Atrial Fibrillation Reduction by Renal Sympathetic Denervation

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

Summary

ID

NL-OMON40581

Source
ToetsingOnline

Brief title
AFFORD

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Research grant vanuit St. Jude Medical,St. Jude Medical

Intervention

Keyword: Atrial fibrilation, Atrial fibrilation burden, Hypertension, Renale denervation

Outcome measures

Primary outcome

To assess whether renal sympathetic denervation will decrease AF burden in patients with symptomatic paroxysmal or persistent AF at 6 months post procedure.

Secondary outcome

Primary safety endpoint

The occurrence of cardiovascular death, stroke, major access site bleeding, acute kidney injury or renal artery stenosis at 6 months.

Secondary endpoints

• To evaluate the change in office based and 24h ambulatory blood pressure at 3, 6 and 12 months post procedure.

• To assess quality of live using the Atrial Fibrillation Effect on QualiTy-of-life (AFEQT) Questionnaire pre- and 3, 6 and 12 months post procedure.

• Newly acquired renal artery stenosis and/or repeat renal artery intervention.

• Need for electrical cardioversion

• Change in left ventricular volumes and dimensions

• Change in left ventricular diastolic function

• The occurrence of stroke

Study description

Background summary

The estimated incidence of hypertension in the general population is estimated to be between 30 and 40% and suboptimal blood pressure control is the largest contributor to death worldwide. Despite the prevalence of hypertension and its associated complications, control of the disease is far from adequate. The prevalence of therapy resistant hypertension reaches up to 25% of all hypertensive patients treated in Europe. Increased sympathetic nervous system (SNS) activity has been documented in systolic-diastolic and isolated systolic hypertension, in white coat and masked hypertension and pregnancy induced hypertension by using sophisticated techniques for measuring adrenergic activity.
A direct relationship has also been established between sympathicus nervous activity and atrial fibrillation.
The contribution of the kidney*s somatic afferent nerves, as an underlying cause of elevated central sympathetic drive, and the consequences of excessive efferent sympathetic signals to the kidney itself, as well as other organs, identify the renal sympathetic nerves as a logical therapeutic target for diseases linked by excessive central sympathetic drive.
Renal sympathetic denervation is an emerging technology for the treatment of therapy resistant hypertension. By one single invasive procedure taking about 45 minutes, approximately 4 to 8 radiofrequency ablations will be delivered to each renal artery. Previous studies already showed that the technology is safe and effective in patients with therapyresistent hypertension.
Thus far, no studies have been performed showing a decrease in atrial fibrillation burden after renal denervation.

Study objective

The objective of the present pilot study is to assess whether renal sympathetic denervation will decrease atrial fibrillation burden in patients with symptomatic paroxysmal of persistent atrial fibrillation

Study design

Single-arm pilot study of patients with symptomatic paroxysmal or persistent AF. A St. Jude Medical Confirm ICM will be implanted 3 months before the renal denervation to continuously monitor heart rate and rhythm during the entire pre-procedural (baseline) and follow-up period.

Intervention

A St. Jude Medical Confirm ICM will be implanted 3 months before the renal

denervation to continuously monitor heart rate and rhythm during the entire pre-procedural (baseline) and 3 year follow-up period.

Placed percutaneously, the Simplicity renal denervation catheter will be advanced into the renal artery using a routine femoral artery approach in a cardiac catheterization laboratory setting. Radiofrequency ablation will be applied by using an automated programmed algorhythm (pre-programmed time and intensity)

Study burden and risks

As of June 2013, the use of implantable cardiac monitors has been part of our routine clinical practice since over 10 years. In contrast to pacemakers or ICD*s, no intracardiac leads will be placed, thereby reducing procedure time and minimizing the risk of infections. Given the small caliber of the device (only 12gr (dimensies 56*19*8mm)), the risk for pocket bleeding is minimal.

Patients will undergo thorough pre-procedure assessment and imaging assessment (both MRI ultrasound) prior to selection and inclusion into the study. The procedure is initiated by puncture of the femoral artery with its inherent risks including bleeding, aneurysm formation, dissection, thrombosis and perforation. However, these risks are not different from each comparable form of angiography in which the groin is punctured and the access procedure is known for its low and acceptable complication risk. An additional potential procedure risk is caused by the radiofrequency ablation of the renal artery with focal damage of the endothelium on the coagulation spots. However, study data thus far do not show any signs of arterial damage due to the ablation procedure.

Based on previous studies using the Simplicity renal denervation system in approximately 350 patient, the following complications were recorded:
- damage to the blood vessels of the kidney in approximately 1% of the patients
- blood clots leading to heart attach or stroke in approximately 1-2%
- extended hospital stay in 1-2%
- pseudoaneurysm of the femoral artery in approximately 1-2% of the patients
- (temporarily) low blood pressure in 1-2% of the patients
- urinary tract infection in 1-2% of the patients
- renal artery stening in 1-2% of the patients
- arrhythmias during the procedure in 1-2%

In addition, in the recently published EnligHTN-I trial (n=46), assessing the safety and efficacy of the St. Jude Medical EnligHTN renal denervation system, no serious vascular adverse events occurred during the procedure. Serious adverse events occurred in 3 patients; 1 patient suffered from hypertension related renal disease progression, 1 patient developed symptomatic hypotension for which antihypertensive drug-therapy was lowered and 1 patients showed progression of a pre-existing renal artery stenosis. Noteworthy, none of the

patients developed a haemodynamically significant renal artery stenosis at 6 months.

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. Age >=18 years;
2. Symptomatic paroxysmal or persistent AF;
3. Systolic blood pressure of 140 mmHg or more despite the use of >=2 antihypertensive drugs;
4. A glomerular filtration rate of 45ml/min/1.73m2 or more;
5. Written informed consent;
6. The patient agrees to the follow-up including the implantation of the ICM.

Exclusion criteria

1. Pregnancy;
2. Renal artery abnormalities;
3. First episode of AF;
4. Long-term persistent or permanent AF
5. The patient has other medical illness (i.e., cancer or congestive heart failure) that may cause the patient to be non-compliant with the protocol, confound the data interpretation or is associated with limited life expectancy (i.e., less than one year);

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	04-06-2014
Application type:	First submission
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	NL47060.078.13