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HD grid vs circular mapping catheter for assessment of pulmonary vein reconnection

Submission date 01/04/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/04/2021	**Overall study status** Completed	
Last Edited 02/07/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is the most common heart rhythm disturbance where the heart does not beat in a regular rhythm.
Normal heart rhythm depends on regular electrical activity of your 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 chambers and lower chambers. In AF, the normal rhythm is lost due to abnormal electrical activity from an area around the pulmonary veins (they bring blood from the lungs to the heart). This results in a chaotic rhythm (fibrillation) in the atria, which stops them contracting effectively.

One available treatment, ablation, works by making small burn marks, to isolate those areas that are causing extra beats in the heart, or the pulmonary veins leading to the heart, and stopping them from sending these signals to the rest of the heart. However, there is a 40-50% chance of AF reoccurrence after a single ablation due to electrical reconnection of at least one vein.

The reason we are performing this multicentre study is to establish whether a new catheter (HD Grid), that has already been tested and approved for safety and efficiency and which can map the heart in higher detail than less advanced catheters currently used in standard practice (Circular Mapping Catheters), results in improved outcomes in 130 patients.

Who can participate?
People can participate who:
- Have documented recurrence of AF
- Have one previous AF ablation
- Are suitable for clinically indicated catheter ablation
- Are aged over18 years
People can not participate who:
- Are pregnant or planning pregnancy
- Are currently enrolled in another investigational trial
- Show pulmonary vein isolation on mapping at the baseline visit

What does the study involve?
Much of the study will involve the same procedures as those needed for a standard ablation procedure, such as assessing fitness to undergo an ablation procedure. In addition to the standard procedure, additional mapping of the atrium (heart chamber) with a second catheter will occur to create a second map of the atrium. In the procedure the first mapping catheter will be inserted and a map made and then withdrawn. Then through the same channel the second mapping catheter will be inserted and a map made. The additional mapping with a second catheter takes approximately 20 minutes.
Once both maps have been created, one of the two maps will be chosen at random in order to identify where the locations of electrical reconnection to the pulmonary veins are. Ablation will be performed in order to remove the electrical reconnection based on the map. After this part of the procedure, the operator can assess if more ablation is required based on both the maps created to decide this.
There is no follow-up required apart from what is standard in routine practice.

What are the possible benefits and risks of participating?
The operator having access to both maps to visualise the area of the heart may mean that there is less chance of AF recurrence.
We do not believe there will be any significant additional or increased risk from taking part in the study. As the mapping and ablation procedure involves the use of ionising radiation the additional mapping may add up to approximately 25% more radiation than the standard AF ablation procedure.

Where is the study run from?
Royal Sussex County Hospitals (UK)

When is the study starting and how long is it expected to run for?
February 2021 to February 2023

Who is funding the study?
Abbot Laboratories (UK)

Who is the main contact?
Dr John Silberbauer, john.silberbauer@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr John Silberbauer

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Additional identifiers

Integrated Research Application System (IRAS)
273987

Central Portfolio Management System (CPMS)
48319

Study information

Scientific Title
Comparative study of Advisor HD grid versus circular mapping catheters in assessment of pulmonary vein isolation following previous ablation for atrial fibrillation

Study objectives
The HD Grid catheter will reduce the RF time to isolation by at least 20% as compared with the standard Circular mapping catheter

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2021, East of England - Cambridge Central Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048384; cambridgecentral.rec@hra.nhs.uk), ref: 21/EE/0033

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

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. All patients recruited will have a clinical indication for AF ablation and will have undergone a previous ablation procedure for AF (using either radiofrequency or freezing for the first procedure). All procedures will be conducted under general anaesthesia or local anaesthetic with sedation.

STANDARD CLINICAL PROCEDURE:
Following general anaesthesia/local anaesthesia with sedation, an ultrasound probe is inserted down the oesophagus (at the discretion of the operator and in accordance with local guidelines). Small tubes will be placed in the femoral veins to allow specialised catheters to be placed inside

the chambers of the heart. Access in to 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 in to the left atrium to allow passage of catheters. At this point, a specially timed electric shock called a cardioversion will be performed to restore the heart to a normal rhythm. A map of the left atrium is created by using a specialised mapping catheter. Once
a map has been created, location in which there are electrical reconnection of the pulmonary veins can be identified, and treated with a series of small burn marks to destroy the unwanted connections.

RESEARCH PROTOCOL:
The research protocol represents only a small modification of the standard clinical procedure. Ordinarily, a single electrical map of the left atrium will be made with a specialised mapping catheter. In research patients, two electrical maps of the left atrium will be created, using both a circular catheter, and an HD Grid catheter. Each of the two mapping catheters will be used, one after the other, to create an electro-anatomical map of the left atrium and pulmonary veins. This is done to identify any areas at the pulmonary veins that have electrically reconnected. The electrical activity on the map will be blinded to the operator. This can be done by changing some settings on the mapping system. One of the two maps created with the two catheters for comparison will be randomly selected. The operator will then be allowed to review the electrical information on the map in order to identify areas in which electrical activation has reconnected at the pulmonary veins in order to direct ablation therapy to re-isolate the pulmonary veins. This minor modification involves mapping with the standard circular catheter, with the addition of mapping to create a second map using the new catheter. It is expected that this will prolong the procedure by around 20 minutes. However, during clinical procedures, we take time to review maps and other information in order to ensure a high quality procedure has been undertaken. We also commonly create multiple maps during a single procedure. Use of two different electroanatomic mapping(s)(EAMs) may shorten procedures, as there would be a greater level of certainty that sufficient treatment has been delivered. It is common that operators use a variety of different techniques to conform that sufficient treatment has been undertaken, beyond the EAMs. These additional techniques can be avoided with the use of two EAMs.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Radiofrequency energy time to isolate reconnected pulmonary veins (measured in seconds during the procedure)

Key secondary outcome(s)
1. Mapping times for both catheters (HD Grid and Circular mapping catheter) (measured in seconds during the procedure using the Ensite electro-anatomical mapping system)
2. Ability to correctly identify the gaps in pulmonary veins (recorded during the procedure by analysis of electroanatomical maps by cardiac electrophysiologist)
3. Location of isolation of pulmonary vein (recorded during procedure using electroanatomical maps)
4. Duration of ablation procedure (recorded during the procedure)
5. Any procedural complication (pericardial effusion, bleeding >2 units, phrenic nerve palsy and other) (recorded during and after the procedure via routine clinical follow up within 30 days)

Completion date

15/02/2023

Eligibility

Key inclusion criteria
1. Documented recurrence of AF
2. One previous AF ablation
3. Suitable for clinically indicated catheter ablation
4. Aged >18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
172

Key exclusion criteria
1. Pregnancy or planning pregnancy
2. Current enrolment in another investigational trial
3. Pulmonary vein isolation on mapping at baseline

Date of first enrolment
01/05/2021

Date of final enrolment
15/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

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

Study participating centre
East Sussex Healthcare NHS Trust
St Annes House
729 the Ridge
St. Leonards-On-Sea
United Kingdom
TN37 7PT

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon and Exeter NHS Hospital Foundation Trust
Barrack Road
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EX2 5DW

Study participating centre
Bristol Royal Infirmary
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United Kingdom
BS1 3NU

Study participating centre
Royal Bournemouth General Hospital
Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Castle Lane East
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BH7 7DW

Study participating centre

Basildon and Thurrock University Hospital
Nethermayne
Basildon
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SS16 5NL

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PL6 8DH

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
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Clifford Bridge Road
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Study participating centre
Golden Jubilee National Hospital
Agamemnon Street
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G81 4DY

Study participating centre
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St. James's University Hospital
Beckett Street
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LS9 7TF

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way

Headington
Oxford
United Kingdom
OX3 9DU

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 fully anonymised datasets generated and analysed during the current study will be available upon request from Dr John Silberbauer (john.silberbauer@nhs.net) after 31/08/2024 to applicants on consideration of relevance to catheter ablation studies.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Basic results	01/07/2024	01/07/2024	No	No
HRA research summary		28/06/2023	No	No