Atrial Fibrillation improvement by renal denervation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26212

Source
Nationaal Trial Register

Brief title
AFFORD Study

Health condition

- paroxysmal of persistent atrial fibrillation - hypertension

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam, the Netherlands
Source(s) of monetary or material Support: St. Jude Medical

Intervention

Outcome measures

Primary outcome

Primary efficacy endpoint

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

Primary safety endpoint

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

Secondary outcome

• To evaluate the change in office based and 24h ambulatory blood pressure at baseline vs. 3, 6 and 12, 24 and 36 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 and atrial volumes and dimensions at baseline vs. 3, 6, 12, 24 and 36 months post-procedure.
• Change in left ventricular diastolic function at baseline vs. 3, 6, 12, 24 and 36 months post-procedure.

• The occurrence of stroke at baseline vs. 3, 6, 12, 24 and 36 months postprocedure.

Study description

Study objective

Rationale: Hypertension is the most common cardiovascular condition responsible for the development and maintenance of atrial fibrillation (AF). Treating drug-resistant hypertension with renal denervation has been reported to control blood pressure, but any effect on AF is unknown.

Objective: The objective of the present pilot study is to assess whether

Study design

baseline vs. 3, 6, 12, 24 and 36 months postprocedure.

Intervention

Renal sympathetic denervation using the St Jude Medical EnligHTN system

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ¡Ý18 years;

2. Symptomatic paroxysmal or persistent AF;

3. Systolic blood pressure of 140 mmHg or more despite the use of ¡Ý2 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-07-2015
Application type:	First submission

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
NTR-new	NL5181
NTR-old	NTR5329
CCMO	NL

Study results