Safety and Effectiveness Evaluation of the OMNYPULSE* Catheter with the TRUPULSE* generator for treatment of Paroxysmal Atrial Fibrillation (PAF)

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The major objective of this clinical investigation is to demonstrate safety and effectiveness of the ablation system (OMNYPULSE* Bi-Directional Catheter and TRUPULSE* Generator) when used for isolation of the atrial PVs in treatment of subjects with...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON56476

Source
ToetsingOnline

Brief title
Omny-IRE

Condition

- Cardiac arrhythmias

Synonym
arrhythmia - cardiac rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Biosense Webster Inc.

Source(s) of monetary or material Support: sponsor: Biosense Webster Inc;part of the Johnson and Johnson Family of Companies

Intervention

Keyword: atrial fibrillation (AF), effectiveness, pulsed field ablation (PFA), safety

Outcome measures

Primary outcome

Safety

The primary safety endpoint is the occurrence of Primary Adverse Events (PAEs)

within seven (7) days of the index ablation procedure where the investigational

OMNYPULSE* Bi-Directional Catheter and TRUPULSE* Generator are used per

clinical investigation plan.

PAEs include the following Adverse Events (AEs):

Atrio-Esophageal Fistula*

Phrenic Nerve Paralysis

Cardiac Tamponade/perforation**

Pulmonary Vein Stenosis*

Device or procedure related death*

Stroke/Cerebrovascular Accident (CVA)

Major Vascular Access Complication/Bleeding

Thromboembolism

Myocardial Infarction

Transient Ischemic Attack (TIA)

Pericarditis

Heart Block

Pulmonary Edema (Respiratory Insufficiency)

Vagal Nerve Injury/Gastroparesis

* Device or procedure related death, pulmonary vein stenosis and atrio-esophageal fistula that occur greater than one week (7 days) and less than or equal to 90 days post-procedure are considered and analyzed as PAEs.

** Cardiac Tamponade/Perforation occurring up to 30 days post AF ablation process procedure will be considered a PAE.

Acute Effectiveness

The acute effectiveness endpoint is the electrical isolation of clinically relevant targeted PVs which is evidenced by confirmation of entrance block after adenosine/isoproterenol challenge at the end of the index ablation procedure. Use of a non-study device to achieve PVI is considered an acute procedural failure.

Secondary outcome

12-month Effectiveness

Freedom from documented (symptomatic and asymptomatic) atrial arrhythmia (Atrial Fibrillation (AF), Atrial Tachycardia (AT) or Atrial Flutter (AFL) of unknown origin*) episodes based on electrocardiographic data (>=30 seconds on arrhythmia monitoring device) during the effectiveness evaluation period (day 91-day 365) on or off antiarrhythmic therapy. Acute procedural failure (i.e., failure to achieve entrance block with the study device in any of the clinically relevant targeted PVs) will also be deemed a 12- month effectiveness failure.

*AFL of unknown origin is defined as all AFL except those CTI dependent AFL as

confirmed by 12-lead electrocardiogram (ECG) or entrainment maneuvers in an EP

study.

Study description

Background summary

The Biosense Webster Pulsed Field (PF) Ablation System consists of the:
- TRUPULSE* Generator (D-1417-01-IC)
- OMNYPULSE* Bi-Directional Catheter (D-1430-05-SI)
- Sterile Interface Cable (D-1422-03-SI)
- Related components and accessories

The Biosense Webster PF Ablation System provides a novel solution for the treatment of cardiac arrythmias through pulsed field ablation (PFA). The PFA technology ablates targeted cardiac tissue by application of ultrashort electrical pulses, pulsed field (PF) energy, which induces cell membrane permeability resulting in irreversible electroporation (IRE).

The principal components of the PF ablation system to be evaluated in this investigation are:

• The OMNYPULSE* Bi-Directional Catheter (used for cardiac electrophysiological mapping, stimulating and recording, and cardiac ablation when used with the Biosense Webster TRUPULSE* Generator).
The catheter will be used in conjunction with the investigational accessory devices: the Sterile Interface Cable and the Guiding Sheath.

• The TRUPULSE* Generator (delivers PF energy when used with the OMNYPULSE* Bi-Directional Catheter).

Both devices are compatible with the Biosense Webster CARTO* 3 System.

Study objective

The major objective of this clinical investigation is to demonstrate safety and effectiveness of the ablation system (OMNYPULSE* Bi-Directional Catheter and TRUPULSE* Generator) when used for isolation of the atrial PVs in treatment of subjects with PAF.

Acute safety and acute effectiveness will be evaluated through hypothesized

primary endpoints and 12-month effectiveness will be evaluated through a hypothesized secondary endpoint.

The additional objectives of this clinical investigation are to evaluate procedural data, quality of life and the incidence of (procedure and/or device related) serious adverse events during and after index ablation procedure up to 12 months

Study design

Prospective, single arm, multi-center, pre-market clinical evaluation of the PF ablation system (OMNYPULSE* Bi-Directional Catheter and TRUPULSE* Generator) to demonstrate safety and effectiveness for the treatment of Paroxysmal Atrial Fibrillation (PAF) comparing to corresponding performance goals.

To minimize any learning curve effect, the first 2 study subjects treated by each ablating physician, will be considered roll-in subjects.
The main study will enroll 135 evaluable subjects with PAF who are candidates for atrial fibrillation ablation. Embedded within the main study will be a Neurological Assessment (NA) subset, a Cardiac Computed Tomography (CT) or Magnetic Resonance Angiogram (MRA) image subset, an Esophageal Endoscopy (EE) subset and a Pulmonary Vein Isolation (PVI) durability subset in a prospective manner. These subsets are intended to delineate safety and assess lesion durability at 2-3 months following ablation. Thirty patients participating to the main study will be included in the subset study. The same subjects will participate in all four (4) subsets. Participation to the substudy is voluntary. If a study participant does not wants to participate to the substudy, this will not influence his/her further care.

All subjects will be followed for 12 months and scheduled for evaluation at 7 days, 1-, 3-, 6- and 12-month following index ablation procedure.

Intervention

Subjects will arrive at the electrophysiology (EP) laboratory for their ablation procedure and will undergo preparation for the procedure per the hospital*s standard protocol (discretion of investigator).

The AF ablation procedure will follow below sequence:

1. Anatomical mapping of the Left Atrium (LA).
2. Pulmonary Vein (PV) Isolation with PF energy using the study catheter and generator.
3. Confirmation of PV Isolation (entrance block) with adenosine/isoproterenol challenge.
4. If necessary, treatment of acute reconnections with additional applications

of PF energy.
5. Confirmation of entrance block of all targeted PVs at the end of procedure.

All subjects will undergo PV ablation with the investigational device until PVI is achieved and confirmed via entrance block. If PVI cannot be achieved with the investigational device, a commercially approved Biosense Webster (RF) catheter and compatible commercially available RF generator can be used to complete the procedure.

A right atrial Cavotricuspid Isthmus (CTI) linear ablation is allowed only in cases with documented typical atrial flutter (AFL) either prior to or during the index ablation procedure. The CTI line should be completed with a commercially approved and compatible Biosense Webster (RF) catheter and (RF) generator.

Study burden and risks

Pre-Procedure/Baseline Visit Assessments:
- Read and signature on Patient Information and Consent
- Collection of Patients Demographics, Medical History and Anticoagulation Therapy information
- Collection of Pregnancy test for all women of childbearing age and potential.
- Imaging (TTE or other acceptable equivalent cardiac imaging) to assess the left atria and left ventricular ejection fraction (assessment only to be performed if this information is not available within 6 months prior to the procedure).
- Imaging for detection of left atrial thrombus or other structural contraindications to an ablation procedure.
- Imaging Cardiac CT/MRA to assess the structure and size of the Pulmonary Veins and anatomy of the left atrium.
- Record a 12-Lead ECG
- Collect Patient Questionnaire - Atrial Fibrillation Effect on Quality of Life.
This visit may take a little bit longer then routine care for the patient, as a questionnaire and consent need to be explained and completed, but will not cause any additional burden or risk compared to routing case.

Cardiac Ablation Procedure:
No additional burden and risk to the patients as in a routine care ablation procedure.

Pre-discharge Visit Assessments:
- Collection of Medication Regimen information.
- Imaging of Pericardial fluid presence (safety check).
- Collection of Adverse Events information
- Record of 12-Lead ECG (as per standard of care).
This visit has no additional burden and risk to the patients.

Assessments at 7 Days follow-up (via clinical visit or via telephone call)
visit assessments:
- Collection of Medication Regimen information.
- Collection of Adverse Events information
This visit has no additional burden or risk to the patients, as the visit can be conducted per telephone call and might take up to 15 minutes.

The 1, 3, 6 and 12-months follow-up visit assessments in the Main Study are:
- Collection of Medication Regimen information.
- Collection of Adverse Events information
- Record of 12-Lead ECG
- Remote Monitoring (on Weekly and Monthly base)
- 24 Hour Holter Monitoring.
These visits have some additional burden to the patients but not additional risks compared with their routine care. In addition the follow-up of the medical health of the patient is more ensured with this tight follow-up scheme.

Patients who will participate in the subset study will have more additional burden and risks, compared with the patients participating only in the Main subject, because these subset patients will have additional Cerebral MRI, Neurological Exam and Neurological Evaluation (using questionnaires) assessments at baseline, discharge, 1, 3, 6 and 12-months follow-up visit.

Refer to the protocol synopsis table 1 for a schematic overview.

Contacts

Public
Selecteer

Leonardo Da Vincilaan 15
Diegem 1831
NL
Scientific
Selecteer

Leonardo Da Vincilaan 15
Diegem 1831
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diagnosed with Symptomatic Paroxysmal AF defined as AF that terminates spontaneously or with intervention within 7 days of onset. This PAF is considered to be symptomatic if symptoms related to AF are experienced by the patient.
2. Selected for AF ablation procedure by pulmonary vein isolation (PVI).
3. Age 18-75 years.
4. Willing and capable of providing consent.
5. Able and willing to comply with all pre-, post- and follow-up testing and requirements.

Exclusion criteria

1. Previously known AF secondary to electrolyte imbalance, thyroid disease, or reversible or non-cardiac cause (e.g., documented obstructive sleep apnea, acute alcohol toxicity, morbid obesity (Body Mass Index >40 kg/m²), renal insufficiency (with an estimated creatinine clearance < 30 mL/min/1.73 m2) *.). 2. Previous LA ablation or surgery. 3. Patients known to require ablation outside the PV region (e.g., atrioventricular reentrant tachycardia, atrioventricular nodal re-entry tachycardia, atrial tachycardia, ventricular tachycardia and Wolff-Parkinson-White). 4. Previously diagnosed with persistent AF (> 7 days in duration). 5. Severe dilatation of the LA (LAD >50mm antero-posterior diameter in case of Transthoracic Echocardiography (TTE)). 6. Presence of LA thrombus. 7. Severely compromised Left Ventricular Ejection Fraction (LVEF <40%). 8. Uncontrolled heart failure or New York Heart Association (NYHA) Class III or IV. 9. History of blood clotting, bleeding abnormalities or contraindication to anticoagulation (heparin, warfarin, or dabigatran). 10. History of a documented thromboembolic event (including TIA) within the past 6 months. 11. Previous Percutaneous Coronary Intervention (PCI) / Myocardial Infarction (MI) within the past 2 months. 12. Previous Coronary Artery Bypass Grafting (CABG) in conjunction with valvular surgery, cardiac surgery (e.g., ventriculotomy, atriotomy) or valvular cardiac (surgical or

percutaneous) procedure. 13. Unstable angina pectoris within the past 6 months. 14. Anticipated cardiac transplantation, cardiac surgery, or other major surgery within the next 12 months. 15. 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 severe chronic symptoms. 16. Known significant PV anomaly that in the opinion of the investigator would preclude enrollment in this study. 17. Prior diagnosis of pulmonary vein stenosis. 18. Pre-existing hemi diaphragmatic paralysis. 19. Acute illness, active systemic infection, or sepsis. 20. Presence of intracardiac thrombus, myxoma, tumor, interatrial baffle or patch or other abnormality that precludes catheter introduction or manipulation. 21. Severe mitral regurgitation. 22. Presence of implanted pacemaker or Implantable Cardioverter-Defibrillator (ICD) or other implanted metal cardiac device that may interfere with the pulsed electric field energy. 23. Presence of a condition that precludes vascular access (such as Inferior Vena Cava (IVC) filter) 24. Significant congenital anomaly or a medical problem that in the opinion of the investigator would preclude enrollment in this study. 25. Categorized as vulnerable population and requires special treatment with respect to safeguards of well-being. 26. Current enrollment in an investigational study evaluating another device or drug. 27. 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. 28. Life expectancy less than 12 months. 29. Presenting contra-indications for the devices used in the study, as indicated in the respective Instructions For Use (IFU). Additional exclusion criteria for Neurological Assessment (NA) subjects: 30. Known contraindication for MRI such as use of contrast agents due to advanced renal disease, claustrophobia etc. (at PI discretion). 31. Presence of iron-containing metal fragments in the body. 32. Known unresolved pre-existing neurological deficit. Additional exclusion criteria for Esophageal Endoscopy (EE) subjects: 33. Known uncontrolled significant GastroEsophageal Reflux Disease (GERD)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2024
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	OMNYPULSE Catheter
Registration:	No

Ethics review

Approved WMO Date:	23-01-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	CIV-23-06-043176
CCMO	NL84145.000.23