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Biatrial global high-density electroanatomical mapping of atrial fibrillation – a prospective mechanistic registry study

Submission date 24/09/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2018	**Overall study status** Completed	
Last Edited 01/06/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation is the commonest sustained heart rhythm problem and can result in significant symptoms and complications. Treatment is challenging with varying effectiveness. Catheter ablation is a procedure where a flexible thin tube is threaded through the blood vessels to the heart to terminate abnormal electrical pathways in the heart tissue. Catheter ablation procedures can be very successful for those with short lasting episodes, but are less effective in patients with more protracted symptoms. This is partly because the mechanisms responsible for maintaining this abnormal rhythm are poorly understood. Acutus Medical have developed a new technology that allows visualisation of the electrical conduction patterns of the whole heart chamber therefore revealing patterns that may be important in triggering and perpetuating atrial fibrillation. The aim of this study is to use two of these systems to evaluate both upper chambers of the heart to further understanding of the important mechanisms involved, which it is hope will improve future treatment strategies.

Who can participate?
Patients aged 18 or above with atrial fibrillation undergoing catheter ablation

What does the study involve?
During catheter ablation, an extra wire is inserted into one of the upper chambers of the heart through a vein at the top of the thigh. This is used to measure the electrical activity in the heart. Participants are followed up 3 months after and 9-12 months after the procedure.

What are the possible benefits and risks of participating?
The possible benefits are difficult to be sure of but it may be that the success rates of the procedure are higher, and if our understanding is furthered, then this may be useful if a repeat procedure is required. The risks include all of those related to an ablation procedure. The only additional risks of this study are those involved with inserting an extra catheter (wire) into the vein. These include bleeding and bruising and damage to the vein or adjacent artery but the risks are minimal.

Where is the study run from?
Oxford University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to September 2021 (updated 01/06/2021, previously: April 2020)

Who is funding the study?
Acutus Medical, Inc. (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38056

Study information

Scientific Title
Biatrial global high-density electroanatomical mapping of atrial fibrillation – a prospective mechanistic registry study

Acronym
BiMAP-AF Version 1.0

Study objectives
This study aims to use two linked novel electroanatomical mapping systems developed by ACUTUS Medical that will allow simultaneous visualisation of whole chamber activation of both the left and right atria during AFib, normal rhythm and when pacing the heart from different regions and at different rates. This will be combined with standard 3-dimensional mapping systems to identify mechanisms involved with AFib propagation such as focal impulses, rotational activity or re-entry circuits, correlate these regions with voltage and conduction properties during normal rhythm and pacing, and explore how both atria interact to perpetuate the arrhythmia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hampshire A REC, 30/08/2018, ref: 18/SC/0409

Study design
Non-randomised; Both; Design type: Treatment, Device, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
This is a prospective non-randomised registry study with a mechanistic and feasibility focus. This design was chosen as the primary objective is not to evaluate the effect of targeted atrial endocardial ablation on outcomes but rather to try to characterise the conduction properties of the atria and demonstrate the feasibility of bi-atrial electroanatomical mapping.

Participants will only be patients who are already planning to undergo a catheter ablation procedure for atrial fibrillation. Once this decision is made the clinical team will provide them with an invitation letter and participant information sheet and seek verbal consent for other members of the research team to contact them. This could either be when they are in the clinic

or by post and telephone afterwards. It will be clear that participation or choosing not to participate has no impact on proceeding with their planned procedure. If they agree to be contacted or contact the research team through the details on the invitation letter and information sheet then the study will be discussed in more detail.

All patients undergoing an ablation for AFib attend for a pre-procedure assessment appointment. Patients who would like more information or who are interested in taking part will be seen by the research team at this time. This appointment will be distinct from the pre-assessment but purely organised to occur during the same hospital visit to minimise the impact on patients. Screening will occur during this visit and if they wish to participate then they will be formally recruited and sign the informed consent form at this stage, which will also serve as the baseline visit. It has been chosen to combine these stages because the inclusion/exclusion criteria are very inclusive and it is not anticipated that there will be significant screen failures as any issue will already have been identified. There are also no baseline procedures beyond measuring height, weight and waist circumference and no randomisation process that requires a delay.

Participants then attend for their procedure, which is performed under general anaesthetic, as is standard practice in this institution. Standard catheters are inserted via femoral venous access and a trans-septal puncture performed in line with standard protocols. Left and right atrial geometry and voltage maps will be obtained in line with a standard procedure. The study component involves the insertion of a second AcQMap (ACUTUS medical) catheter via the femoral vein into the right atrium. If the patient is in sinus rhythm at this stage then electrophysiological recordings will be taken during sinus rhythm and during pacing from different regions of the atria at different rates. AFib will then be induced by incremental burst atrial pacing and electrophysiological recordings taken. Standard ablation is then carried out (pulmonary vein isolation) and recordings repeated afterwards. Any additional ablation performed based on the appearances of the ACUTUS mapping is at the discretion of the operator in line with their clinical practice and does not form part of the study.

Patients may otherwise attend in AFib. These patients will undergo ACUTUS mapping of the AFib prior to direct current cardioversion to sinus rhythm. Recordings during sinus rhythm will then be undertaken and the procedure continued as outlined above. The recordings taken during the course of the procedure form the study data. These will be anonymised and exported electronically from the mapping system and stored on secure trust servers.

Patients are discharged following the procedure in the standard fashion and clinical follow up will occur as usual. Study visits will be timed to take place at the same hospital visit as clinical follow up visits at 3 months and between 9-12 months following the procedure. These visits will include a review of medication, symptom assessment, 12 lead ECG, and at the final visit, a 72 hour ambulatory monitor.

It is planned to recruit a total of 30 patients for this study. As this study is not evaluating clinical outcomes of a procedure, greater numbers are not needed. This number is thought to be enough to reveal any patterns in electrophysiological properties and be able to demonstrate the feasibility of the bi-atrial mapping approach.

Data analysis will occur offline using the anonymised datasets. Results will be collated and a report compiled at the end of the study.

Intervention Type
Procedure/Surgery

Primary outcome measure
Presence and number of pre-defined electrophysiological phenomena such as “rotors” and “focal firing”; Timepoint(s): during ablation procedure

Secondary outcome measures
1. Freedom from recurrent atrial fibrillation, defined as that seen on 12-lead ECG recording or >30 seconds on ambulatory monitoring at 12 months
2. Difference in conduction velocity, measured as a single vector and average vector in each atrial segment at longest and shortest cycle length and 3 vectors during catheter ablation procedure

Overall study start date
06/01/2018

Completion date
10/09/2021

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female, aged 18 years or above
3. Diagnosed with paroxysmal or persistent atrial fibrillation and planned for a catheter ablation procedure
4. In the Investigator’s opinion is able and willing to comply with all trial requirements

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

Total final enrolment
22

Key exclusion criteria
1. Physical or anatomical barriers to the use of two simultaneous mapping catheters
2. Previous cardiac surgery
3. Previous ablation (catheter or surgical)
4. Female participant who is pregnant, lactating or planning pregnancy during the course of the

trial
5. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial
6. Participants who have participated in another research trial involving an investigational medicinal product in the past 12 weeks. (Involvement in any other research trial is not a contraindication per se)

Date of first enrolment
11/10/2018

Date of final enrolment
14/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Industry

Funder Name
Acutus Medical, Inc.

Results and Publications

Publication and dissemination plan
The trialists plan to present the data at scientific meetings and publish in peer reviewed journals towards the end of 2020.

Intention to publish date
31/12/2021

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?
Participant information sheet	version V1.1	23/08/2018	28/09/2018	No	Yes
Protocol file	version v1.0	15/06/2018	28/09/2018	No	No
HRA research summary			28/06/2023	No	No