CARTO® 3 System-guided RF Ablation Using the THERMOCOOL® Catheter Versus Fluoroscopy-guided RF Ablation Using the Pulmonary Vein Ablation Catheter® (PVAC®) in Subjects with Paroxysmal Atrial Fibrillation: A Prospective, Multi-center, Randomized (2:1), Controlled, Two-arm, Unblinded Clinical Study

Published: 25-06-2010
Last updated: 30-04-2024

The objective of this study is to evaluate the efficacy, safety and efficiency of RF ablation when guided by the CARTO® 3 System (using the THERMOCOOL® Catheter and LASSO® Circular Mapping Catheter) compared to fluoroscopy-guided RF ablation (using...

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

Summary

ID

NL-OMON34575

Source
ToetsingOnline

Brief title
CLARITY study

Condition

- Cardiac arrhythmias

Synonym
atrial tachyarrhythmia, quivering of the heart muscles of the atria

Research involving
Human

Sponsors and support

Primary sponsor: Johnson & Johnson
Source(s) of monetary or material Support: Biosense Webster Inc;a Johnson & Johnson company

Intervention

Keyword: ablation, atrial, fibrillation, radiofrequency

Outcome measures

Primary outcome

The primary endpoints supporting the objective are:

Efficacy: Freedom from documented AF/AT recurrences without new AADs through 1

year follow-up

Safety: Incidence of PV Stenosis (number of PVs with a reduction in diameter >=

50% at 6 months compared to baseline per CT or MRI)

Efficiency: Total procedure time (minutes from introduction of first catheter

to withdrawal of last catheter)

Secondary outcome

Efficacy:

1. Acute procedural success (% of subjects with confirmed entrance block at the end of the ablation procedure)

2. Repeat ablation procedures for AF/AT recurrences through 1 year follow-up

3. Freedom from documented AF/AT recurrences without AAD(s)

4. Freedom from documented AF/AT recurrences with AAD(s)

5. Freedom from documented AF/AT recurrences after more than one ablation procedure

6. Freedom from documented AF recurrences without AADs

7. Freedom from documented AF recurrences with AAD(s)

8. Freedom from documented symptomatic AF/AT recurrences without AAD(s)

9. Freedom from documented symptomatic AF/AT recurrences with AAD(s)

Safety:

1. Incidence of any procedure-related and/or device-related adverse events occurring during the study

2. Incidence of any catheter-related adverse events occurring during the study

3. Total Fluoroscopy exposure time from time point of first catheter inserted until last catheter removed (cumulative time including both fluoroscopy and cine-fluoroscopy times; minutes)

4. Total Fluoroscopy Dose-Area Product (DAP) ($Gy.cm^2$) / Source Intensifier Distance

5. Incidence of any phrenic nerve paralysis

6. Incidence of any symptomatic Transient Ischemic Attack (TIA) or Cerebrovascular Accident (CVA)

Efficiency:

• Number of mapping and ablation catheters used per subject

Health Economics (HE) Outcomes:

1. Quality of Life (SF-36®) and Atrial Fibrillation Symptom Frequency and Severity Checklist assessment at 3, 6, and 12 months compared to baseline

2. Total procedure hospital visit and ablation procedure costs

3. Total number of initial or prolonged hospitalizations and unscheduled arrhythmia-related health care provider visits (including emergency department visits).

Study description

Background summary

Atrial fibrillation (AF) is the most common sustained arrhythmia in man. At any time it affects 0.4% to 1% of the general population and increases in prevalence with age to 8% in those older than 80 years. Different technologies have been developed and are currently being used to achieve PVI, including the NAVISTAR® THERMOCOOL® Catheter (Biosense Webster, Inc), which is an irrigated tip ablation catheter. This catheter was evaluated in a randomized, controlled clinical trial in combination with the CARTO® EP Navigation system (Biosense Webster Inc) and represents a major advancement in the field of ablation catheters. Available for commercial use in EU since 1998, the NAVISTAR® THERMOCOOL® Catheter is the first ablation catheter to receive Food and Drug Administration (FDA) approval for the treatment of drug refractory recurrent symptomatic PAF (February 2009). More recently, the Pulmonary Vein Ablation Catheter® (PVAC®) (Medtronic) has been developed for the treatment of atrial fibrillation and has been commercially available in EU since 2006. The PVAC® is a circular, decapolar mapping and ablation catheter with a 25-mm-diameter array at the distal portion. However, there are some important differences in the technology and design of both catheters that have the potential to impact efficacy, safety and efficiency of RF ablation treatment.

Currently, the THERMOCOOL® Catheter with the CARTO® 3 System is widely used for

treating PAF, whereas the PVAC® has been recently introduced as an alternate mapping and ablation catheter; however, well-controlled studies are needed to compare the efficacy, safety and efficiency of the PVAC® with other standards of care. To evaluate differences between the THERMOCOOL® Catheter and PVAC®, these devices should be compared in a randomized, controlled clinical study.

Study objective

The objective of this study is to evaluate the efficacy, safety and efficiency of RF ablation when guided by the CARTO® 3 System (using the THERMOCOOL® Catheter and LASSO® Circular Mapping Catheter) compared to fluoroscopy-guided RF ablation (using the PVAC®) in patients undergoing treatment for symptomatic PAF.

Study design

A Prospective, Multi-center, Randomized (2:1), Controlled, Two-arm, Unblinded Clinical Study

Intervention

Eligible subjects who sign the study informed consent form will be randomized into one of two study arms:

THERMOCOOL® Group: RF ablation to achieve PVI using the CARTO® 3 System, THERMOCOOL® Catheter, and LASSO® Circular Mapping Catheter.

PVAC® Group: RF ablation to achieve PVI using fluoroscopy and the PVAC®.

Study burden and risks

Burden:
The ablation procedures and follow-up schedule do not or only slighly deviate from the standard of care, resulting in limited additional burden and inconvenience for the patients participating in this research. The following lists the assessments planned in this study:
- Clinic visits prior to the ablation, at time of study procedure, at 3, 6, 9 and 12 months follow-up
- Transthoracic Echocardiography before the ablation procedure
- Transesophageal Echocardiography before the ablation procedure
- SF-36 questionnaire at baseline, 3, 6 and 12 months
- Atrial Fibrillation Symptom and severity Checklist at baseline, 3, 6 and 12 months
- Computed Tomography or Magnetic Resonance Imaging at baseline and at 6 months
- Transtelephonic Monitoring in month 5, 6, 11, and 12 of follow-up

Risks:
RF catheter ablation has been used for nearly two decades, and the risks and complications are well understood. The use of non-irrigated and saline-irrigated ablation catheters is routine for many PAF ablation procedures. No additional risks are anticipated for subjects enrolled in this study compared to subjects undergoing ablation of symptomatic PAF outside of the study (protocol section 12 Risk management).

Potential benefits:
The direct benefit for patients undergoing RF catheter ablation is the potential elimination of AF episodes. It is furthermore expected that quality of life will improve and less frequent hospitalization will be needed. The information gained from the conduct of this study may benefit patients with AF by improving future treatment modalities.

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

Patients with PAF who have had two (2) symptomatic PAF episodes in the six (6) months prior to randomization, and who are selected for catheter ablation for the treatment of their AF. Additionally patients with recurrent AF with episodes up to 30 days with sinus rhythm maintained for more than one week following cardioversion and who require PVI only for the treatment of their AF. AT least one AF episode should be documented either on ECG, TTM, HM or telemetry strip.

Exclusion criteria

1. Longstanding persistent atrial fibrillation
2. Patients with a history of any atrial flutter requiring ablation in the right atrium during the study procedure
3. Patients in whom sinus rhythm was maintained for less than 1 week after electrical cardioversion
4. Previous ablation for AF
5. LA size > 55 mm

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2010

Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	ThermoCool® catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-06-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-06-2011
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
CCMO	NL32380.060.10