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Study utilizing a novel mapping catheter in heart arrhythmias

Submission date 17/07/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/08/2018	**Overall study status** Completed	
Last Edited 13/03/2019	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims:
Study catheters are used to understand and record electrical impulses in various places in a person's heart, which can be used to help doctors find places in hearts that may need to be treated. Catheters also help doctors to visualise important locations in a person's heart. Therefore, catheters are used for diagnosis, rather than delivering therapy.
The purpose of this study is to look at the safety and design of a new type of catheter used to support procedures to treat cardiac arrhythmias (irregular heartbeat). This new cathether is designed to provide higher quality signals from the heart compared to other diagnostic catheters.

Who can participate?
Patients diagnosed with and who are eligible for ablation procedures for ventricular tachycardia, atrial tachycardia, or atrial fibrillation.

What does the study involve?
The new mapping catheter will be used to help a patient’s doctor understand the electrical activity in the patient’s heart before, during, and after a standard ablation procedure for a study patient’s cardiac arrhythmia. This catheter does not deliver any therapy to the patient. The intent of this study is to confirm the study catheter can perform as it is has been designed. It will be used in place of the standard catheter that would have otherwise been used in the procedure. The delivery of therapy to treat the cardiac arrhythmia following use of the new catheter will be according to the doctor’s normal practice (the “standard of care”) using a commercially available therapeutic catheter, but the use of the diagnostic mapping catheter is not expected to impose any additional direct safety risks. A standard radiofrequency ablation procedure may pose complications such as pericardial or pleural effusion (accumulation of excess fluid around the heart or lungs), pericarditis (inflammation of the external layer of the heart, 0% to 50%), pericarditis (inflammation of the external layer of the heart, 0% to 50%), phrenic nerve injury (injury of the nerve that originates in the neck and passes down between the lungs and heart to reach the diaphragm, risk 0 to 0.4%), and other complications. Patients interested in participating in this study should discuss these risks with a study doctor.

What are the possible benefits and risks of participating?
There are no known benefits to participants taking part in this study; however, the new catheter may allow the doctor to better identify problematic electrical activity in the heart of patients. The possible risks to participants taking part are the standard risks of a radiofrequency ablation procedure, therefore, the use of the diagnostic mapping catheter is not expected to impose any additional direct safety risks. A standard radiofrequency ablation procedure may pose complications such as pericardial or pleural effusion (accumulation of excess fluid around the heart or lungs), pericarditis (inflammation of the external layer of the heart, 0% to 50%), pericarditis (inflammation of the external layer of the heart, 0% to 50%), phrenic nerve injury (injury of the nerve that originates in the neck and passes down between the lungs and heart to reach the diaphragm, risk 0 to 0.4%), and other complications. Patients interested in participating in this study should discuss these risks with a study doctor.

Where is the study run from?
1. UZ Anterwerpen, Antwerp, Belgium
2. OLV Ziekenhuis, Aalst, Belgium
3. Virga Jessa Ziekenhuis, Hasselt, Belgium
4. St. Bart's Hospital, London, UK
5. Royal Brompton Hospital, London, UK

When is study starting and how long is it expected to run for?
The start date of the trial is July 2018. The study duration is expected to be approximately 7 months, which includes the enrollment phase.

Who is funding the study?
Biosense Webster, Inc (USA)

Who is the main contact?
Nathalie Macours
nmacours@its.jnj.com

Contact information

Type(s)
Public

Contact name
Ms Nathalie Macours

Contact details
Leonardo Da Vincilaan 15
Diegem
Belgium
1831

Additional identifiers

Protocol serial number
BWI_2017_05

Study information

Scientific Title
Prospective early feasibility study utilizing a novel mapping catheter for mapping in the atria and ventricles

Study objectives
Assess the feasibility and safety of the use of a novel mapping catheter for mapping in the atria and ventricles

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Belgium: Universiteit Anterwepen Ethisch Comite, UZA, Wilrijkstraat 10, 2650 Edegem, Belgium, 09/07/2018, REC ref: 18/18/227
2. UK: West of Scotland REC 4, Research Ethics, Clinical Research and Development, West Glasgow Ambulatory Care Hospital, Dalnair Street, Glasgow, G3 8SJ, UK, 11/10/2018, REC ref: 18 /WS/0165

Study design
Interventional prospective multi-center single-arm non-randomised open-label early feasibility study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Ventricular tachycardia, atrial tachycardia, atrial flutter, atrial fibrillation

Interventions
The novel diagnostic mapping catheter will be used by doctors to better understand areas of the heart that initiate or sustain irregular heart rhythms (“cardiac arrhythmias”). The patient will have this novel catheter used in place of an institution’s standard diagnostic mapping catheter during the study procedure (i.e. in place of what would have been used had the study patient not chosen to participate in the study but still have a procedure for their cardiac arrhythmia). Diagnostic catheters do not delivery therapy and aid doctors in identifying areas that may need therapy and help doctors confirm the treatment has been delivered.
At the beginning of the procedure, the doctor will create a three-dimensional map of a patient’s heart and gather information from areas of potential irregular electrical activity using the study catheter with the Biosense Webster CARTO® 3 System. After collecting this information, the doctor will provide the standard treatment of the patient’s cardiac arrhythmia (i.e. what would normally be provided had the study patient not participated in the study). During and after the standard procedure for the study patient’s arrhythmia, the doctor is asked to continue to use the novel diagnostic mapping catheter for any other activities.

Enrolled study patients will be discharged per the hospital’s standard of care following these types of procedures. Study patients will have either a phone call or in-clinic check-up at 7 to 9 days later.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. Completion of pre-ablation mapping and clinically indicated mapping with the novel mapping catheter without resort to using a nonstudy mapping catheter, assessed during the patient's procedure.
2. Incidence of serious adverse events, self-reported by patients and assessed from the time of enrolment through to the 7 day follow-up visit.

Key secondary outcome(s))
Deployment, use, and mapping of the novel mapping catheter in the atria and ventricles during the study procedure, characterised with descriptive statistics.

Completion date
08/02/2019

Eligibility

Key inclusion criteria
1. Diagnosed with and is a candidate for clinicallyindicated catheter ablation procedure for the management of:
1.1. Ischemic ventricular tachycardia
1.2. Atrial tachycardia/atypical atrial flutter/paroxysmal atrial fibrillation following a pulmonary vein isolation ablation or mitral valve repair procedure
1.3. Persistent atrial fibrillation
2. Aged 18 years or older
3. Able to provide informed consent
4. Able and willing to comply with all pre, post, and followup testing and requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. History of continuous atrial fibrillation (AF) sustained longer than 12 months
2. History of AF <7 days and no previous AF ablation procedure
3. Previously diagnosed with longstanding persistent atrial fibrillation
4. Previously diagnosed with idiopathic PVC/VT
5. Study arrhythmia secondary to reversible cause
6. Atrial arrhythmias: patients with a left atrial size >55 mm
7. LVEF ≤ 25% for VT patients
8. LVEF ≤ 40% for AF patients
9. Documented thrombus in the chamber to be mapped by the study catheter on imaging
10. Contraindication to anticoagulation (i.e. heparin, warfarin, dabigatran)
11. History of blood clotting or bleeding abnormalities (e.g. hypercoagulable state)
12. Myocardial infarction within the past 2 months (60 days)
13. Documented thromboembolic event (including TIA) within the past 12 months (365 days)
14. Uncontrolled heart failure or NYHA function class III or IV
15. Implanted with a pacemaker or intracardiac cardiac defibrillator within the past 3 months (90 days)
16. Implanted with a prosthetic valve
17. Active systemic infection
18. Diagnosed atrial or ventricular myxoma
19. Implanted with an interatrial baffle or patch
20. Atrial septal closure within the past 6 weeks (42 days)
21. Presence of a condition that precludes vascular access
22. Presence of intramural thrombus, tumor or other abnormality that precludes catheter introduction or manipulation
23. Women who are pregnant (as evidenced by pregnancy test if premenopausal)
24. Enrollment in an investigational study evaluating another device or drug

Date of first enrolment
03/08/2018

Date of final enrolment
20/12/2018

Locations

Countries of recruitment
United Kingdom

England

Belgium

Study participating centre
UZ Anterwerpen
Belgium
2650

Study participating centre
Onze Lieve Vrouwziekenhuis Aalst
Belgium
9300

Study participating centre
Virga Jessa Ziekenhuis
Belgium
3500

Study participating centre
Royal Brompton Hospital
United Kingdom
SW3 6NP

Study participating centre
St Bartholomew's Hospital
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Biosense Webster, Inc.

ROR
https://ror.org/04yzcpd71

Funder(s)

Funder type
Not defined

Funder Name
Biosense Webster, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

Datasets generated during and/or analysed during the current study may be available upon request from Richard Schilling, MD (Richard.Schilling@bartshealth.nhs.uk). Study patient identity and participation in the study will be treated strictly confidential and patients will not be identified by name or in any other identifying manner in files, results, or publications concerning this study. Study patient Information will be encoded in order to safeguard confidentiality and if the results of the scientific and clinical researches are published, used in reports of the study, or for scientific presentations, identities will remain confidential. The sponsor will take all necessary steps to protect privacy and will review all requests for data.

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