Initial Safety and Performance of the CellFX® nsPFA* Cardiac Surgery System for the Treatment of Atrial Fibrillation

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

Summary

ID

NL-OMON56875

Source
ToetsingOnline

Brief title
CellFX® nsPFA* for the Treatment of Atrial Fibrillation

Condition

- Cardiac arrhythmias

Synonym
arrythmia, Atrial Fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Pulse Biosciences, Inc
Source(s) of monetary or material Support: Pulse Biosciences;Inc

Intervention

Keyword: ablation, atrial fibrilation, cardiac surgery

Outcome measures

Primary outcome

Primary safety endpoint is the rate of acute major adverse events (MAEs) which includes death, stroke, myocardial infarction (MI), and transient ischemic attack (TIA) or excessive bleeding (> 2units of blood and surgical intervention) within 30 days post-ablation procedure.

Primary effectiveness is acute electrical isolation of the bilateral pulmonary veins and left atrial Box by means of intraoperative entrance or exit block testing

Secondary outcome

Safety

• Subjects presenting with Primary SAEs up to the 12-month post-procedure follow-up

• Subjects presenting with any AEs or SAEs up to the 12-month post-procedure follow-up

Effectiveness

• Long-term technical success is defined as confirmation of electrical isolation of the bilateral pulmonary veins and left atrial Box by cardiac electroanatomical mapping at 60-120 days following the index procedure

Study description

Background summary

Accompanying the aging of populations worldwide, and increased survival with chronic diseases, the incidence and prevalence of atrial fibrillation (AF) are rising, justifying the term global epidemic. Atrial fibrillation is the most prevalent cardiac arrhythmia, with an estimated prevalence of 1.5-2.0%, affecting approximately 2.5 million people in the United States and 4.5 million in the European Union.

The incidence increases with advancing age, affecting 6% of the population over age 60 and 10% of the population over age 80. Age-adjusted population trending projects 16 million people in the United States will have AF and approximately 72 million globally by 2050. Atrial fibrillation remains a significant cause of morbidity and mortality in industrialized societies. The annual risk of AF related stroke is 5% per year and one of every six strokes diagnosed occurs in the presence of AF.

Therefore, patients with AF require long-term anticoagulation to prevent embolic events. Failure to manage AF may also lead to anatomic and electrical remodeling of the left atrium, tachycardia-induced cardiomyopathy, and reduced left ventricular function (heart failure).

Atrial fibrillation remains an extremely costly public health burden, with annual per patient cost of care approaching ¤3000 (approximately U.S. $3200).

Study objective

The primary objective of this feasibility study is to demonstrate the initial safety and effectiveness of the CellFX® nsPFA* Cardiac Clamp in performing a box lesion around the 4 pulmonary veins as an isolated procedure or as a part of a more extensive surgical ablation set in conjunction with concomitant cardiac surgical procedure.

Study design

The study design is a prospective, multicenter, single arm, non-randomized, feasibility study to evaluate the safety and effectiveness of the CellFX® nsPFA* Cardiac Surgery System for the treatment of atrial fibrillation.

Adult subjects who are clinically indicated for a concomitant cardiac surgical procedure will undergo left pulmonary vein, roof and floor ablations to form a left atrial posterior box.

Following the surgical ablation procedure and hospital discharge, all study subjects will be followed at 1 month, 6 months, and 12 months, and will be exited from the study at the conclusion of the 12-month follow-up visit.

All subjects will return to the hospital between 60-120 days post-surgical ablation procedure to undergo a cardiac electrophysiology study with electroanatomical mapping to assess electrical isolation of the pulmonary veins and left atrial posterior wall.

Intervention

- Left Pulmonary Vein Isolation -
Right atriotomy may be performed. The left veins are bluntly dissected and encircled with umbilical tape. Pacing thresholds are obtained from the left superior and left inferior PVs using a bipolar pacing probe. The left PVs are then isolated using the CellFX nsPFA Cardiac Clamp creating as large a cuff of atrial tissue as possible. PVI is documented by pacing at 20mA from both the left superior and inferior PVs in order to confirm exit block. Additional ablations are performed as needed until exit block is obtained.

- Roof and Floor Lesions -
Complete posterior LA isolation is achieved by completing a *box* lesion set. From the inferior aspect of the left atriotomy, the CellFX nsPFA Cardiac Clamp is used to create an ablation line across the floor of the left atrium towards the orifice of left inferior PV. From the superior aspect of the left atriotomy, the CellFX nsPFA Cardiac Clamp is used to create another ablation line across the roof of the left atrium towards the left superior PV.

- Exit or Entrance Block Testing of the Posterior Wall-
At the conclusion of the procedure when the heart is off bypass, exit or entrance block testing of the posterior wall should be completed.

Study burden and risks

There are no guaranteed benefits from participation in this study. The study will provide an initial safety profile of the CellFX® nsPFA* Cardiac Surgery System in treating this patient population.

The risk profile associated with the CellFX® nsPFA* Cardiac Surgery System, and the ablation procedure is expected to be minimal and consistent with standard surgical clamps that are always under the direct control of the surgeon.
When surgical AF ablation is an adjunctive procedure in a patient already indicated for cardiac surgery, the additional risk of adding the ablation procedure is quite minimal.
For detailed information on the risks of the devices used in the study procedure, including a complete list of warnings, precautions, and potential

adverse events, please refer to the Instructions for Use (IFUs) for the Pulse Biosciences CellFX nsPFA Cardiac Surgery System, and the Investigator Brochure.

The CellFX® nsPFA* Cardiac Surgery System is indicated to ablate cardiac tissue during a concomitant procedure, such as, open coronary artery bypass grafting and/or valvular replacement or repair.
Below is a list of potential adverse effects (e.g., complications) that are associated with this combined procedure:

- Atelectasis
- Atrial perforation or rupture
- Cardiac Tamponade/Pericardial Effusion
- Cardiac valve injury
- Congestive Heart Failure
- Coronary Artery Spasm
- Damage to adjacent nerve and/or blood vessels
- Death
- Deep sternal wound infection, mediastinitis
- Diaphragmatic (phrenic nerve) paralysis
- Drug Reaction to General Anaesthesia
- Esophageal-left atrial fistula or esophageal rupture
- Excess Haptoglobin Levels (Hemolysis)
- Excessive bleeding that may require re-intervention
- Excessive pain and discomfort
- Extension of extracorporeal bypass time or aortic cross clamp time
- Infection resulting in sepsis or endocarditis
- Injury to unintended surrounding tissues, including tears and punctures
- Myocardial Infarction per ACC Guidelines
- Pericarditis (restrictive or constrictive)
- Perioperative atrial or ventricular rhythm/conduction disturbance
- Phrenic nerve damage
- Pneumonia
- Pneumothorax (persistent)-requiring intervention
- Pulmonary Vein Stenosis
- Stroke/Transient Ischemic Attack
- Thromboembolism
- Ventricular Arrhythmia (V. Tachycardia or V. Fibrillation)
- Ventricular perforation or rupture

Adverse effects specific to the ablation procedure includes arrhythmias, coronary artery spasm, esophageal tissue damage, excess haptoglobin levels (hemolysis), injury to the cardiac ablation treatment site, perforation and phrenic nerve damage.
There may be other risks that are unknown at this time. Adverse events will be collected and reviewed throughout the duration of the study and follow-up period. The investigators will be notified of any additional risks identified that could affect the health, safety, or welfare of the study subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject must be between 18 and 85 years of age
2. Subject is willing and capable of providing Informed Consent to undergo study procedures which includes surgical AF ablation and completing follow-up visits as specified in the clinical study protocol
3. Subject has history of documented atrial fibrillation within one year prior to enrollment. Documentation may include ECG, transtelephonic monitor (TTM), holter monitor or telemetry strip
4. Subject is scheduled to undergo non-emergent cardiac surgical procedure(s) to be performed on cardiopulmonary bypass including open-heart surgery for one or more of the following: Mitral valve repair or replacement, Aortic valve repair or replacement, Ascending aortic aneurysms, or Coronary artery bypass procedures

5. Left ventricular ejection fraction >= 30% (determined by echocardiography or cardiac catheterization performed within 60 days of enrollment as documented in patient medical history)
6. Subject has a life expectancy of at least 5 years

Exclusion criteria

1. Subject has an implantable electronic medical device. (i.e., pacemaker, ICD, or CRT) or left atrial appendage device
2. Subject has a prosthetic heart valve
3. Stand- alone AF without indication(s) for concomitant Coronary Artery Bypass Graft (CABG) and/or valve surgery
4. Previous surgical Maze procedure
5. Prior cardiac surgery (Redo)
6. Wolff-Parkinson-White syndrome or other Supra-Ventricular arrhythmia, Atrioventricular (AV) nodal reentry
7. Subjects requiring surgery other than CABG and/or cardiac valve surgery and/or atrial septal defect repair
8. Prior history of medical procedure involving instrumentation of the left atrium (e.g., previous ablation)
9. Class IV New York Heart Association (NYHA) heart failure symptoms
10. Prior history of cerebrovascular accident or TIA within 6 months or at any time if there is residual neurological deficit
11. Documented ST-segment elevation Myocardial Infarction (MI) within the 6 weeks prior to study enrollment
12. Need for emergent cardiac surgery (i.e., cardiogenic shock)
13. Known carotid artery stenosis greater than 80%
14. Current diagnosis of active systemic infection
15. Severe peripheral arterial occlusive disease defined as claudication with minimal exertion
16. Renal failure requiring dialysis or hepatic failure
17. A known drug and/or alcohol addiction
18. Mental impairment or other conditions which may not allow the subject to understand the nature, significance and scope of the study
19. Pregnancy or desire to get pregnant within 12-months of the study treatment
20. Preoperative need for an intra-aortic balloon pump or intravenous inotropes
21. Subjects who have been treated with thoracic radiation
22. Subjects in current chemotherapy
23. Subjects on long term treatment with oral or injected steroids (not including intermittent use of inhaled steroids for respiratory diseases)
24. Subjects with known hypertrophic obstructive cardiomyopathy
25. Subjects with known cold agglutinin
26. History of abnormal bleeding and/or clotting disorder
27. Contraindication to anticoagulation (i.e., Heparin, Dabigatran, Apixaban, Vitamin K Antagonists such as warfarin)

28. Solid organ or hematologic transplant, or currently being evaluated for an organ transplant
29. Body mass index > 40 kg/m2
30. Use of any other investigational drug, therapy, or device within 30 days prior to enrollment or concurrent participation in another research study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-07-2024
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Pulse Biosciences CellFX® nsPFA Cardiac Surgery System
Registration:	No

Ethics review

Approved WMO Date:	19-06-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-10-2024

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT06355063
CCMO	NL86709.000.24