Safety and Effectiveness of TactiFlex* Ablation Catheter, Sensor Enabled* (TactiFlex SE) for the Treatment of Drug Refractory, Symptomatic, Paroxysmal Atrial Fibrillation (TactiFlex PAF IDE Trial)

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON49407

Source
ToetsingOnline

Brief title
TactiFlex PAF IDE Trial

Condition

- Cardiac arrhythmias

Synonym
arrhytmia, symptomatic paroxysmal atrial fibrillation (PAF)

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Ablation catheter, atrial fibrillation, Paroxysmal Atrial Fibrillation, Tactiflex SE

Outcome measures

Primary outcome

The primary safety endpoint is the rate of device and/or procedure-related

serious adverse events with onset within 7-days of any ablation procedure that

uses the TactiFlex SE catheter (initial or repeat procedure performed 31-80

days of initial procedure) that are defined below:

• Atrio-esophageal fistula1

• Cardiac tamponade/perforation1

• Death

• Heart block

• Myocardial infarction

• Pericarditis

• Phrenic nerve injury resulting in diaphragmatic paralysis

• Pulmonary edema

• Pulmonary vein stenosis1

• Stroke/cerebrovascular accident

• Thromboembolism

• Transient ischemic attack

• Vagal nerve injury/gastroparesis

• Vascular access complications (including major bleeding events2)

Secondary outcome

not applicable

Study description

Background summary

It has been estimated that 33.5 million people have atrial fibrillation (AF) worldwide [1]. AF has a prevalence of approximately 3% in adults aged 20 years or older [2, 3]. Additionally, one in four middle-aged adults in the US and EMEA will develop AF in their lifetime [4, 5].
AF remains a major cause of stroke, heart failure, sudden death, and cardiovascular morbidity. In a meta-analysis of contemporary, well-controlled, randomized clinical trials in AF, the average annual stroke rate is 1.5% with an annualized death rate of 3% in anticoagulated AF patients [6]. A minority of these deaths are related to stroke, while sudden cardiac death and death from progressive heart failure are more frequent, emphasizing the need for interventions beyond anticoagulation [7, 8]. AF is also associated with high rates of hospitalization for AF management, treatment-associated complications, heart failure and myocardial infarction [9, 10]. Patients with AF have significantly reduced quality of life vs. healthy controls, experiencing a variety of symptoms including lethargy, palpitations, dyspnea, chest pain, sleeping difficulties, and mental distress [10-14] .
Treatment for AF includes thromboembolic risk management, heart rate control, and heart rhythm control, which includes cardioversion and catheter ablation. The 2014 AHA/ACC/HRS AF Guidelines, 2016 ESC AF Guidelines, and 2017 HRS/EHRA/ECAS/APHRS/SOLAECE Expert Consensus on AF Ablation all provide a Class I recommendation (Level of Evidence: A) for catheter ablation to maintain sinus rhythm for patients with symptomatic, drug refractory, paroxysmal AF [15-17].
Contact force-sensing ablation catheter systems are a technology that is growing in adoption for AF ablation. These contact force-sensing catheter systems provide catheter operators additional feedback by allowing the operator to know how much force is being applied by the catheter tip on the cardiac tissue.
The TactiCath family of contact force-sensing catheters from Abbott has been studied extensively in human clinical trials [18-22]. The latest TactiCathTM contact force sensing catheter from Abbott is the TactiCath SE ablation catheter, which incorporates a magnetic sensor for tracking with the EnSite Precision Mapping System and utilizes a new handle and shaft to improve

catheter handling. The TactiCath SE catheter is being investigated by the TactiSense clinical trial [23].
The flexible-tip (*flex-tip*) family of ablation catheters (TherapyTM CoolFlexTM, FlexAbilityTM, FlexAbilityTM SE) from Abbott offers a tip design that is significantly different from the rigid-tip TactiCath family. While both catheter families provide irrigating saline through 4-6 discrete holes at the distal tip, only the flex-tip family provides irrigating saline through an interlocking pattern of kerfs laser-cut into the side of the electrode that is both flexible and porous. The purpose of having the saline irrigated over a more widely distributed area is to produce a more uniform temperature profile, potentially increasing the efficiency of energy transfer [24] and reducing the risk of steam-pops [25]. The Therapy CoolFlex ablation catheter has been studied in humans for the treatment of typical atrial flutter [26] and the entire flex-tip family is indicated for the treatment of typical atrial flutter in the US. Outside of the US, the flex-tip family of catheters is indicated for treating cardiac arrhythmias and is used to treat AF. The safety and effectiveness of flex-tip catheters has been studied for the treatment of paroxysmal AF in a real-world setting through the ABLATOR patient registry [27].
The TactiFlex* Ablation Catheter, Sensor-Enabled* (TactiFlex SE) is the next generation design from Abbott, and it has several elements that are similar or identical to the FlexAbility SE and/or TactiCath SE ablation catheters. The contact force sensor, handle (uni- or bi-directional) and shaft are like TactiCath SE. Meanwhile, the porous flex-tip ablation electrode and therapy RF circuit are like FlexAbility SE. Unlike TactiCath SE and FlexAbility SE, TactiFlex SE has a second magnetic sensor that enables the force direction arrow and deflection/direction features in the EnSite Precision cardiac mapping system (v2.5).

Study objective

The primary objective of the TactiFlex PAF IDE clinical trial is to demonstrate that ablation with the TactiFlex* Ablation Catheter, Sensor-Enabled* (TactiFlex SE), in conjunction with a compatible RF generator and three-dimensional mapping system, is safe and effective for the treatment of drug refractory, symptomatic paroxysmal atrial fibrillation (PAF) when following standard electrophysiology mapping and radiofrequency (RF) ablation procedures.

Study design

Prospective, non-randomized multi-center clinical investigation. Design includes a main study and a separate substudy. Subjects in the main study are to be treated using the full range of ablation power settings in the IFU. Subjects in the substudy are to be treated in the upper end of the recommended ablation power settings (40-50 Watts).
Remark: Erasmus MC will not participate to the sub-study.

Intervention

Catheter ablation

Study burden and risks

We expect that the risks associated with the investigation are the same as the normal risks associated with an ablation procedure.
Additional risks are described in the protocol Page 63 -15.0 Risk Analysis.
These are also included / described in the Patient Information Letter.

Contacts

Public
St. Jude Medical

Standaardruiter 13
VEENENDAAL 3905 PT
NL
Scientific
St. Jude Medical

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. Plans to undergo a catheter ablation procedure due to symptomatic PAF that is refractory or intolerant to at least one Class I or III antiarrhythmic drug.
2. Physician*s note indicating recurrent self-terminating AF
3. One electrocardiographically documented AF episode within 6-months prior to the initial ablation procedure. 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.
4. At least 18 years of age
5. Able and willing to comply with all trial requirements
6. 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. Persistent or long-standing persistent atrial fibrillation
2. Active systemic infection
3. Known presence of cardiac thrombus
4. Hypertrophic cardiomyopathy
5. Arrhythmia due to reversible causes including thyroid disorders, acute alcohol intoxication, and other major surgical procedures in the 90-day period preceding procedure
6. Myocardial infarction (MI), acute coronary syndrome, percutaneous coronary intervention (PCI), or valve or coronary bypass grafting surgery within 90 days of procedure
7. Left atrial diameter > 5.0 cm measured within 180 days of procedure (echocardiography or CT)
8. Left ventricular ejection fraction < 35% measured within 180 days of procedure (echocardiography or CT)
9. New York Heart Association (NYHA) class III or IV
10. Previous left atrial surgical or catheter ablation procedure
11. Left atrial surgical procedure or incision with resulting scar (including LAA closure device)
12. Previous tricuspid or mitral valve replacement or repair
13. Heart disease in which corrective surgery is anticipated within 180 days after the procedure
14. Bleeding diathesis or suspected pro-coagulant state
15. Contraindication to long term anti-thromboembolic therapy
16. Presence of any condition that precludes appropriate vascular access
17. Renal failure requiring dialysis
18. Known sensitivity to contrast media (if needed during the procedure) that cannot be controlled with pre-medication

19. 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
20. Women who are pregnant or breastfeeding
21. Presence of other anatomic or comorbid condition that, in the investigator*s opinion, could limit the patient*s ability to participate in the clinical trial or to comply with follow up requirements, or impact the scientific soundness of the clinical trial results
22. 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
23. Patient is unlikely to survive the protocol follow up period of 12-months after the procedure
24. Body mass index > 40 kg/m2
25. Presence of other medical, 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.
26. Individuals without legal authority
27. Individuals unable to read or write
28. Patients who have had a ventriculotomy or atriotomy within the preceding 4 weeks of procedure,
29. Patients with prosthetic valves,
30. Patients with a myxoma,
31. Patients with an interatrial baffle or patch as the transseptal puncture could persist and produce an iatrogenic atrial shunt
32. Patient unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	TactiFlex Ablation Catheter;Sensor Enabled;EnSiteTM IDE Display Workstation;TactiSys Quartz;Tacti
Registration:	No

Ethics review

Approved WMO Date:	13-07-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL72742.078.20