Pulmonary Vein Ablation versus Amiodarone in the Elderly

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

Summary

ID

NL-OMON39450

Source
ToetsingOnline

Brief title
PAVANE

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, Palpitations

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Amiodarone, Atrial fibrillation (AF), elderly, Pulmonary Vein Isolation (PVI)

Outcome measures

Primary outcome

Recurrence of episodes of AF, atypical atrial flutter or left sided atrial tachycardia lasting longer than 30 seconds after blanking period in both treatment groups, is considered therapy failure. In the intervention group 2 PVI-procedures are allowed. Recurrence of episodes of AF, atypical atrial flutter or left sided atrial tachycardia lasting longer than 30 seconds in an amiodarone intolerant patient is also considered an end point.

Secondary outcome

* Composite end point of hospitalization (cardiac causes, including cardioversion), stroke, major bleedings, death.

* Composite end point of recurrence of AF with absence or significant reduction of symptoms not necessitating change of therapy.

* Incidence of procedure related and drug related adverse events

* Quality of life as measured by SF-36, and AFSS.

Study description

Background summary

Atrial fibrillation (AF) is the most common arrhythmia. The prevalence of AF is highly age dependent as 70% of AF patients is between 65 and 85 years old. With increasing life expectancy, AF prevalence will increase 2,5 times during the next 50 years and constitute an even more important health concern. Treatment of AF in the elderly is characterized by special challenges. Co-morbid conditions, degenerative changes of the sinus node and cardiac conduction

system, as well as age-related changes in pharmacokinetics and usage of multiple drugs are typical in the elderly population. Amiodarone is considered the most effective anti-arrhythmic drug (AAD) for the prevention of recurrence of atrial fibrillation. However amiodarone also has numerous and potentially serious side effects. In the literature on amiodarone for the treatment of paroxysmal AF up to 18% of patients discontinued amiodarone because of side effects. PVI through catheter ablation of AF could prove to be a relevant treatment option in the elderly population. PVI has proven to be a safe and effective treatment in younger patients with paroxysmal AF. PVI in elder patients will introduce additional, procedure related risks. The hypothesis in this trial is that in patients of 65 years or older with symptomatic paroxysmal atrial fibrillation (AF) pulmonary vein isolation (PVI) using RF ablation therapy is superior to medical treatment with amiodarone to prevent recurrence of AF.

Study objective

The purpose of the study is to demonstrate that in patients of 65 years or older with symptomatic paroxysmal atrial fibrillation (AF) pulmonary vein isolation (PVI) using RF ablation therapy is superior to medical treatment with amiodarone to prevent recurrence of AF.

Study design

Prospective, randomised open label study

Intervention

Pulmonary Vein Isolation using RF catheter ablation

Study burden and risks

Pulmonary Vein Isolation through RF ablation is an accepted treatment for atrial fibrillation. The additional risk in this study is solely dependent on the fact that the patient population is at least 65 years of age. All possible measures to reduce risks of the procedure will be taken. Each participating investigator/physician will evaluate eligibility of the patients for inclusion in the study. Several registries on PVI in the elderly have shown that procedural risk is similar compared to younger patients.
Additional it might be uncomfortable to wear the holter recorder 4 times 7 days. However this does not add any risk for the patient.
The additional vena punctures for blood analysis might give bruises.
The benefit of the study might be that patients of over 65 years could benefit from PVI ablation and thus reduce the risks associated with AF, provided that safety and efficacy can be demonstrated in this study.

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

* Age * 65 years at moment of screening, able to sign informed consent.
* Documented paroxysmal AF in association with complaints in the last year, with at least 2 episodes of complaints attributed to AF in the previous 2 months.
* Paroxysmal AF documented with at least one ECG with sinus rhythm not after cardioversion in the last year.
* No prior use of amiodarone in the last 6 months and no usage longer than 4 weeks in total.

Exclusion criteria

* EF < 35 % or description of *poor left ventricular function* on echocardiogram. Measurement should not be older than 6 months at moment of screening.

* Aortic ,mitral, pulmonary or tricuspid valve regurgitation or stenosis, if graded severe (grade >3).
* Acute illness: unstable angina, infectious disease.
* Primary structural or electrical heart disease: dilated cardiomyopathy, hypertrophic cardiomyopathy, Brugada syndrome, long QT syndrome.
* Reversible causes (thyroid dysfunction, uncontrolled hypertension, ischemia).
* Previous PVI ablation.
* Contraindications for amiodarione; liver dysfunction (serum alanine aminotransferase >2.5 times upper limit); thyroid dysfunction; chronic lung disease; baseline QTc >460 ms. sinus node dysfunction (pause more than 3 seconds in sinus rythm); second or third degree AV-block.
* Contraindications for anti-coagulation: prior life threatening hemorrhage under use of Vitamine K antagonists.
* Any myocardial infarction or PCI in previous 6 months.
* CABG in previous 6 months.
* Renal dysfunction: creatinin clearance <45 ml/min
* Severe co-morbidity. Life expectancy less than 1 year.
* Thrombus in left atrium
* Untreatable allergy to contrast media

Study design

Design

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):	10-08-2011
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-05-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	12-09-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-01-2014
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	NCT01276093
CCMO	NL35318.060.11