Multi-electrode PulmonarY Vein isolation vs Single Tip wide area Catheter ablation for Paroxysmal Atrial Fibrillation

Published: 06-01-2011
Last updated: 04-05-2024

Purpose is to show that multi-electrode ablation is not inferior to irrigated single tip catheter ablation guided by 3-D mapping to treat paroxysmal atrial fibrillation.

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

Summary

ID

NL-OMON36751

Source
ToetsingOnline

Brief title
MYSTIC-PAF

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, heartrhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: R&D Cardiologie
Source(s) of monetary or material Support: Investigator initiated onderzoek met grant door industrie,Medtronic B.V.

Intervention

Keyword: multi-electrode ablation catheter, paroxysmal atrial fibrillation, percutaneous

Outcome measures

Primary outcome

The primary effectiveness endpoint for the study is

-absence of symptomatic atrial fibrillation

-and freedom from secondary atrial arrhythmias at 3, 6 and 12 months

post-procedure by:

· Repeated ECG

· repeated 48-hour Holter in asymptomatic patients

· event-recorder in symptomatic patients.

The safety endpoint is the measurement of a composite list of

procedure and device related serious adverse events followed for seven days.

SAEs will include:

· Stroke· Major bleeding requiring surgical intervention

· Cardiac tamponade· PV stenosis· Myocardial infarction

· Diaphragmatic paralysis

· Atrio-esophageal fistula

· Death

Secondary outcome

Secondaire effectiviteits eindpunten:

- Improvement of symptoms after 3 and 12 month

- Duration of RF burden

- Skin-skin time for the ablation procedure

- Fluoroscopy time

Study description

Background summary

Atrial fibrillation (AF) is a very common cardiac arrhythmia affecting more than 8 million people in the US and Europe with still growing numbers. AF is associated with a 2.5 fold increase in mortality, and significant. Drugs have been found effective in no more than 60% of patients., regardless of whether a rate- or rhythm-control strategy was chosen. In symptomatic patients catheter ablation has become an accepted second line therapy. For paroxysmal AF efficacy rates of over 80% have been reported. The standard accepted technique nowadays is circumferential ablation in the antrum of the pulmonary veins (PVs) to achieve electrical isolation. This procedure is time consuming and the creation of lesions, which may add up to 50-100 point by point applications, is difficult and slow. Recently, a novel technology has been introduced that uses multi-electrode catheter technology for PV isolation. The procedure may be performed with only 2 catheters. In a single center study, the procedure was found to have an 83% efficacy and procedure times appeared to be much shorter than with conventional technology.

Study objective

Purpose is to show that multi-electrode ablation is not inferior to irrigated single tip catheter ablation guided by 3-D mapping to treat paroxysmal atrial fibrillation.

Study design

Prospective, multicenter-, multinational, randomised, non-inferiority trial with two groups.

Intervention

Catheterablation with either the multi-electrode PVAC catheter, or the single-tip catheter

Study burden and risks

Participation in this study will not increase additional burden to the patient

and will not lead to benefit. After the ablation procedure the patient will have 1 additional visits to the outpatient clinic and will undergo 1 additional holter recording 12 months after ablation

Contacts

Public
Selecteer

Koekoekslaan 1
3435 cm
NL
Scientific
Selecteer

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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.History of symptomatic paroxysmal atrial fibrillation defined as:·
-Self-terminating AF lasting no more than seven days ·
-AF events demonstrating spontaneous conversion back to sinus rhythm·
-Documentation of one or more events with PAF tracings by ECG, event recordings, pacemaker strips or monitor rhythm strips within the past year6 months·
-AF symptoms defined as the manifestation of any of the following
-Palpitations

- Fatigue
-Exertional dyspnea
-Effort intolerance
2.Patient is refractory for at least 1 anti-arrhythmic drug

Exclusion criteria

1.Structural heart disease of clinical significance including:
-Previous cardiac surgery (excluding CABG)
-Symptoms of congestive heart failure including, but not limited to, NYHA Class III or IV CHF and/or documented ejection fraction < 40% measured by acceptable cardiac testing
-Left atrial diameter of > 50mm as measured in the parasternal long axis on transthoracic echocardiogram
-Stable/unstable angina or ongoing myocardial ischemia
-Myocardial infarction (MI) within three months of enrollment
-Aortic or mitral valve disease > Grade II
-Congenital heart disease (not including ASD or PFO without a right to left shunt) where the underlying abnormality increases the risk of an ablative procedure
-Prior ASD or PFO closure with a device using a percutaneous approach
-Hypertrophic cardiomyopathy (LV wall thickness > 1.5 cm)
-Pulmonary hypertension (mean or systolic PA pressure >50mm Hg on Doppler echo)
2.Prior ablation for arrhythmias other than AF within the past three months
3.Cardioversion < 7 days before ablation procedure
4.Prior left sided AF ablation

Study design

Design

Study phase:	3
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):	25-01-2011
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Multi-electrode ablation catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-01-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-11-2012
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	NL31688.100.10