Volt CE Mark Study

Published: 06-02-2024
Last updated: 02-12-2024

The VOLT CE Mark study will collect data to demonstrate that the Volt PFA System is functioning as intended in a clinical setting and to demonstrate acute safety and effectiveness for the treatment of symptomatic, recurrent paroxysmal atrial...

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

Summary

ID

NL-OMON56560

Source
ToetsingOnline

Brief title
Volt Study

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation, heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Abbott

Intervention

Keyword: atrial fibrillation, Catheter, Pulsed field ablation

Outcome measures

Primary outcome

1. Safety will be summarized as the rate of subjects experiencing a device and/or procedure-related serious adverse event with onset within 7-days of any ablation procedure (index or repeat procedure) that uses the Volt PFA System that are defined below:

• Atrio-esophageal fistula1

• Cardiac tamponade/perforation2

• Death

• Heart block

• Myocardial infarction

• Pericarditis3

• Phrenic nerve injury resulting in permanent diaphragmatic paralysis

• Pulmonary edema

• Pulmonary vein stenosis1

• Stroke/cerebrovascular accident

• Thromboembolism

• Transient ischemic attack

• Vagal nerve injury/gastroparesis

• Major vascular access complications4 / major bleeding events5

• Device and/or procedure related cardiovascular and/or pulmonary adverse event that prolongs hospitalization for more than 48 hours (excluding hospitalization

solely for arrhythmia recurrence or non-urgent cardioversion)

2. Acute Effectiveness

Acute procedural effectiveness will be summarized as the rate of pulmonary veins treated with the Volt PFA system that are isolated at the end of the index ablation procedure. Acute procedural failure for each pulmonary vein is defined as any of the following:

1. Inability to isolate a pulmonary vein at the end of the index ablation procedure or after maximum allowed therapy applications. Isolation will be assessed via confirmation of electrical isolation in each targeted pulmonary vein after a minimum waiting period of 20 minutes via entrance block at a minimum. Touch-up ablation to achieve isolation will be allowed for any pulmonary vein reconnection detected during the index procedure with the investigational catheter (to the maximum delivery allowed per vein) and will not be considered a failure.
2. Any use of a non-study ablation device for pulmonary vein isolation.

Long term effectiveness

Long-term 6-month effectiveness will be summarized as the rate of freedom from documented (symptomatic or asymptomatic) AF/AFL/AT episodes of >30 seconds duration that are documented by protocol-specified 12-lead ECG,

trans-telephonic monitoring (TTM) or Holter monitor after the index ablation procedure through 6 months of follow-up (after a 90-day blanking period following the index ablation procedure).

Secondary outcome

Additional data

1. 12- Month Long-term effectiveness: Freedom from documented (symptomatic or asymptomatic) AF/AFL/AT episodes of >30 seconds duration that are documented by protocol-specified 12-lead ECG, transtelephonic monitoring (TTM) or Holter monitor after the index ablation procedure through 12 months of follow-up (after a 90-day blanking period following the index ablation procedure), utilizing the long-term effectiveness endpoint failures defined above.
2. Rate of subjects with procedural success of PVI ablation with the Volt PFA System defined as in Section 4.1.2 in the PFAD population and in the Per Protocol population (defined in Section 8.1), where inability to isolate any pulmonary vein would constitute a failure.
3. Proportion of subjects with successful first-pass isolation of all targeted veins, and proportion of all targeted pulmonary veins with successful first-pass PV isolation, where first pass isolation is defined as confirmation of entrance block in the ablated pulmonary vein following the initial minimum waiting period of 20 minutes without any ablation after the start of the 20-minute waiting period.
4. Proportion of subjects that experience any procedure and/or Volt PFA System-related adverse event (AE) throughout the 12-month follow-up period.

5. 6-month and 12-month single procedure effectiveness, defined as 6-month or 12-month effectiveness as above after a single ablation procedure. Any repeat ablation procedure required by the subject at any time will be deemed a failure.

6. Proportion of subjects requiring one or more repeat AF ablations at 12 months following the index AF ablation procedure. Of those subjects with repeat ablations, the proportion of treated pulmonary veins ablated with reconnections, and locations of pulmonary vein reconnections (of treated veins) upon electro-anatomical remapping.

7. Changes in EQ-5D-5L and AFEQT scores from baseline to follow up at 3, 6, and 12-months after the index procedure.

8. Procedure data, including but not limited to ablation data, mapping data, usage of Automark, usage of the LivePoint, method(s) used for catheter placement (e.g., fluoroscopy, intracardiac ultrasound, etc.), procedure time, fluoroscopy time, total ablation time, LA dwell time, time to perform PVI, and number and location of PFA energy applications.

9. Cardiovascular-related health care utilization through 12-months after the index procedure, including but not limited to, cardiovascular or AF-related hospitalization (includes readmission) or emergency visit, cardioversion, repeat ablations, use of AADs after 3-month blanking period, and primary SAEs.

10. Arrhythmia monitoring (12-lead ECG, HM, and TTM) compliance

11. Change in PV diameter from baseline to 3 months post procedure.

12. Incidence, number, size (diameter and volume) and anatomic location of cerebral lesions detected on post-procedure brain MRI compared to pre-procedure

brain MRI.

Study description

Background summary

AF is associated with mortality and comorbidities such as stroke, heart failure and sudden cardiac death. In a meta-analysis of contemporary, well-controlled, randomized clinical trials in AF, the mean annual stroke rate was 1.5% and the annualized mortality rate was 3% in AF patients on anticoagulants.6 A minority of these deaths are stroke-related , while sudden cardiac death and death from progressive heart failure are more common, highlighting the need for interventions beyond anticoagulation.7, 8 Atrial fibrillation is also associated with high hospitalization rates. This hospitalization is usually for AF treatment, but is also often due to heart failure, myocardial infarction, and treatment-related complications. 9, 10 In addition, patients with AF have a significantly worse quality of life than healthy controls, and experience a variety of symptoms, including lethargy, palpitations, shortness of breath, chest pain, sleep problems and mental problems. The current conventional approach to perform catheter ablation is via thermal energy such as cryoablation or radiofrequency (RF) energy to achieve pulmonary vein isolation (PVI). However, there are many limitations to current standard care ablation technologies, and even when PVI is performed in highly experienced centers, recurrences are observed in approximately 20% of patients [ref]. In addition, the reliance of these technologies on conductive heating and cooling carries risks to organs or tissues adjacent to the heart, which can lead to side effects such as atrial esophageal fistula, pulmonary vein stenosis, phrenic nerve palsy, among others [ref].
Irreversible electroporation (IRE) is a mechanism for inducing cell death through the application of pulsed electric fields (PEF). Pulsed field ablation (PFA) uses IRE to selectively destabilize cell membranes to initiate cell death, resulting in a non-thermal ablation lesion. Interestingly, myocardial tissue has a lower voltage threshold susceptible to PFA compared to surrounding tissues such as the esophagus, blood vessels and nerve fibers [ref], reducing the risk of damage to these non-cardiac tissues and potentially lowering the number of associated side effects . events. In a review of the current literature, studies/surveys such as the IMPULSE/PEFCAT/PEFCAT II, **PersAFOne, PULSED AF, 5S, and MANIFEST-PF have shown that PFA catheters are as safe or safer than other ablation strategies.16-21 In addition, none of clinical trials reviewed found PFA catheters to be less safe than current standard ablation catheters. Each PFA device currently in preclinical or clinical research is unique in terms of electrode design, pulse length, number of pulses, and voltage. These parameters are critical in developing optimal PFA energy delivery for safe and sustainable lesions.

To date, all studies have demonstrated high acute efficacy in achieving PVI and a low rate of recurrent atrial arrhythmias. With the increasing healthcare burden of AF and the continued need for greater safety and effectiveness in treatments, the Volt* PFA System was developed to deliver high voltage therapy for the safe and effective treatment of symptomatic recurrent AF.

referenties:

6. Kirchhof P, Breithardt G, Camm AJ, Crijns HJ, Kuck KH, Vardas P and Wegscheider K. Improving outcomes in patients with atrial fibrillation: rationale and design of the Early treatment of Atrial fibrillation for Stroke prevention Trial. Am Heart J. 2013;166:442-8.
7. Marijon E, Le Heuzey JY, Connolly S, Yang S, Pogue J, Brueckmann M, Eikelboom J, Themeles E, Ezekowitz M, Wallentin L, Yusuf S and Investigators R-L. Causes of death and influencing factors in patients with atrial fibrillation: a competing-risk analysis from the randomized evaluation of long-term anticoagulant therapy study. Circulation. 2013;128:2192-201.
8. Senoo K, Lip GY, Lane DA, Buller HR and Kotecha D. Residual Risk of Stroke and Death in Anticoagulated Patients According to the Type of Atrial Fibrillation: AMADEUS Trial. Stroke. 2015;46:2523-8.
9. Steinberg BA, Kim S, Fonarow GC, Thomas L, Ansell J, Kowey PR, Mahaffey KW, Gersh BJ, Hylek E, Naccarelli G, Go AS, Reiffel J, Chang P, Peterson ED and Piccini JP. Drivers of hospitalization for patients with atrial fibrillation: Results from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF). Am Heart J. 2014;167:735-42 e2.
10. Thrall G, Lane D, Carroll D and Lip GY. Quality of life in patients with atrial fibrillation: a systematic review. Am J Med. 2006;119:448 e1-19.
16. Reddy VY, Anic A, Koruth J, Petru J, Funasako M, Minami K, Breskovic T, Sikiric I, Dukkipati SR, Kawamura I and Neuzil P. Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation. Journal of the American College of Cardiology. 2020;76:1068-1080.
17. Reddy VY, Dukkipati SR, Neuzil P, Anic A, Petru J, Funasako M, Cochet H, Minami K, Breskovic T, Sikiric I, Sediva L, Chovanec M, Koruth J and Jais P. Pulsed Field Ablation of Paroxysmal Atrial Fibrillation: 1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II. JACC: Clinical Electrophysiology. 2021;7:614-627.
18. Reddy VY, Neuzil P, Koruth JS, Petru J, Funosako M, Cochet H, Sediva L, Chovanec M, Dukkipati SR and Jais P. Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation. Journal of the American College of Cardiology. 2019;74:315-326.
19. Verma A, Boersma L, Haines DE, Natale A, Marchlinski FE, Sanders P, Calkins H, Packer DL, Hummel J, Onal B, Rosen S, Kuck K-H, Hindricks G and Wilsmore B. First-in-Human Experience and Acute Procedural Outcomes Using a Novel Pulsed Field Ablation System: The PULSED AF Pilot Trial. Circulation: Arrhythmia and Electrophysiology. 2022;15.
20. Ekanem E, Reddy VY, Schmidt B, Reichlin T, Neven K, Metzner A, Hansen J, Blaauw Y, Maury P, Arentz T, Sommer P, Anic A, Anselme F, Boveda S, Deneke T, Willems S, van der Voort P, Tilz R, Funasako M, Scherr D, Wakili R, Steven D,

Kautzner J, Vijgen J, Jais P, Petru J, Chun J, Roten L, Futing A, Rillig A, Mulder BA, Johannessen A, Rollin A, Lehrmann H, Sohns C, Jurisic Z, Savoure A, Combes S, Nentwich K, Gunawardene M, Ouss A, Kirstein B, Manninger M, Bohnen JE, Sultan A, Peichl P, Koopman P, Derval N, Turagam MK, Neuzil P and Cooperative M-P. Multi-national survey on the methods, efficacy, and safety on the post-approval clinical use of pulsed field ablation (MANIFEST-PF). Europace. 2022.
21. Schmidt B, Bordignon S, Tohoku S, Chen S, Bologna F, Urbanek L, Pansera F, Ernst M and Chun KRJ. 5S Study: Safe and Simple Single Shot Pulmonary Vein Isolation With Pulsed Field Ablation Using Sedation. Circ Arrhythm Electrophysiol. 2022;15:e010817.

Study objective

The VOLT CE Mark study will collect data to demonstrate that the Volt PFA System is functioning as intended in a clinical setting and to demonstrate acute safety and effectiveness for the treatment of symptomatic, recurrent paroxysmal atrial fibrillation (PAF) and persistent atrial fibrillation (PersAF).

Study design

Pre Market, prospective, single arm, non-randomized study with a substudy of the first 30 subjects in who additional diagnostic test will be done.

Intervention

Pulsed Field Ablation therapy using Volt PFA System

Study burden and risks

Extensive risk analysis and mitigation plans will be implemented to mitigate any residual risk from the Volt* PFA

catheter, Sensor Enabled*, along with the Volt* PFA Generator, Agilis* NxT Steerable Introducer Dual-Reach*, and EnSite* X EP System for subjects. The risks associated with Abbott's Volt PFA System are expected to be similar to those associated with the use of other commercially available ablation catheters approved for the treatment of symptomatic recurrent PAF and PersAF. The patients participating in this study are indicated for cardiac ablation for the treatment of symptomatic recurrent PAF or PersAF as part of their standard medical care and are subject to the risks associated with these devices.

Contacts

Public
Abbott

Standaardruiter 13
VEENENDAAL 3905 PT
NL
Scientific
Abbott

Standaardruiter 13
VEENENDAAL 3905 PT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Documented symptomatic PAF or PersAF. Documentation requirements are as follows: Paroxysmal:
• Physician's note indicating recurrent self-terminating AF AND
• One electrocardiographically documented PAF episodes within 12 months. Documented evidence of the PAF episode must either be continuous AF on a 12-lead ECG or include at least 30 seconds of AF from another ECG device.

Persistent: Continuous AF sustained beyond 7 days and less than 1 year that is documented by
• Physician's note, AND either
• 24-hour Holter within 180-days prior to the procedure, showing continuous AF, OR

• Two electrocardiograms (from any form of rhythm monitoring) showing continuous AF:
o that are taken at least 7 days apart but less than 12 months apart
o If electrograms are more than 12 months apart, there must be one or more Sinus Rhythm recordings in between or within 12 months prior to consent/enrollment
with the most recent electrocardiogram within 180 days of enrollment. Documented evidence of the AF episode
must either be continuous AF on a 12-lead ECG or include at least 30 seconds of AF from another ECG device

2. Plans to undergo a PVI catheter ablation procedure due to symptomatic PAF or PersAF that is refractory or intolerant to at least one Class I or Ill antiarrhythmic drug
3. At least 18 years of age
4. Able and willing to comply with all trial requirements including pre-procedure, post- procedure, and follow-up testing and requirements
5. Informed of the nature of the trial, agreed to its provisions, and has provided written informed consent as approved by the Institutional Review Board/Ethics Committee (IRB/EC) of the respective clinical trial site.

Exclusion criteria

1. Previously diagnosed long-standing persistent atrial fibrillation (Continuous AF greater than 1 year in duration) 2. Arrhythmia due to reversible causes including thyroid disorders, acute alcohol intoxication, electrolyte imbalance, severe untreated sleep apnea, and other major surgical procedures in the preceding 90 days
3. Participant known to require ablation beyond PVI at the time of consent
4. Known presence of cardiac thrombus
5. Left atrial diameter 5.5 cm (anteroposterior diameter) within 180 days of index procedure
6. Left ventricular ejection fraction < 35% as assessed with echocardiography within 180 days of index procedure 7. New York Heart Association (NYHA) class Ill or IV heart failure 8. Body mass index > 40 kg/m2 9. Pregnant, nursing, or planning to become pregnant during the clinical investigation follow-up period
10. Patients who have had a ventriculotomy or atriotomy within the preceding 30 days of procedure, 11. Myocardial infarction (MI), acute coronary syndrome, percutaneous coronary intervention (PCI), or valve or coronary bypass grafting surgery within preceding 90 days
12. Unstable angina
13. Stroke or TIA (transient ischemic attack) within the last 90 days
14. Heart disease in which corrective surgery is anticipated within 180 days after procedure
15. History of blood clotting or bleeding abnormalities including

thrombocytosis, thrombocytopenia, bleeding diathesis, or suspected anti-coagulant state
16. Contraindication to long term anti-thromboembolic therapy
17. Patient unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation
18. Known sensitivity to contrast media (if needed during the procedure) that cannot be controlled with pre-medication
19. Previous left atrial surgical or left atrial catheter ablation procedure (including LAA closure device)
20. Presence of any condition that precludes appropriate vascular access
21. Severe mitral regurgitation (regurgitant volume 60 ml/beat, regurgitant fraction 50%, and/or effective regurgitant orifice area 0.40cm2).
22. Previous tricuspid or mitral valve replacement or repair
23. Patients with prosthetic valves
24. Patients with a myxoma
25. Patients with an interatrial baffle or patch as the transseptal puncture could persist and produce an iatrogenic atrial shunt
26. Stent, constriction, or stenosis in a pulmonary vein
27. Rheumatic heart disease
28. Hypertrophic cardiomyopathy
29. Diagnosed with amyloidosis or atrial amyloidosis
30. Active systemic infection
31. Renal failure requiring dialysis
32. Severe 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
33. Presence of an implantable therapeutic cardiac device including permanent pacemaker, biventricular pacemaker, or any type of implantable cardiac defibrillator (with or without biventricular pacing function) or planned implant of such a device for any time during the follow up period. Presence of an implantable loop recorder is acceptable as long as it is removed prior to insertion of the investigational device.
34. Presence of an implanted LAA closure device or plans to have an LAA closure device implanted during the follow-up period
35. Patient is currently participating in another clinical trial or has participated in a clinical trial within 30 days prior to screening that may interfere with this clinical trial without pre-approval from this study Sponsor
36. Unlikely to survive the protocol follow up period of 12 months
37. Presence of other medical, anatomic, comorbid, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results.
38. Individuals without legal authority
39. Individuals unable to read or write

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-02-2024
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Volt Pulsed Field Ablation Systeem
Registration:	No

Ethics review

Approved WMO Date:	06-02-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	30-05-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NCT06106594
CCMO	NL85151.000.23