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Patient-tailored ablation of persistent atrial fibrillation (psGP)

Submission date	Recruitment status	[ ] Prospectively registered
19/02/2021	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/02/2022	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/04/2026	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The heart rhythm problem called Atrial Fibrillation (AF) is caused by abnormal electrical currents in the small chambers of the heart termed the atria.
Landmark studies have shown that in about half of people with AF, these abnormal electrical currents originate from the pulmonary veins, which join the left atrium to the lungs. A procedure called 'pulmonary vein isolation' (PVI) is done using catheters inside the heart that are introduced through the blood vessels in the groin. Once inside the left atrium, the catheters are used to make small burns along the base of the pulmonary veins where they join the heart to prevent the abnormal electrical currents from reaching the rest of the atria. This prevents AF in about 50% of people.
However, the PVI procedure that we perform is not tailored to each individual patient and we don't know exactly why it works.
A different approach is to target the nerve cells in the atria called ganglionated plexi (GPs). It is thought that these GPs trigger AF and so ablating the GP could be more effective than PVI. They are often found at the base of the pulmonary veins, and also within the atria. Our group has developed a method for locating these GPs and have shown that ablating GP sites can prevent AF. This work has been done mainly in patients who are in normal rhythm most of the time (paroxysmal AF). We now want to see if the same benefit is found in people who are in AF all of the time (so called persistent AF).

Who can participate?
Adults over 18 years, with AF and due to undergo an AF ablation procedure.

What does the study involve?
For the patient, the experience of and recovery from the GP ablation will be the same as the conventional procedure. Patients will be followed up for 1 year with heart rhythm monitors every 3 months to check for recurrence of AF.

What are the possible benefits and risks of participating?
Participating in this research will increase our understanding of the location & function of the nerve cells (GP) in the heart, and help us to understand their role in triggering and maintaining AF. Our research looking at patients with paroxysmal AF suggests that ablating the GPs is at

least as good as the standard
PVI procedure, and with less tissue injury. We hope to confirm these preliminary findings and assess whether there may be improved outcomes compared to PVI. Participants will also receive the benefit of increased monitoring during follow up through additional access to the research staff which enables review of any home ECG monitoring they may have and follow up of symptoms.
The risks of this research study are incurred during the catheter ablation procedure. The risks of a catheter ablation procedure are not affected by the GP mapping. The mapping protocol may increase the length of time that the overall procedure takes, by up to an hour, but this is still within a normal range for the time taken to complete an ablation procedure as the duration varies from patient to patient. A procedure using conventional mapping and a procedure undertaken as part of the research protocol are expected to have an identical risk profile as the same equipment and ablation techniques will be used, but the location of the ablation will vary.

Where is the study run from?
The research will be undertaken by Dr Clare Coyle as a part of her PhD thesis. She will be guided by Professor Prapa Kanagaratnam from the National Heart and Lung Institute with input from Dr Nicholas Linton from the Department of Bioengineering at Imperial College London. The procedures will take place at Imperial College Healthcare NHS Trust (UK).

When is the study starting and how long is it expected to run for?
January 2020 to December 2027

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Jamie Kay, jamie.kay@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Jamie Kay

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
265850

Central Portfolio Management System (CPMS)
44984

Study information

Scientific Title
Feasibility of identifying autonomic drivers for human Atrial Fibrillation

Study objectives
Does patient-tailored ablation of the atrial autonomic nervous system result in reduced recurrence of AF in patients with persistent AF compared to standard ablation targets?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/04/2020, South Central Berkshire Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 207 104 8121; berkshire.rec@hra.nhs.uk), ref: 20/SC/0081

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
All participants will receive a medication (Amiodarone) for at least 6 weeks prior to their procedure. Study participants will provide informed consent prior to commencement of the study protocol. The preparation for the procedure will be the same as for routine PVI with the patient receiving a general anaesthetic, trans-oesophageal echo (TOE) to assess for left atrial appendage thrombus and the left atrium accessed under TOE guidance as per usual clinic procedure. To start, the
patient needs to be in a normal heart rhythm. This may already have been achieved with the Amiodarone but if not they will have a cardioversion (a small electrical current to revert the heart temporarily to a normal rhythm). High frequency stimulation will be used to identify sites of nerve cells (ganglionated plexi) that can trigger ectopic beats and a map of these sites created. Once this is complete, these areas will be ablated. We will then re-test the sites to ensure there is no evidence of the nerve cells remaining. If the patient goes into AF before mapping is complete, then the sites already mapped will be ablated to trigger a return to sinus rhythm. If this doesn't work then the patient will have up to three cardioversions. If the patient

is still in AF, we will map nerve cells that affect the heart rate which we know can be associated with ectopy triggering nerve cells.
All patients will be followed up with heart monitors (24 hour Holters) at 3, 6, 9 and 12 months and at routine clinical appointments to see if the AF returns.
We will compare their outcomes to a group with similar characteristics but who have received routine PVI treatment (taken from the routine data collected as part of the Cardiology department's routine auditing). We will use statistical tests to measure whether there is a true difference between the two groups.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Recurrence of >30 seconds of AF or atrial tachycardia at 1 year as measured on 24 hour Holters at 3, 6, 9, & 12 months post procedure (after a 90-day blanking period)

Key secondary outcome(s))
1. Acute cessation of ectopy and/or AF with ablation during the procedure (noted during the procedure)
Measured using patient records at the end of the study:
2. Repeat ablation for AF/AT after a 90-day blanking period
3. Mortality
4. Any significant complications related to the procedure requiring intervention

Completion date
01/12/2027

Eligibility

Key inclusion criteria
1. Atrial fibrillation due to undergo an AF ablation procedure
2. Informed consent
3. Willing to attend follow up for Holter monitoring
4. Suitable for AF ablation procedure under general anaesthetic

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Left Ventricular Ejection Fraction <35%
2. Left atrial size >4.8 cm
3. Failed cardio version with sinus rhythm lasting <1 week
4. Any significant co-morbidity precluding general anaesthetic or a contra-indication to ablation
5. Pregnant women
6. Patients with life expectancy less than follow up period
7. Unwillingness to attend follow up HoltersIf
8. Patients who have undergone previous experimental ablation procedures
9. Patients involved in research that could itself be affected by our intervention protocols

Date of first enrolment
01/08/2020

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Marys Hospital
Imperial College Healthcare NHS Trust
South Wharf Road
London
England
W2 1BL

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type

Charity

Funder Name
British Heart Foundation; Grant Codes: FS/20/14/34917

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised datasets generated during and analysed during the current study will be available upon reasonable request from Dr Clare Coyle, c.coyle@imperial.ac.uk, for up to 10 years following the study end date provided the patient consented to data sharing on recruitment to the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1	11/06/2019	09/02/2022	No	Yes