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Early feasibility first-in-human study using a novel radiofrequency ablation catheter

Submission date
18/01/2017

Recruitment status
No longer recruiting

Registration date
30/01/2017

Overall study status
Completed

Last Edited
13/12/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims:
Atrial fibrillation (AF) is a common heart condition that around 1 in 4 adults are at risk of developing. It is caused by a fault in the electrical control centre in the heart which is found in the upper right chamber (right atrium), causing it to fire erratically. These uncoordinated signals cause the heart to beat irregularly and often very fast (arrhythmia), which means that blood is not effectively pumped around the body. Although this is usually not a life threatening condition, it can limit a person's quality of life by causing fatigue (extreme tiredness), weakness, shortness of breath and chest pain. Radiofrequency ablation (RFA) is a procedure in which uses a is used to destroy the areas of the heart which are sending out the irregular signals. In the procedure, a thin flexible tube (catheter) is inserted into a major artery in the groin and guided up to the heart. The tip of the catheter then burns the affected areas, which destroys the abnormal electrical circuit and stop the fast, irregular heartbeat to restore and maintain normal heartbeat. The aim of this study is to evaluate the safety and the design of a new type of RFA catheter during the standard ablation procedure.

Who can participate?
Patients with AF who have not responded to heart rhythm medication and are suitable for treatment with RAF.

What does the study involve?
All participants receive a catheter ablation to treat their atrial fibrillation. This involves the catheter delivering electrical energy when in direct contact with the heart muscle which heats the heart tissue and results in a small, localized burn on the inside of the heart that interrupts the abnormal electrical circuit and stop the fast, irregular heartbeat to restore and maintain normal heartbeat.

What are the possible benefits and risks of participating?
Participants may benefit from the treatment used in this study as it could cure their AF, improving their quality of life. Risks involved with participating include the general risks of undergoing a radiofrequency catheter ablation. The use of this new type RF catheter in combination with additional already-approved technology as a part of standard care, may pose an increased risk of unwanted side effects.

Where is the study run from?
1. St. Bartholomew's Hospital (UK)
2. Na Homolce Hospital (Czech Republic)
3. Centro Cardiologico Monzino (Italy)
4. Ospedale Generale Regionale F. Miulli (Italy)

Who is funding the study?
Biosense Webster (USA)

Who is the main contact?
Mrs Stephanie Plaza
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Contact information

Type(s)
Public

Contact name
Mrs Stephanie Plaza

Contact details
Biosense Webster, Inc.
Part of Johnson & Johnson Families of Companies
33 Technology Drive
Irvine
United States of America
92618

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HELI-169

Study information

Scientific Title
Prospective, multi-center, single-arm, early feasibility utilizing a novel radiofrequency ablation catheter

Acronym
RADIANCE

Study objectives

The aim of this study is to evaluate the design, utility and safety of a novel radiofrequency ablation catheter in the treatment of paroxysmal atrial fibrillation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Yorkshire & The Humber - Sheffield Research Ethics Committee, 25/01/2017, ref: 16/YH/0424 (UK)
2. Comitato Etico degli Istituto di Ricovero e Cura a Carattere Scientifico Istituto Europeo di Oncologia e Centro Cardiologico Monzino (Ethics Committee of the Scientific Institute for Research, Hospitalisation and Healthcare European Institute of Oncology and Monzino Cardiology Centre), 10/10/2016, ref: R 487/16 - CCM 506 (Italy)
3. Etická komise Nemocnice Na Homolce (Ethics Committee Na Homolce Hospital), 02/09/2016, ref: 31.8.2016/33 (Czech Republic)

Added 22/03/2017:
4. Comitato Etico Independente - Azienda Ospedaliero- Universitaria “Consorziale Policlinico”, 10 /02/2017, ref: 5180

Study design
Interventional prospective multi-center single-arm early feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Drug refractory symptomatic paroxysmal atrial fibrillation

Interventions
Patient will undergo atrial fibrillation ablation procedure using the novel radiofrequency catheter. The intervention involves introduction of the study RF catheter, ablation of targeted pulmonary veins (PVs) and confirmation of entrance block in all targeted PVs using a diagnostic catheter. The duration of the intervention, including procedure preparation, time lasts anywhere from two to four hours or more.

There are a total of 3 follow-up visits over the 3 month follow-up period for all participants.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Occurrence of primary adverse events* within 7 days of the ablation procedure is measured by an assessment by the doctor either via telephone or in-clinic who will check the patient's overall status and whether or not any primary adverse events have occurred since the ablation procedure, 7 days post-ablation.

*Primary adverse events include: Cardiac Tamponade/Perforation, Death, Diaphragmatic Paralysis, Heart Block, Myocardial Infarction, Pericarditis, Pneumothorax, Pulmonary Edema, Stroke/Cerebrovascular Accident, Thromboembolism, Transient Ischemic Attack, Vascular Access Complication, Atrio-Esophageal Fistula, and Pulmonary Vein Stenosis.

Secondary outcome measures
1. Serious adverse events and other adverse events are assessed by the doctor at the 30-day peri-procedural clinic visit and 3 months post-procedure
2. PV stenosis rate is assessed using CT/MRA pre-ablation and 3 months
3. Incidence of pre- and post-ablation asymptomatic cerebral emboli is assessed using cerebral MRI pre-ablation and pre-discharge
4. Incidence of new or worsening neurologic deficits is assessed using a neurological assessment pre and post-ablation
5. Incidence of post-ablation esophageal lesion/injury is assessed using an endoscopy within 48 hours post-ablation

Overall study start date
01/01/2015

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Symptomatic paroxysmal atrial fibrillation with at least one documented atrial fibrillation episode within one year prior to enrollment
2. Failed at least one antiarrhythmic drug (class I or III)
3. Pre-procedural anticoagulation on warfarin, rivaroxaban or apixaban. If receiving warfarin therapy, patients must agree to take warfarin for at least 4 weeks prior to the scheduled ablation procedure.
4. Age 18 years or older
5. Able and willing to comply with all pre-, post- and follow-up testing and requirements (e.g. Patient not confined by a court ruling)
6. Signed Patient Informed Consent Form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 40

Total final enrolment
39

Key exclusion criteria
1. Atrial fibrillation secondary to electrolyte imbalance, thyroid disease, or reversible or non-cardiac cause
2. Previous surgical or catheter ablation for atrial fibrillation
3. Previously diagnosed with persistent or longstanding atrial fibrillation
4. Any percutaneous coronary intervention (PCI), cardiac surgery, or valvular cardiac surgical or percutaneous procedure (e.g. ventriculotomy, atriotomy) within the past 2 months
5. Valve repair or replacement and presence of a prosthetic valve
6. Any carotid stenting or endarterectomy
7. Coronary artery bypass grafting surgery within the past 6 months
8. Documented left atrium thrombus on baseline/pre-procedure imaging
9. LA size > 55 mm
10. Left Ventricular Ejection Fraction (LVEF) < 40%
11. Contraindication to anticoagulation (heparin or warfarin)
12. Contraindication to use of contrast agents for MRI such as advanced renal disease, etc.
13. History of blood clotting or bleeding abnormalities
14. Myocardial infarction within the past 2 months
15. Documented thromboembolic event (including transient ischemic attack [TIA]) within the past 12 months
16. Rheumatic Heart Disease
17. Uncontrolled heart failure or New York Heart Association (NYHA) function class III or IV
18. Awaiting cardiac transplantation or other cardiac surgery within the next 12 months
19. Unstable angina
20. Acute illness or active systemic infection or sepsis
21. Diagnosed atrial myxoma
22. Presence of implanted pacemaker, implantable cardioverter defibrillator (ICD), or tissue-embedded, iron-containing metal fragments
23. Significant pulmonary disease, (e.g. restrictive pulmonary disease, constrictive or chronic obstructive pulmonary disease) or any other disease or malfunction of the lungs or respiratory system that produces chronic symptoms
24. Significant congenital anomaly or medical problem that, in the opinion of the investigator, would preclude enrollment in this study
25. Unresolved pre-existing neurological deficit
26. Women who are pregnant (as evidenced by pregnancy test if pre-menopausal), lactating, or who are of child bearing age and plan on becoming pregnant during the course of the clinical investigation

27. Enrollment in an investigational study evaluating another device, biologic, or drug
28. Has known pulmonary vein stenosis
29. Presence of intramural thrombus, tumor or other abnormality that precludes vascular access, or manipulation of the catheter
30. Presence of a condition that precludes vascular access
31. Life expectancy or other disease processes likely to limit survival to less than 12 months
32. Presenting contra-indication for the devices (e.g. esophageal endoscope, CT, etc.) used in the study, as indicated in the respective instructions for use
33. Categorized as a vulnerable population and require special treatment with respect to safeguards of well-being (e.g. cognitively impaired, veteran, prisoner, etc.)

Date of first enrolment
25/11/2016

Date of final enrolment
13/03/2017

Locations

Countries of recruitment
Czech Republic

England

Italy

United Kingdom

Study participating centre
St. Bartholomew's Hospital
W Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Na Homolce Hospital
Czech Republic
15030

Study participating centre
Centro Cardiologico Monzino
Italy
20138

Study participating centre
Ospedale Generale Regionale F. Miulli
Acquaviva delle Fonti
Italy
70021

Sponsor information

Organisation
Biosense Webster, Inc.

Sponsor details
33 Technology Drive
Irvine
United States of America
92618

Sponsor type
Industry

ROR
https://ror.org/04yzcpd71

Funder(s)

Funder type
Industry

Funder Name
Biosense Webster

Alternative Name(s)
Biosense Webster, Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
There are no plans for publication of the study results as this is a very early feasibility study.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Richard Schilling, MD (Richard.Schilling@bartshealth.nhs.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	13/12/2019	Yes	No
HRA research summary			28/06/2023	No	No