and clinical assessment at 6 and 12 months

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
16/12/2022

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

Total final enrolment
20

Key exclusion criteria
1. Pregnancy
2. Current enrolment in another trial

Date of first enrolment
01/10/2020

Date of final enrolment
06/01/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		19/12/2023	19/12/2023	No	No
HRA research summary			28/06/2023	No	No