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The safety and efficacy of using shorter ablation times during pulmonary vein isolation using a multielectrode radiofrequency balloon catheter

Submission date
04/12/2023

Recruitment status
No longer recruiting

Registration date
19/12/2023

Overall study status
Completed

Last Edited
19/12/2023

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pulmonary vein isolation (PVI) remains the main goal during catheter ablation for atrial fibrillation (AF). Although the most used balloon catheter in clinical practice is the cryoballoon, the new multielectrode RF balloon (HelioStar, Biosense Webster) has been demonstrated to be a safe and effective tool for PVI. Atrio-oesophageal fistula formation is one of the most rare and severe complications related to ablating at the posterior left atrial wall -in the vicinity of the oesophagus- during AF ablation. Although its incidence is low (0.2%), its mortality can reach 93% without surgery and 20% when surgery is performed. The current ablation workflow with the multielectrode RF balloon includes a maximum of 20 seconds in at least 3 posterior electrodes. Using an oesophageal temperature probe to identify any oesophageal temperature rises and prevent potential oesophageal damage is also recommended. Although this workflow has demonstrated its safety and efficacy in previous studies, our intraprocedural data suggests that posterior wall isolation might be achieved within 5 to 7 seconds, which means that the problems of oesophageal temperature rises should be reduced.

Who can participate?
Patients aged 18 years old and over with symptomatic paroxysmal or persistent atrial fibrillation suitable for clinically indicated catheter ablation

What does the study involve?
Patients will have a normal ablation procedure with reduced time and they will then be followed up with an endoscopy to see if there are any signs of lesion formation.

What are the possible benefits and risks of participating?
The new procedure could reduce the risk of oesophageal injury for patients. There are no additional risks expected from the AF ablation procedure. However, since there will be less treatment time there is the possibility that the ablation will be less effective.

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 2023 to May 2025

Who is funding the study?
Biosense Webster Inc, Johnson and Johnson

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

Study website
Not applicable

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
328017

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56923, IRAS 328017

Study information

Scientific Title

Safety and efficacy of shorter ablation times to the posterior wall during pulmonary vein isolation with a multielectrode radiofrequency balloon catheter

Acronym
BRIGHT

Study objectives
The hypothesis is that the modified workflow, reducing ablation time to the posterior electrodes when using the multipolar electrode ablation catheter, will lead to similar success in isolating the pulmonary vein to those reported for the regular ablation times.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/10/2023, London - Harrow Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8154, (0)207 104 8357; harrow.rec@hra.nhs.uk), ref: 23/PR/1010

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
This will be a multicentre study, in which it is anticipated that six sites will be involved. These sites will initially be selected from those with significant experience with the multielectrode radiofrequency balloon (Heliostar).

The lead site for the study will be the University Hospitals Sussex NHS Foundation Trust, which is also the sponsor for the study. The sponsor will provide trial management services for the study, including a Trial Manager, database and safety monitoring, meeting coordination and Master File maintenance.

An electronic case report form (eCRF) designed by the study team will capture the anonymised data generated by the research sites on its database which the Trial Manager will have access to for monitoring and participant accrual assessment purposes. Training documents for use of the system will be developed by the trial management team and understanding and compliance will be confirmed before a site is granted permission to recruit by the sponsor. The eCRF will require secure login credentials and will provide an audit of who has logged into the system and entered or edited data.

The procedure will only be performed by a Consultant Electrophysiologist who is on the study's site delegation log. Periprocedural anticoagulation will be managed as per the centre's protocol. All patients recruited will have a clinical indication for a first AF ablation. Patients not tolerating insertion of the oesophageal temperature probe will not be able to have their ablation with the Heliostar catheter and, hence, will be excluded from the study.

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 or local anaesthesia. The standard clinic procedure at all participating sites is the use of both a Heliostar AF ablation catheter and an oesophageal temperature probe as detailed below, before the research procedures.

STANDARD CLINICAL PROCEDURE:
Following general or local anaesthesia and sedation, a TOE or ICE catheter may be used to guide the procedure and exclude blood clots in the heart chamber, as per the centres' routine practice. A temperature probe will be advanced under fluoroscopic guidance. This is standard clinical practice worldwide when performing ablation using the Heliostar ablation catheter and allows safe monitoring of oesophageal temperatures. Patients not tolerating insertion of the oesophageal temperature probe will not be able to have their ablation with the Heliostar catheter and, hence, will be excluded from the study. 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, the Heliostar ablation catheter and a circular mapping catheter (LassoStar NAV) will build a 3D map of the heart. The Heliostar catheter will then be used to deliver energy in the pulmonary veins, whilst monitoring for changes in temperature in the oesophagus. Within standard practice, 20 seconds of radiofrequency energy are delivered to the posterior wall. 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 a modification of the standard clinical procedure in two aspects. The first one is that the radiofrequency time delivered to the posterior wall will be reduced from 20 to 15 seconds. The second one is that an oesophageal endoscopy will be performed within the first week after the ablation, to exclude the presence of any oesophageal lesions. Although this is routine practice in many European centres, it is not standard practice in the UK.

Following local anaesthesia and sedation or general anaesthesia, a TOE or ICE catheter may be used to guide the procedure and exclude blood clots in the heart chamber. A temperature probe will be advanced under fluoroscopic guidance. Patients not tolerating insertion of the oesophageal temperature probe will be excluded from the study. 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, the Heliostar ablation catheter and the circular mapping catheter (LassoStar NAV) will build a 3D map of the heart. The Heliostar catheter will then be used to deliver energy in the pulmonary veins, whilst monitoring for changes in temperature in the oesophagus. Within the research protocol, 15 seconds of radiofrequency energy will be delivered to the posterior wall. 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.

Within the research protocol, patients will undergo a gastroscopy within 7 days of the ablation procedure to help determine if there is any evidence of oesophageal injury. This will involve a long flexible tube containing a camera and a light through the mouth, over the back of the tongue, and down the oesophagus. This allows the endoscopist to view the lining of the oesophagus. Patients will be offered conscious sedation, which can be delivered by inserting a plastic tube (cannula) in the arm. Alternatively, patients will be given the choice of a local anaesthetic throat spray to numb the back of the throat to make the procedure more comfortable. If there is evidence of any significant oesophageal injury patients will be offered a further endoscopy, after a course of medical therapy.

As per routine practice, all patients should remain anticoagulated for a minimum of 2 months post-procedure, in the absence of emergent contraindications. Amiodarone must be stopped before discharge, but any other antiarrhythmic drugs may be continued only during the blanking period. Standard beta-blockers may be continued throughout the study period.

Patients will be followed up at 6 months and 12 months post-procedure for a review of current cardiac medication, AF/ AT recurrence assessment, a 7-day Holter monitor and review of adverse events. In addition, at 12 months, patients will complete the questionnaires EQ5D and AFEQT, and receive a transthoracic echocardiogram.

Intervention Type
Procedure/Surgery

Primary outcome measure
Rate of acute Pulmonary Vein Isolation (PVI), defined as entrance block in all treated Pulmonary Veins measured using electronic case report form (eCRF) during the procedure

Secondary outcome measures
The following secondary outcome measures will be measured using electronic case report form (eCRF) recording during the procedure:
1. Rate of “first pass” PVI will be defined as the percentage of PVs where only one RF application is required to achieve entrance block
2. Time to PVI, expressed in seconds
3. Rate of significant oesophageal temperature rises (>2°C from baseline) will be defined as the total number of oesophageal temperature rises within the entire sample size
4. Time for temperature to return to baseline (when a significant (>2˚C) oesophageal temperature rise occurs) will be expressed in seconds
5. The rate of endoscopically detected oesophageal lesions (EDEL). These will be defined as a typical endoscopical finding of the oesophageal mucosa in an area neighbouring the LA and are

classified as either category 1 lesion (mild: erythema/erosion or small ulcers ≤5mm diameter) or category 2 (severe) lesion (ulcer >5mm diameter). This will be expressed as a proportion and descriptive statistics will be provided.

Overall study start date
11/10/2023

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Symptomatic paroxysmal or persistent atrial fibrillation
2. Suitable for clinically indicated catheter ablation
3. Aged > 18 years
4. Patients must be willing and able to provide informed consent
5. Patients must be willing and able to comply with peri-ablation and follow-up requirements

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 80

Key exclusion criteria
1. Pregnancy or planning pregnancy
2. Current enrollment in another interventional trial
3. Previous ablation for atrial fibrillation
4. Previous cardiac surgery
5. LA diameter > 55 mm in TTE
6. Patients with contraindications to systemic anticoagulation
7. Congenital heart disease
8. Body Mass Index > 40
9. Longstanding persistent atrial fibrillation (> 1 year)

Intraprocedural criteria:
Patients not tolerating insertion of the oesophageal temperature probe

Postprocedural criteria:
Patients not completing oesophageal endoscopy within 7 days of the ablation procedure

Date of first enrolment
11/12/2023

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
Belgium

England

Greece

United Kingdom

Study participating centre
Royal Sussex County Hospital
University Hospitals Sussex Nhs Foundation Trust
Clinical Research Facility
2nd Floor Sussex House
1 Abbey Road
Brighton
Brighton
United Kingdom
BN2 1ES

Study participating centre
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
General Hospital of Athens Hippokration
Vas. Sofias 114
Athens
Greece
11527

Study participating centre

University Hospital Brussels
Brussels Health Campus
Laarbeeklaan 101
Brussels
Belgium
1090 Jette

Sponsor information

Organisation
University Hospitals Sussex NHS Foundation Trust

Sponsor details
Worthing Hospital
Lyndhurst Road
Worthing
England
United Kingdom
BN11 2DH
+4 (0)1273696955
scott.harfield@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.uhsussex.nhs.uk/

ROR
https://ror.org/03wvsyq85

Funder(s)

Funder type
Government

Funder Name
Johnson and Johnson

Alternative Name(s)
Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type

Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Trial results will be released in several manuscripts providing outcomes of the trial as a whole

Intention to publish date
30/06/2027

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