A prospective, randomized, multicenter, interventional study to evaluate the safety and effectiveness of the TactiCath® percutaneous ablation catheter for the treatment of symptomatic paroxysmal atrial fibrillation using contact force assisted irrigated radiofrequency ablation

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Effectiveness: To provide valid scientific evidence that use of the TactiCath® Set is an effective treatment for symptomatic paroxysmal atrial fibrillation (PAF).Safety: To provide valid scientific evidence that use of the TactiCath® Set is safe as...

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

Summary

ID

NL-OMON39773

Source
ToetsingOnline

Brief title
Toccastar

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atrial Fibrillation, Contact Force, Percutaneous Ablation Catheter

Outcome measures

Primary outcome

Effectiveness

The primary effectiveness endpoint of the study is a non-inferiority comparison of treatment success between the TactiCath® Set and the control device as defined by both:

• Acute procedural success - electrical isolation of all 4 pulmonary veins (PVs), or in the event of a common PV, the clinical equivalent of all PVs by the end of index procedure

• Chronic success - acute procedural success and freedom from recurrence of symptomatic PAF, atrial flutter (AFL), and atrial tachycardia (AT) lasting longer than 30 seconds through 9 months of follow-up after a 3 month blanking period. Re-treatment for AF with ablation or the use of Class I or Class III antiarrhythmic drugs after the blanking period constitutes a treatment failure.

Safety

The primary safety endpoint is a non-inferiority comparison of device-related early onset primary SAEs between the TactiCath® Set and the control device occurring within 7 days of the index procedure or hospital discharge, whichever is later, and diagnosed at any time during the follow up period.

Secondary outcome

Effectiveness

The secondary effectiveness endpoints are related to the use of the contact force sensor and will assess procedural effectiveness superiority of the TactiCath® Set over the control device. It is hypothesized that the use of the contact force sensor information will result in added procedural effectiveness through a reduction of:

1. Number of electrically reconnected pulmonary veins following a 30 minute waiting period assessed by entrance block
2. Time to achieve total PV isolation measured from initial application of RF energy to all target vessels isolated
3. Total time of RF application required for full PV isolation

Safety

Incidence of all serious adverse events (SAEs) during the 12 month follow up period

Study description

Background summary

Long term outcomes for symptomatic atrial fibrillation (AF) patients treated exclusively with drugs remains poor.
Circumferential electrical isolation of the entire pulmonary vein (PV) musculature, also known as PV isolation, is now common practice for patients with paroxysmal atrial fibrillation (PAF) in whom one or more antiarrhythmic agents have failed.
Establishing a stable contact force between the catheter and the endocardial surface remains one of the key challenges in the catheter ablation procedure.
To address this need, Endosense has developed a novel contact force sensor that is embedded in the TactiCath® catheter that allows measurement of the tip to tissue contact force during the RF ablation procedure.
The purpose of this study is to evaluate the safety and effectiveness of the TactiCath® Set when used to treat PAF when compared to an approved control device.

Study objective

Effectiveness: To provide valid scientific evidence that use of the TactiCath® Set is an effective treatment for symptomatic paroxysmal atrial fibrillation (PAF).

Safety: To provide valid scientific evidence that use of the TactiCath® Set is safe as measured by the incidence of early-onset serious adverse events (SAEs) when compared to the control device.

Study design

TOCCASTAR is a prospective, randomized, multicenter, interventional study to evaluate the safety and effectiveness of the TactiCath® Set for the treatment of symptomatic atrial fibrillation (PAF) using contact force assisted irrigated RF ablation.
Patients undergoing elective catheter ablation for symptomatic PAF who are refractory or intolerant to at least one antiarrhythmic drug (Class I-IV) will be screened for enrollment. Patients who meet the study entry criteria and sign the patient informed consent form will be enrolled and treated following the 2007 Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) Expert Consensus Statement on Catheter and Surgical Ablation for Atrial Fibrillation.
Eligible patients will be randomly assigned 1:1 to receive treatment with either the TactiCath® Set or the control device (the NaviStar® ThermoCool® open irrigated RF ablation catheter manufactured by Biosense Webster, Inc.) Use of three dimensional (3D) mapping equipment will be required in both treatment groups. Patients will be blinded to treatment assignment. This study aims to demonstrate non inferiority of the study device to the control device for both safety and effectiveness.
After the index procedure, patients will be followed for a total of 12 months

for chronic effectiveness assessment, beginning with a 3-month blanking period and ending with a 9-month effectiveness assessment period. During the blanking period, patients may be prescribed a previously ineffective antiarrhythmic drug and undergo up to 2 repeat ablation procedures (up to 10 days prior to end of the blanking period) using the same device specified by the initial randomization. Patients will be evaluated at pre-discharge, at 7 days, at 3, 6 and 12 months post-index procedure and every 6 months thereafter until PMA approval.
Patients will be enrolled at up to 30 sites in the United States (US) and elsewhere. A maximum of 50% of patients may be enrolled outside the US.

Intervention

The following evaluations will be done as per the protocol requirements (not standard of care)
Baseline Evaluations:
Determination of the NYHA functional class
Quality of life assessment
Pregnancy test (women of childbearing potential)
Computed tomography (CT) scan or magnetic resonance imaging (MRI)

Ablation Procedure:
The patients will randomly be treated with one of the following devices:
• TactiCath® Set, or
• Control device (the NaviStar® ThermoCool® open irrigated RF ablation catheter manufactured by Biosense Webster, Inc.)

Follow up :

7 Day (± 2 days):
Cardiac medications,
Reporting of adverse events

3-Month (± 2 weeks)
Imaging study (CT scan or MRI, consistent with pre treatment method),
NYHA functional class,
TTM: Transtelephonic monitoring (weekly for 4 and 5 months)

6-Month (± 3 weeks)
NYHA functional class,
TTM: Transtelephonic monitoring (Monthly for months 6-12)

12-Month (± 3 weeks):
NYHA functional class,
TTM: Transtelephonic monitoring
Quality of life questionnaire

Every 6 months (± 4 weeks) thereafter until PMA approval (patients will be contacted via telephone by the investigator)
Adverse events (related to survival and cardiac-related hospitalization)
Arrhythmia history

Study burden and risks

Potential Risks:
TactiCath® Set is CE-marked.
Risks to patients enrolled in this study include all those risks currently associated with all electrophysiology diagnostic procedures and RF catheter ablation procedures. The risks of the procedure are related primarily to mechanical injury to the heart and vessels from catheter manipulation and thermal injury due to RF current delivery, including the risk of thromboembolism and myocardial perforation, especially for ablations in the left atrium.

For those procedures where the physician applies sedation or anesthesia, the standard risks of anesthesia also exist and include allergic reactions, pneumonia, aspiration pnuemonitis, atelectesis, prolonged sedation, other medical complications and in very rare cases, death.

Potential Benefits:
Receiving benefit from participation in the study is not guaranteed.
Anticipated benefits to patients may include, but are not limited to, the following:

• Patients who receive treatment with the study device may experience shorter ablation procedure time and improved outcomes, although these objectives may not be demonstrated in this study
• Patients who participate in the study may receive more frequent and/or detailed follow up than is normally prescribed as standard of care in any given practice
• Overall advancement of medical and scientific knowledge may benefit future patients with similar conditions

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. Patient is planned to undergo a catheter ablation procedure due to symptomatic PAF that is refractory or intolerant to at least one Class I-IV antiarrhythmic drug
2. Minimum of one episode of PAF greater than 30 seconds in duration within 12 months prior to enrollment documented by 12 lead electrocardiogram (ECG), Holter monitor, transtelephonic event monitor, telemetry strip, or implanted device
3. Minimum of 3 episodes of PAF within the preceding 12 months documented by patient history
4. Patient is 18 years of age or older
5. Patient is willing and capable of complying unassisted with the study protocol requirements including all specified follow up visits
6. Patient provides written informed consent prior to enrollment in the study

Exclusion criteria

1. Persistent or long-standing persistent atrial fibrillation (AF)
2. Patient has had 4 or more cardioversions in the last 12 months
3. Active systemic infection
4. Presence of implantable cardiac defibrillator (ICD)
5. Arrhythmia due to reversible causes including thyroid disorders, acute alcohol intoxication, and other major surgical procedures in the preceding 3 months

6. Myocardial infarction (MI), acute coronary syndrome, percutaneous coronary intervention (PCI), or valve or coronary bypass grafting surgery within preceding 3 months
7. Left atrial diameter > 5.0 cm
8. Left ventricular ejection fraction < 35%
9. New York Heart Association (NYHA) class III or IV
10. Previous left atrial ablation procedure, either surgical or catheter ablation
11. Patient has had a left atrial surgical procedure or incision with resulting scar
12. Previous tricuspid or mitral valve replacement or repair
13. Heart disease in which corrective surgery is anticipated within 6 months
14. Bleeding diathesis or suspected pro coagulant state
15. Contraindication to long term antithromboembolic therapy
16. Presence of 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. Contraindication to computed tomography and magnetic resonance angiography
20. 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
21. Positive pregnancy test results for female patient of childbearing potential
22. Patient has other anatomic or co morbid conditions that, in the investigator*s opinion, could limit the patient*s ability to participate in the study or to comply with follow up requirements, or impact the scientific soundness of the study results
23. 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 study
24. Patient is unlikely to survive the protocol follow up period of 12 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2011
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	TactiCath® Set (TactiCath® Catheter and TactiSys Equipment)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-07-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-12-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-04-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2014
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	NL34761.078.11