VICTORY AF evaluation of multielectrode phased RF technology in persistent Atrial Fibrilation

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Demonstrate that the observed incidence of procedure and/or device related incidence of new stroke (excludes transient ischemic attack) within 30 days of an ablation procedure (index or reablation) with the Phased RF System is less than 1.8% with...

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

Summary

ID

NL-OMON40478

Source
ToetsingOnline

Brief title
VICTORY AF

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation- abnormal heart rhytm

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ablation, multIelectrode, phased Rf technology

Outcome measures

Primary outcome

The primary endpoint of the safety is made up of the evaluation of the risk of

procedure and / or device-related strokes, in subjects with persistent or

long-term persistent atrial fibrillation (AF), which undergo an ablation with

the phased RF system

Secondary outcome

nvt

Study description

Background summary

Atrial fibrillation is a debilitating disease with symptoms that reduce quality of life and put subjects at a higher risk of stroke than subjects with no atrial fibrillation.
Current treatment options include antiarrhythmic drug therapy, catheter ablation for paroxysmal atrial fibrillation and concomitant surgical therapy. These treatment options have poor effectiveness outcomes and carry side effects from antiarrhythmic drugs and procedural risks from the surgical therapies.
Currently in the U.S. catheter ablation is not indicated for the treatment of persistent and long standing persistent (herein referred to as persistent) atrial fibrillation and therefore subjects that have failed antiarrhythmic drug therapy and are not candidates or have failed surgical therapies have no other FDA approved treatment options.
Previous to this proposed study, the tailored treatment for permanent atrial fibrillation (TTOPAF) study was conducted to demonstrate the safety and effectiveness the Phased RF system.
TTOP-AF was conducted between 2007 and 2010 and presented to the FDA Circulatory System Devices Panel on October 27, 2011.
Based on the TTOP-AF data the panel voted that the Phased RF system was effective in the treatment of subjects with persistent atrial fibrillation.
However, the panel was concerned with the peri-procedural stroke rate and

pulmonary vein stenosis rates.
Therefore the panel voted that the benefits of the Phased RF system did not outweigh the risks of treating subjects with persistent atrial fibrillation.
Thus, Medtronic with the agreement of the FDA is conducting this study to demonstrate that the Phased RF system is safe after the implementation of mitigation strategies to lower the periprocedural stroke rate (i.e. anticoagulation and catheter programming requirements). Therefore, the primary objective of the study is to confirm the safety of the Phased RF system and not to evaluate the system*s effectiveness.

Study objective

Demonstrate that the observed incidence of procedure and/or device related incidence of new stroke (excludes transient ischemic attack) within 30 days of an ablation procedure (index or reablation) with the Phased RF System is less than 1.8% with observed upper confidence boundary that is less than 3.5%.
The definition of stroke is provided in the Table 5 in the protocol pag. 20

Primary study objective
* 30-day procedure and/or device related stroke rate
Secondary study objectives
* 6-month post-procedural effectiveness
* Acute procedural success
* Pulmonary vein stenosis (PVS)
Ancillary study objectives
* Single procedural effectiveness
* 6-month reduction in AF burden
* Post-procedural asymptomatic cerebral embolism (ACE) rate
* Peri-procedural serious adverse events
* Peri-procedural stroke and transient ischemic attack (TIA)
* Summarize adverse events

Study design

This study is a prospective, unblinded, multi-center, investigational (U.S. and Canada), global, clinical study designed to evaluate the procedure and/or device related stroke rate within 30 days of an ablation procedure with the Medtronic Phased RF System. In regions where the system is market released, the system will be used in the manner for which it was intended.
The primary safety objective will be evaluated after at least 300 ablated subjects complete the 30 day post index or reablation procedure visit and have had the opportunity for a reablation visit. The study may stop early for futility if more than six (6) procedure and/or device related strokes occur prior to completing enrollment.

Intervention

100 subject will be submitted to a subgroup ACE, these subjects will have 3x a brainscan. For 100 subjects whom will submitted to the subgroup PVS these subjects will undergo 2x a thoracic scan. All subjects will have a TEE, and anticoagulant medicines.

Study burden and risks

Based on the current knowledge, participation into het Victory AF, does noet impose additional risks. The potential benefits of the study outweigh thepotential risks; therefore he investigation is jusified. It is possible in any clinical trial that harmful things can happen which are not know at this time. All efforts will be made to minimze the risks in this study by selecting investigators who are experienced and trained in the use of the study device and trained to the study portocol, by clearly defining inclusion/exclusion criteria to ensure only appropariate subjects are inrolled, and by ensuring that treatment and follow-up of the subject are consistent with current medical practices.

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

* History of symptomatic persistent or long-standing persistent atrial fibrillation defined as:
o Persistent AF: sustained AF lasting > 7 days and less than one year, or lasting < 7 days but necessitating pharmacologic or electrical cardioversion; OR
o Long-standing persistent AF: sustained AF lasting at least 1 year, but no more than 4 years in duration.
o Continuous AF as demonstrated on a 48-hour Holter at baseline
o AF symptoms defined as the manifestation of:
* Palpitations
* Fatigue
* Exertional dyspnea
* Increased intolerance to routine activities (exercise intolerance)
* Age between 18 and 70
* Failure of at least one class I or III rhythm control AAD

Exclusion criteria

Structural heart disease of clinical significance including:
o Previous cardiac surgery other than CABG or mitral valve repair
o NYHA Class III or IV CHF and/or documented ejection fraction <40% measured by acceptable cardiac testing
o Left atrial diameter of >55mm
o Moderate to severe mitral or aortic valvular heart disease
o Stable/unstable angina or ongoing myocardial ischemia
o Myocardial infarction (MI) within three months of enrollment
o Congenital heart disease other than ASD or PFO without a right to left shunt where the underlying abnormality increases the risk of an ablative procedure
o Prior ASD or PFO closure with a device using a percutaneous approach
o Hypertrophic cardiomyopathy (LV septal wall thickness >1.5 cm)
o Pulmonary hypertension (mean or systolic PA pressure >50mm Hg on Doppler echo)
* Any prior ablation for atrial fibrillation in the left atrium
* Enrollment in any other ongoing arrhythmia study protocol
* Any ventricular tachyarrhythmia currently being treated where the arrhythmia or the management may interfere with this study
* Active infection or sepsis
* Any history of cerebral vascular disease including stroke or TIAs

* Pregnancy or lactation
* Left atrial thrombus at the time of ablation
* Untreatable allergy to contrast media
* Any diagnosis of atrial fibrillation secondary to electrolyte imbalance, thyroid disease, or any other reversible or non-cardiovascular causes
* History of blood clotting (bleeding or thrombotic) abnormalities
* Known sensitivities to heparin or vitamin K antagonists (ie. Warfarin/Coumadin)
* Prescribed to direct thrombin or factor inhibitors
* Severe COPD (defined as an FEV1 <1)
* Severe co-morbidity or poor general physical/mental health that, in the opinion of the Investigator, will not allow the subject to be a good study candidate (i.e. other disease processes, mental capacity, substance abuse, shortened life expectance, etc.)
* MRI contraindicated
* Any invasive cardiovascular procedure performed or planned within the 3 month period prior to the ablation procedure

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	PVAC Gold 90078 Pulmonary Vein Ablation Catheter;MAAC 99000 Multy-Array Ablation Catheter;MASC 90001
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-11-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-02-2014
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	NCT01693120
CCMO	NL44784.060.13