FOCALFLEX; A study of FOCAL pulsed field ablation with the TactiFLEX SE Catheter and VOLT Generator for the treatment of paroxysmal atrial fibrillation

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The objective of this clinical trial is to demonstrate that ablation with the TactiFlex PFA System is safe and effective for the treatment of symptomatic, recurrent PAF.

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

Summary

ID

NL-OMON57139

Source
ToetsingOnline

Brief title
FOCALFLEX

Condition

- Cardiac arrhythmias

Synonym
Atrium fibrillation, heart rhythm disturbance

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Catheter, Paroxysmal atrial fibrillation, Pulsed field ablation

Outcome measures

Primary outcome

The primary safety endpoint is the proportion of subjects experiencing a device and/or procedure-related serious adverse event (SAE) with onset within 7 days of any ablation procedure (index or repeat procedure performed 0-90 days post initial procedure) that uses the TactiFlex PFA System defined below

• Atrio-esophageal fistula

• Cardiac tamponade/perforation

• Death

• Heart block

• Myocardial infarction

• Pericarditis

• Phrenic nerve injury resulting in diaphragmatic paralysis

• Pulmonary edema

• Pulmonary vein stenosis

• Stroke/cerebrovascular accident

• Thromboembolism

• Transient ischemic attack

• Vagal nerve injury/gastroparesis

• Major Vascular access complications / major bleeding event

• 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)

The primary effectiveness endpoint for this clinical trial is freedom from documented (symptomatic or asymptomatic) AF/AFL/AT episodes of >30 seconds duration that are documented by protocol-specified 12-lead ECG, TTM or Holter monitor (HM) devices after the index ablation procedure through 6 months of follow-up (after a 90-day blanking period following the index ablation procedure).

Secondary outcome

Descriptive endpoints are reported using only summary statistics and no hypothesis testing will be performed.

• Acute procedural effectiveness, defined as confirmation of entrance block in all pulmonary veins after a minimum waiting period of 20-minutes.

• Proportion of subjects with successful first-pass isolation of all targeted veins, and proportion of all targeted pulmonary veins with successful first-pass pulmonary vein isolation. First pass isolation is defined as confirmation of entrance block in each pulmonary vein after completion of the initial lesion set and 20-minute wait period, with no reconnection occurring during the 20-minute wait period.

• 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, TTM or Holter monitoring devices after the index ablation procedure through 12-months of follow-up (after a 90-day blanking period following the index ablation procedure), utilizing the primary

effectiveness endpoint failures defined above.

• Clinical success (same definition as the primary effectiveness endpoint, except that documented recurrence without documentation of symptoms will not count as a failure) through 6 and 12-months.

• AAD-Free effectiveness (same definition as the primary effectiveness endpoint, except that any use of Class I or III AADs after the 90-day blanking period will count as a failure) through 6 and 12-months.

• 6- and 12-month single procedure effectiveness, defined the same as the Primary Effectiveness Endpoint, except that any repeat ablation procedure (excluding CTI-dependent AFL) required by the subject at any time will be deemed a failure.

• Proportion of subjects requiring one or more repeat AF, non-CTI dependent AFL, or AT ablations through 6- and 12-months following the initial AF ablation procedure.

• Changes in EQ-5D-5L and AFEQT (AF Effect on Quality-Of-Life Questionnaire) scores from baseline to follow up at 3, 6, and 12-months after the initial procedure.

• Procedure data, including but not limited to ablation data, mapping data, usage of PFA and RF energy, contact force, procedure time, fluoroscopy time, total ablation time, left atrial (LA) dwell time, time to perform pulmonary vein isolation (PVI), and ablation performed in addition to PVI.

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

Study description

Background summary

It has been estimated that 33.5 million people have atrial fibrillation (AF) worldwide.
AF is associated with mortality and comorbidities such as stroke, heart failure, and sudden cardiac death. Atrial fibrillation is also associated with high rates of hospitalization. This hospitalization is commonly for AF management, but is also often due to heart failure, myocardial infarction, and treatment associated complications. Additionally, patients with AF have significantly poorer quality of life than healthy controls, experiencing a variety of symptoms including lethargy, palpitations, dyspnea, chest pain, sleeping difficulties, and mental distress.

Treatment for AF includes thromboembolic risk management, heart rate control, and heart rhythm control, which includes cardioversion and catheter ablation. The 2023 ACC/AHA/ACCP/HRS Guidelines for the Diagnosis and Management of Atrial Fibrillation provide Class I recommendations (Level of Evidence: A) for catheter ablation to improve symptoms in patients with drug-refractory, paroxysmal AF (PAF) and as a first-line therapy to improve symptoms and reduce progression to persistent AF in selected patients with symptomatic paroxysmal AF in whom rhythm control is desired. The effect of AF treatment is supported by reports of persistently improved quality of life 10 years after paroxysmal AF catheter ablation in patients with a low AF progression rate.

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 some limitations to the current standard of care ablation technologies. The reliance of these technologies on conductive heating and cooling results in a thermal response that is not selective to myocardial tissue. Irreversible electroporation (IRE) is a mechanism of inducing cell death via the application of pulsed electric fields (PEF). Pulsed field ablation (PFA) utilizes IRE to selectively destabilize cellular membranes to initiate cell death, resulting in a non-thermal ablation lesion. Interestingly, myocardial tissue has a lower voltage threshold susceptible to PFA when compared to surrounding tissues such as the esophagus, blood vessels, and nerve fibers, therefore reducing risk of damage to these non-cardiac tissues and potentially lowering rates of associated adverse events.

The majority of PFA catheters in clinical trials to date have been *single-shot* devices for PVI alone. These catheters are limited in their ability to ablate beyond the pulmonary veins and have been limited to delivering PFA. Focal catheters are used for the majority of atrial fibrillation ablation procedures and provide flexibility of lesions sets beyond PVI. Additionally,

they may allow for the flexibility to deliver either PFA or RF energy through the same catheter. Studies of focal PFA catheters to date have demonstrated safety, procedural efficiency, and lesion durability.

The TactiFlex SE catheter previously demonstrated safe and effective delivery of RF energy for the treatment of symptomatic, recurrent, drug-refractory PAF and concomitant atrial flutter.31 With the growing burden of AF on the healthcare system and continued need for increased safety and effectiveness in treatments, the TactiFlex* PFA System has been developed for enhanced flexibility to deliver either RF or PF energy for the safe and effective treatment of symptomatic, recurrent PAF

Study objective

The objective of this clinical trial is to demonstrate that ablation with the TactiFlex PFA System is safe and effective for the treatment of symptomatic, recurrent PAF.

Study design

Premarket, prospective, single-arm, non-randomized, multicenter clinical investigation

Intervention

Pulsed Field Ablation using the TactiFlex PFA System

Study burden and risks

The risks associated with Abbott's TactiFlex 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. Patients participating in the study are indicated for cardiac ablation for the treatment of their symptomatic recurrent PAF as part of their standard medical care and are subject to the risks associated with these devices.

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. Documented symptomatic paroxysmal AF (PAF). Documentation requirements are as follows:
a. Physician*s note indicating recurrent self-terminating AF with >= 2 episodes of PAF within the 6 months prior to enrollment AND
b. One electrocardiographically documented PAF episode within 12 months prior to enrollment.

NOTE: Documented evidence of the AF episode must either be continuous AF on a 12-lead ECG or include 30 seconds of AF from another ECG device.

2. Plans to undergo a catheter ablation procedure due to symptomatic PAF
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 persistent or 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. Known presence of cardiac thrombus
4. Left atrial diameter (LAD) >= 5.0 cm (anteroposterior diameter) within 180 days prior to the index procedure
5. Left ventricular ejection fraction (LVEF) < 35% as assessed with echocardiography or computerized tomography (CT) within 180 days prior to the index procedure
6. New York Heart Association (NYHA) class III or IV heart failure
7. Body mass index > 40 kg/m2
8. Pregnant or nursing
9. Patients who have had a ventriculotomy or atriotomy within the preceding 28 days of procedure
10. Myocardial infarction (MI), acute coronary syndrome, percutaneous coronary intervention (PCI), or valve or coronary bypass grafting surgery within preceding 90 days
11. Stroke or TIA (transient ischemic attack) within the last 90 days
12. Heart disease in which corrective surgery is anticipated within 180 days after procedure
13. History of blood clotting or bleeding abnormalities including thrombocytosis, thrombocytopenia, bleeding diathesis, or suspected anti-coagulant state
14. Contraindication to long term anti-thromboembolic therapy
15. Patient unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation
16. Known sensitivity to contrast media (if needed during the procedure) that cannot be controlled with pre-medication
17. Previous left atrial surgical or left atrial catheter ablation procedure (including left atrial appendage (LAA) closure device)
18. Plans to have an LAA closure device implanted during the follow-up period
19. Presence of any condition that precludes appropriate vascular access
20. Severe mitral regurgitation (regurgitant volume >= 60 mL/beat, regurgitant fraction >= 50%, and/or effective regurgitant orifice area >= 0.40cm2).
21. Previous tricuspid or mitral valve replacement or repair
22. Patients with prosthetic valves
23. Patients with a myxoma
24. Patients with an interatrial baffle or patch as the transseptal puncture could persist and produce an iatrogenic atrial shunt
25. Stent, constriction, or stenosis in a pulmonary vein
26. Rheumatic heart disease
27. Hypertrophic cardiomyopathy

28. Active systemic infection
29. Renal failure requiring dialysis
30. 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
31. 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.
32. 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
33. Unlikely to survive the protocol follow up period of 12 months
34. 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.
35. Individuals without legal authority
36. 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):	02-12-2024
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	TactiFlex PFA System
Registration:	No

Ethics review

Approved WMO Date:	23-10-2024
Application type:	First submission
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	NCT06271967
CCMO	NL86262.000.24